Registration No. 333-213891

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 3

to

FORM S-1

REGISTRATION STATEMENT

UNDER THE SECURITIES ACT OF 1933

Myovant Sciences Ltd.

Bermuda (State or other jurisdiction of incorporation or organization) (Exact name of registrant as specified in its charter) 2834 (Primary Standard Industrial Classification Code Number)

Clarendon House 2 Church Street

Hamilton HM 11, Bermuda +1 (441) 824-8101

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Corporation Service Company 2711 Centerville Road Wilmington, DE 19808 (866) 846-8765

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

Copies to:

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement. If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective

Frank F. Rahmani John T. McKenna Alison A. Haggerty Coolev LLP 3175 Hanover Street Palo Alto, CA 94304 (650) 843-5000

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Latham & Watkins LLP

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 under the Securities Exchange Act of 1934. (Check one): Non-accelerated filer ⊠ Accelerated filer \Box

Smaller reporting company

(Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

Title of Securities being Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Share(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee(2)(3)
Common shares, \$0.000017727 par value per common share	14,950,000	\$15.00	\$224,250,000	\$23,369

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

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

(3) The Registrant previously paid the registration fee of \$23,369.

earlier effective registration statement for the same offering. \Box

registration statement for the same offering. \Box

statement for the same offering. \Box

Large accelerated filer

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

Not Applicable (I.R.S. Employer Identification Number)

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

SUBJECT TO COMPLETION, DATED OCTOBER 20, 2016

PRELIMINARY PROSPECTUS

13,000,000 Shares



Common Shares

We are offering 13,000,000 common shares. Prior to this offering there has been no public market for our common shares. We currently expect the initial public offering price to be between \$12.00 and \$15.00 per common share.

Our common shares have been authorized for listing on the New York Stock Exchange under the symbol "MYOV." Upon the closing of this offering, we will be a "controlled company" within the meaning of applicable New York Stock Exchange rules.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, and, as such, will be subject to reduced public company reporting requirements.

Investing in our common shares involves a high degree of risk. See "<u>Risk Factors</u>" beginning on page 11.

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

	Per Share	Total
Initial public offering price	\$	\$
Underwriting discounts and commissions(1)	\$	\$
Proceeds to us, before expenses	\$	\$

(1) See "Underwriting" for additional information regarding underwriting compensation.

We have granted the underwriters the right to purchase up to 1,950,000 additional common shares to cover over-allotments, if any. The underwriters can exercise this right at any time within 30 days after the date of this prospectus.

The underwriters expect to deliver the shares against payment in New York, New York on or about , 2016.

Neither the Securities and Exchange Commission in the United States nor any other regulatory body has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

Citigroup

Cowen and Company

Evercore ISI

Barclays

JMP Securities

Baird

Prospectus dated , 2016

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

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

Until , 2016 (25 days after the date of this prospectus), all dealers that buy, sell or trade our common shares, whether or not participating in this offering, may be required to deliver a prospectus. This delivery is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.

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PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common shares, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes thereto and the information set forth in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Unless the context otherwise requires, we use the terms "company," "we," "us" and "our" in this prospectus to refer to Myovant Sciences Ltd. and our wholly-owned subsidiaries. Our fiscal year ends on March 31.

Company Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for women's health diseases and other endocrine-related disorders. Our lead product candidate is relugolix, an oral, once-daily, small molecule that acts as a gonadotropin-releasing hormone, or GnRH, receptor antagonist. We are advancing relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids, endometriosisassociated pain and advanced prostate cancer.

Relugolix has been evaluated in over 1,300 subjects to date, in Phase 1 and multiple large, randomized Phase 2 clinical trials, some of which are ongoing. These trials have produced favorable results in each indication. In these trials, relugolix was shown to be generally well tolerated and to successfully suppress estrogen and progesterone levels in women and testosterone levels in men. The suppression of estrogen and progesterone levels in women has been shown to effectively treat the symptoms of uterine fibroids and endometriosis, and the suppression of testosterone levels in men has been shown to effectively treat advanced prostate cancer.

In a double-blind, placebo-controlled Phase 2 clinical trial in 216 women, relugolix markedly decreased menstrual blood loss associated with uterine fibroids. The result was statistically significant for each treatment arm versus placebo, with the greatest benefit observed at a dose of 40 mg once daily (p<0.0001). In a double-blind, placebo-controlled Phase 2 clinical trial in 487 women with endometriosis, relugolix decreased pelvic pain associated with endometriosis. As assessed by the visual analogue scale, a patient-reported scale for the quantification of pain, the decline in pain was statistically significant between each dose arm and placebo, with the greatest benefit observed at a dose of 40 mg once daily (p<0.0001).

In two randomized Phase 2 clinical trials in 228 men with advanced prostate cancer, relugolix demonstrated an ability to decrease testosterone to very low levels and to reduce levels of prostate-specific antigen, a key prostate cancer biomarker. These results for relugolix were consistent with those for leuprolide acetate, or leuprolide, a GnRH agonist typically used in androgen deprivation therapy, or ADT, and for degarelix, an injectable GnRH antagonist. Unlike GnRH agonists, relugolix, when orally administered once daily, was shown in these trials to rapidly decrease testosterone levels. In addition, testosterone levels returned to baseline more rapidly after discontinuation of relugolix than after discontinuation of degarelix.

We plan to initiate three multinational Phase 3 clinical programs for relugolix, one in the first quarter of 2017 in women with heavy menstrual bleeding associated with uterine fibroids, a second in the first half of 2017 in women with endometriosis-associated pain, and a third in the first quarter of 2017 in men with advanced prostate cancer. For our uterine fibroid and endometriosis programs, we intend to co-administer relugolix with low-dose estradiol and progestin as add-back therapy. Estradiol is a major estrogen and progestin is a synthetic progestational agent. We expect to report top-line data from each of these Phase 3 programs in 2019.

We plan to develop our second product candidate, RVT-602, an oligopeptide kisspeptin analog, for the treatment of female infertility as part of assisted reproduction. Kisspeptin is a naturally-occurring peptide that stimulates GnRH release. RVT-602 has been evaluated in approximately 150 men, but has not yet been studied in women. In the second half of 2017, we expect to initiate a Phase 1 healthy-volunteer study in women followed by a

Phase 2 proof-of-concept trial for RVT-602. We believe RVT-602 has the potential to be a safer alternative to human chorionic gonadotropin when used as part of assisted reproduction for the treatment of female infertility, based on published data evaluating native kisspeptin in women undergoing assisted reproduction.

The following chart represents our current product candidate pipeline:

Product Candidate	Indication	Phase 1	Phase 2	Phase 3	Upcoming Milestones	Commercial Rights
Relugolix with Add-	Uterine Fibroids— Heavy Menstrual Bleeding				Phase 3 Initiation in First Quarter of 2017 ¹	Global, Excluding Takeda Territory ⁵
Back Therapy	Endometriosis— Pain				Phase 3 Initiation in First Half of 2017 ²	Global, Excluding Takeda Territory ⁵
Relugolix	Advanced Prostate Cancer				Phase 3 Initiation in First Quarter of 2017 ³	Global, Excluding Takeda Territory ⁵
RVT-602	Female Infertility as Part of Assisted Reproduction ⁴				Phase 1 Initiation in Second Half of 2017	Global

Subject to the submission of our investigational new drug application to the U.S. Food and Drug Administration, or FDA, which we expect to occur in 2016.

2 Subject to our End of Phase 2 meeting with the FDA, which we expect to occur in the first quarter of 2017. 3

An End of Phase 2 meeting confirmed that there are no additional clinical trials or nonclinical studies required to support the initiation of a Phase 3 trial. RVT-602 has been evaluated in Phase 1 and Phase 2a clinical trials conducted by Takeda in men for the treatment of prostate cancer and hypogonadotropic hypogonadism, or a state of low testosterone

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levels. We plan to initiate a Phase 1 healthy-volunteer study in women followed by a Phase 2 proof-of-concept trial. Takeda Territory includes Japan, China, Hong Kong, Indonesia, Korea, Malaysia, Philippines, Singapore, Taiwan, Thailand and Vietnam, including, in each case, the territories and possessions of each 5 of the foregoing

In April 2016, we entered into a license agreement with Takeda Pharmaceuticals International AG, or Takeda, in which we were granted an exclusive, royalty-bearing license to develop and commercialize relugolix and RVT-602. The territory for our exclusive license for relugolix covers all countries worldwide, excluding the Takeda Territory, to which Takeda retains exclusive rights. The territory for our exclusive license for RVT-602 covers all countries worldwide. Takeda is currently conducting two Phase 3 trials evaluating relugolix in Japan for the treatment of uterine fibroid-related pain and heavy menstrual bleeding, respectively. Takeda expects to report top-line data from each of these trials in the second half of 2017, and we expect to submit Takeda's Phase 3 data as part of our new drug application, or NDA, to the FDA for relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids.

Relugolix

Relugolix is an oral, once-daily, small molecule that acts as a GnRH receptor antagonist that binds to and inhibits receptors in the anterior pituitary gland. Inhibition of GnRH receptors decreases the release of gonadotropins, thereby decreasing the down-stream production of estrogen and progesterone by the ovaries in

women and testosterone by the testes in men. This is a clinically-validated mechanism of action and there is a commercially available injectable GnRH receptor antagonist for the treatment of advanced prostate cancer.

We intend to commercialize relugolix, if approved, in our target women's health indications as a fixed-dose combination product, which is a oncedaily, single pill containing both relugolix and low-dose estradiol and progestin. During development, relugolix will be co-administered with low-dose estradiol and progestin for the uterine fibroid and endometriosis indications. We believe relugolix with add-back therapy has the potential to be used longer term, unlike the currently approved GnRH agonist therapies, because it may minimize bone mineral density loss in women and improve tolerability. We therefore believe relugolix has the potential to be a best-in-class oral GnRH receptor antagonist for the treatment of heavy menstrual bleeding associated with uterine fibroids and endometriosis-associated pain. For the treatment of advanced prostate cancer, we believe relugolix has the potential to be both a first-inclass and best-in-class oral GnRH receptor antagonist based upon its high potency and long half-life. A first-in-class product is the first drug, in a class of drugs, approved for the treatment of a medical condition.

We believe relugolix may offer several significant advantages over currently approved injectable therapies, as well as therapies in late-stage clinical development:

- Demonstrated clinical benefit with a favorable safety profile
- Once-daily, oral administration
- Highly potent GnRH receptor antagonist
- Rapid onset of action
- Rapid reversal of hormone suppression
- Longer-term treatment with hormone add-back therapy
- Fixed-dose combination product

Market Opportunity

Uterine fibroids are non-cancerous tumors composed of smooth muscle and fibrous connective tissue that develop in or on the walls of the uterus, which can cause debilitating symptoms such as heavy or painful periods, anemia, or low red blood cell counts, abdominal pain, pregnancy loss and, in some cases, infertility. We estimate approximately 5.0 million women in the United States suffer from symptomatic uterine fibroids, approximately 3.0 million of whom are inadequately treated by current medical therapy and require further treatment. Endometriosis is a gynecological medical condition in which cells from the lining of the uterus grow outside the uterine cavity, most commonly on the ovaries, which can lead to pelvic pain, painful intercourse and, in some cases, infertility. We estimate that approximately 6.0 million women in the United States suffer from symptomatic endometriosis, approximately 1.2 million of whom are inadequately treated by oral contraceptives and require additional treatment. The current treatment landscape for our target women's health indications includes both medical and surgical options. For uterine fibroids, medical options include oral contraceptives and GnRH agonists. For endometriosis-associated pain, initial treatment includes oral contraceptives and over-the-counter pain medications. In more severe cases, GnRH agonists are used for short-term treatment and may involve hormone add-back therapy. For many patients suffering from uterine fibroids or endometriosis, surgical intervention is frequently required. In the treatment of both uterine fibroids and endometriosis, surgical intervention is or complications with future pregnancy or even preclude the potential for future pregnancy.

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 United States. According to the National Cancer Institute, approximately 2.9 million men are currently living with prostate cancer in the United States, and approximately 180,000 men are newly

diagnosed in the United States each year. Treatment for advanced prostate cancer typically involves treatment with ADT, which are therapies that reduce testosterone to very low levels, commonly referred to as castration levels. GnRH agonists, such as leuprolide depot, or slow-release, injections, are the current standard of care for medical castration, causing long-term desensitization and down-regulation of the GnRH-axis. GnRH agonists may be associated with mechanism-of-action limitations, including the potentially detrimental initial exacerbation of clinical symptoms, which is known as clinical or hormonal flare. Other approved forms of ADT include injectable GnRH antagonists, such as degarelix.

Our Strategy

Our goal is to be the leading global biopharmaceutical company focused on the innovative treatment of women's health diseases and other endocrinerelated disorders in areas of high unmet medical need, and to improve the lives of millions of patients suffering from these diseases. The key elements of our strategy to achieve this goal include the following:

- Rapidly advance clinical development of relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids and endometriosis-associated pain
- Rapidly advance clinical development of relugolix for the treatment of advanced prostate cancer
- Advance clinical development of RVT-602
- · Expand clinical development of relugolix for additional indications
- Acquire or in-license additional clinical- or commercial-stage product candidates for the treatment of women's health diseases or endocrine-related disorders in a capital-efficient manner
- · Maximize the commercial potential of our product candidates

Our Leadership

Lynn Seely, M.D., our Principal Executive Officer, has substantial experience in developing and obtaining approval for drugs for oncology and endocrine-related disorders. Dr. Seely is a board certified endocrinologist and the former Chief Medical Officer of Medivation, Inc. At Medivation, Dr. Seely led the development of Xtandi (enzalutamide) for the treatment of patients with metastatic castration-resistant prostate cancer, which achieved global sales of \$1.87 billion in 2015.

Risks Associated with Our Business

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

- We have a limited operating history and have never generated any product revenue. We were incorporated in February 2016, and our operations to date have been limited to organizing and staffing our company, acquiring rights to our product candidates and preparing for and advancing our product candidates into clinical development.
- We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability. Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.
- We are heavily dependent on the success of relugolix and RVT-602, our only product candidates, and if relugolix or RVT-602 does not receive regulatory approval or is not successfully commercialized, our business may be harmed.
- We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of relugolix and RVT-602.

- Under our amended and restated bye-laws, we may reduce the voting power of your common shares without your consent.
- Clinical trials are very expensive, time-consuming, difficult to design and implement and involve an uncertain outcome. We estimate that our clinical trials of relugolix and RVT-602 will take at least several years to complete.
- We intend to rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.
- 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 do not have our own manufacturing capabilities and will rely on Takeda and its affiliates and other third parties to produce clinical and commercial supplies of relugolix and RVT-602 and any future product candidate.
- We face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.
- We currently have nine employees who are employed by our wholly-owned subsidiary, Myovant Sciences, Inc., and we rely on Roivant Sciences, Inc. to provide various administrative, research and development and other services.
- Prior to our acquisition of the rights to relugolix and RVT-602 in April 2016, we were not involved in the development of either of these product candidates and, as a result, we are dependent on Takeda having accurately reported the results and correctly collected and interpreted the data from all clinical trials conducted to date.

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

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

Relationship with Roivant Sciences Ltd., Roivant Sciences, Inc. and Myovant Sciences, Inc.

Roivant Sciences Ltd. will be our controlling shareholder. We are a majority-owned subsidiary of Roivant Sciences Ltd., a biopharmaceutical company focused on realizing the full value of promising late-stage drug candidates to improve the lives of patients and their families. Upon the closing of this offering, we will be a "controlled company" within the meaning of the corporate governance rules of the New York Stock Exchange, or NYSE. Assuming we sell the number of the common shares set forth on the cover page of this prospectus, Roivant Sciences Ltd. will own, in the aggregate, approximately 63.6% of our outstanding common shares, or approximately 61.3% if the underwriters exercise their option to purchase additional common shares in full. Roivant Sciences Ltd. will be able to exercise control over all matters requiring shareholder approval, including the election of our directors and approval of significant corporate transactions.

Services Agreement with Roivant Sciences, Inc. We and our wholly-owned subsidiary, Myovant Sciences, Inc., have received, and will continue to receive, various services provided by our affiliate, Roivant Sciences, Inc., which is a wholly-owned subsidiary of Roivant Sciences Ltd. These services include, but are not limited to, the identification of potential additional product candidates, project management of clinical trials and other development, administrative and financial activities. Following the completion of this offering, we expect that our reliance on Roivant Sciences, Inc. will decrease over time as we, Myovant Sciences, Inc. and any other current or future subsidiary of ours continue to hire the necessary personnel to manage the development and potential commercialization of relugolix and RVT-602. We and Myovant Sciences, Inc. have entered into a services agreement with Roivant Sciences, Inc. in connection with the provision of these services. For a description of this agreement, see the section titled "Certain Relationships and Related Party Transactions—Relationship with Roivant Sciences, Inc.—Services Agreement."

Corporate Information

We are an exempted limited company incorporated under the laws of Bermuda on February 2, 2016. Our registered office is located at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda, and we also have business operations at Park Place, 55 Par-La-Ville Road, 2nd Floor, Hamilton HM11, Bermuda. Our telephone number is +1 (441) 824-8101. Our website address is www.myovant.com. The information contained on our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common shares.

We have three wholly-owned subsidiaries, including Myovant Sciences, Inc., a Delaware corporation, Myovant Holdings Limited, a private limited company incorporated under the laws of England and Wales, and Myovant Sciences GmbH, a company with limited liability formed under the laws of Switzerland. We expect that Myovant Sciences GmbH will be the principal operating company for conducting our business and the entity which will hold our intellectual property rights in relugolix and RVT-602.

Solely for convenience, the trademarks and trade names in this prospectus are referred to without the $^{\text{\tiny B}}$ and $^{\text{\tiny M}}$ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners.

THE OFFERING				
Common shares offered by us	13,000,000 common shares			
Common shares to be outstanding immediately after this offering	58,523,408 common shares (or 60,739,319 common shares if the underwriters exercise their option to purchase additional common shares in full)			
Option to purchase additional shares	We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase an additional 1,950,000 common shares.			
Use of proceeds	We estimate that the net proceeds to us from this offering, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately \$160.7 million, assuming the common shares are offered at \$13.50 per common share, which is the midpoint of the price range set forth on the cover page of this prospectus.			
	We intend to use the net proceeds from this offering primarily for the clinical development of our product candidates, relugolix and RVT-602. The remaining proceeds will be used for working capital and general corporate purposes. See the section titled "Use of Proceeds" for additional information.			
Controlled company	Upon the closing of this offering, Roivant Sciences Ltd. will beneficially own a controlling interest in us and we will be a "controlled company" under NYSE rules. As a controlled company, we may elect to avail ourselves of the controlled company exemption under the corporate governance requirements of the NYSE.			
Risk factors	You should read the section titled "Risk Factors" for a discussion of factors to consider carefully before deciding to invest in our common shares.			
NYSE symbol	"MYOV"			
The number of common shares that will be outstand 30, 2016, and excludes:	ding immediately after this offering is based on 43,590,411 common shares outstanding as of June			

- an indeterminate number of capital shares that may be issued after the closing of this offering pursuant to a warrant we issued to Takeda, which allows Takeda, together with its affiliates, to maintain a 12% ownership interest in us, as determined after such exercise, through April 2017, unless earlier terminated upon a change in control, as further described in the section titled "Certain Relationships and Related Party Transactions— Relationship with Takeda Pharmaceuticals International AG—Warrant;" and
- 3,384,667 common shares reserved for future issuance under our 2016 Equity Incentive Plan, as amended, of which stock options for an aggregate of 1,175,311 common shares were granted in August and September 2016, as well as any automatic increases in the number of common shares reserved for future issuance under this plan.

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

- a 100,000-for-1 stock split effected on April 27, 2016;
- a 1-for-1.7727 reverse stock split to be effected prior to the effective date of the registration statement of which this prospectus is a part;
- an aggregate of 160,273 common shares issued to Takeda in August and September 2016 upon the automatic exercise of a warrant we issued to Takeda at an exercise price of \$0.000017727 per share, which was initiated by the grant of stock options for an aggregate of 1,175,311 common shares;
- the issuance of an additional 1,772,724 common shares to Takeda upon the closing of this offering pursuant to the automatic exercise of a warrant
 we issued to Takeda, based upon the sale and issuance of 13,000,000 common shares to investors in this offering at an assumed initial public
 offering price of \$13.50 per common share, which is the midpoint of the price range set forth on the cover page of this prospectus;
- no exercise by the underwriters of their option to purchase an additional 1,950,000 common shares and no issuance of an additional 265,911 common shares to Takeda as a result thereof, pursuant to the automatic exercise of a warrant we issued to Takeda; and
- the effectiveness of our amended and restated bye-laws immediately prior to the closing of this offering.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth our summary consolidated statement of operations data for the periods indicated. We derived the consolidated statement of operations data for the period from February 2, 2016 (date of inception) through March 31, 2016 from our audited consolidated financial statements appearing elsewhere in this prospectus. Our consolidated statement of operations data for the three months ended June 30, 2016 and the consolidated balance sheet data as of June 30, 2016 are derived from our unaudited consolidated financial statements appearing elsewhere in this prospectus. We have prepared the unaudited consolidated financial statements on the same basis as the audited consolidated financial statements and have included, in our opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results to be expected in the future, and our operating results for the period ended March 31, 2016 and the three months ended June 30, 2016 are not indicative of the results that may be expected for a full fiscal year or any other future period. You should read this summary consolidated financial data below, together with our consolidated financial statements and related notes thereto appearing elsewhere in this prospectus, as well as the sections titled "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our fiscal year ends on March 31.

	Period from February 2, 2016 (Date of Inception) to March 31, 2016	Three Months Ended June 30, 2016
Consolidated Statement of Operations Data:		
Operating expenses:		
Research and development	\$ —	\$ 14,573,014
General and administrative	1,656,788	2,561,878
Total operating expenses	1,656,788	17,134,892
Other (expense) income:		
Changes in the fair value of the warrant liability		(1,832,543)
Loss before provision for income tax	(1,656,788)	(18,967,435)
Income tax expense		3,054
Net loss and comprehensive loss	\$ (1,656,788)	\$(18,970,489)
Net loss per common share—basic and diluted(1)	\$ (0.04)	\$ (0.47)
Weighted average common shares outstanding—basic and diluted(1)	37,231,342	40,771,548
Pro forma net loss per common share—basic and diluted (unaudited)(2)		\$ (0.45)
Pro forma weighted average common shares outstanding—basic and diluted (unaudited)(2)		42,544,277

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

	As of Ju	As of June 30, 2016	
	Actual	Pro Forma As Adjusted(1) (2)(3)	
Consolidated Balance Sheet Data:			
Cash	\$ —	\$160,715,000	
Total assets	523,681	160,715,000	
Total liabilities	9,121,775	9,121,775	
Accumulated deficit	(20,627,277)	(46,722,737)	
Total shareholders' (deficit) equity	(8,598,094)	151,593,225	

- (1) The pro forma as adjusted balance sheet data gives effect to: (1) the issuance and sale of 13,000,000 common shares in this offering at an assumed initial public offering price of \$13.50 per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us; (2) an aggregate of 160,273 common shares issued to Takeda in August and September 2016 upon the automatic exercise of a warrant we issued to Takeda at an exercise price of \$0.000017727 per share, which was initiated by the grant of stock options for an aggregate of 1,175,311 common shares; and (3) the issuance of an additional 1,772,724 common shares to Takeda upon the closing of this offering pursuant to the automatic exercise of a warrant we issued to Takeda, based upon the sale and issuance of 13,000,000 common shares to investors in this offering at an assumed initial public offering price of \$13.50 per common share, which is the midpoint of the price range set forth on the cover page of this prospectus. The foregoing issuances to Takeda will increase both accumulated deficit and additional paid-in capital by \$26,095,460 (calculated by multiplying an aggregate of 1,932,997 common shares by the assumed initial public offering price of \$13.50 per common share, which is the midpoint of the price range set forth on the cover page of this prospectus).
- (2) Total assets are comprised solely of deferred initial public offering costs of \$523,681, which, upon the closing of this offering, will be reclassified to additional paid-in capital.
- (3) Each \$1.00 increase or decrease in the assumed initial public offering price of \$13.50 per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, would increase or decrease each of cash, total assets and total shareholders' (deficit) equity on a pro forma as adjusted basis by approximately \$12.1 million, assuming that the number of common shares offered by us, as set forth on the cover page of this prospectus, remains the same. Similarly, each increase or decrease of 1.0 million common shares offered by us at the assumed initial public offering price of \$13.50 per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, and commissions, would increase or decrease each of cash, total assets and total shareholders' (deficit) equity on a pro forma as adjusted basis by approximately \$12.6 million. The pro forma as adjusted information is illustrative only, and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

RISK FACTORS

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

Risks Related to Our Business, Financial Position and Capital Requirements

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

We are a clinical-stage biopharmaceutical company with a limited operating history. We were formed in February 2016, and our operations to date have been limited to organizing and staffing our company, acquiring worldwide rights, excluding Japan and certain other Asian countries, to relugolix, and worldwide rights to RVT-602 and preparing for and advancing our product candidates into clinical development. We have not yet demonstrated an ability to successfully complete a large-scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, we have no meaningful operations upon which to evaluate our business and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

Our ability to generate product revenue and become profitable depends upon our ability to successfully complete the development of our product candidates, relugolix, for the treatment of heavy menstrual bleeding associated with uterine fibroids, endometriosis-related pain and advanced prostate cancer and RVT-602, for the treatment of female infertility as part of assisted reproduction and obtain the necessary regulatory approvals for their commercialization. We have never been profitable, have no products approved for commercial sale and to date have not generated any product revenue.

Even if we receive regulatory approval for the sale of relugolix or RVT-602, we do not know when relugolix or RVT-602 will generate product revenue, if at all. Our ability to generate product revenue depends on a number of factors, including our ability to:

- successfully complete clinical trials and obtain regulatory approval for the marketing of relugolix and RVT-602;
- set an acceptable price for relugolix and RVT-602 and obtain coverage and adequate reimbursement from third-party payors;
- establish sales, marketing and distribution systems for relugolix and RVT-602;
- add operational, financial and management information systems and personnel, including personnel to support our clinical, manufacturing and planned future commercialization efforts and operations as a public company;
- initiate and continue relationships with third-party manufacturers and have commercial quantities of relugolix and RVT-602 manufactured at acceptable cost levels;
- attract and retain an experienced management and advisory team;
- 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; and
- maintain, expand and protect our intellectual property portfolio.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, or the FDA, and comparable non-U.S. regulatory authorities, to perform studies or clinical trials in addition to those that we currently anticipate. Even if relugolix or RVT-602 is approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of this product. If we cannot successfully execute any one of the foregoing, our business may not succeed and your investment will be adversely affected.

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

Investment in 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 become commercially viable. We have never generated any product revenue, and we cannot estimate with precision the extent of our future losses. We do not currently have any products that are available for commercial sale and we may never generate product revenue or achieve profitability. We expect to continue to incur substantial and increasing losses through the projected commercialization of relugolix and RVT-602. Neither relugolix nor RVT-602 has been approved for marketing in the United States and may never receive such approval. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to generate product revenue and achieve profitability is dependent on our ability to complete the development of relugolix and RVT-602, obtain necessary regulatory approvals, and have relugolix or RVT-602. If we do successfully obtain regulatory approval to market relugolix or RVT-602, our revenue will be dependent, in part, upon, among other things, the size of the markets in the territories for which we gain regulatory approval, the number of competitors in such markets, the accepted price for relugolix and RVT-602 and whether we own the commercial rights for that territory. If the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of relugolix or RVT-602, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Failure to become and remain profitable may adversely affect the market price of our common shares and our ability to raise capital and continue operations. As of June 30,

We expect our research and development expenses to be significant in connection with our development programs for relugolix and RVT-602. In addition, if we obtain regulatory approval for either relugolix or RVT-602, we expect to incur increased sales and marketing expenses. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have an adverse effect on our financial position and working capital.

Our auditors have issued a going concern opinion on our consolidated financial statements as of March 31, 2016 and for the period from February 2, 2016 (date of inception) to March 31, 2016, expressing substantial doubt that we can continue as an ongoing business due to insufficient capital for us to fund our operations. Our consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we are unable to successfully complete this offering, we will need to create alternate financing or operational plans to continue as a going concern.

We are heavily dependent on the success of relugolix and RVT-602, our only product candidates, which are still under clinical development, and if relugolix or RVT-602 does not receive regulatory approval or is not successfully commercialized, our business may be harmed.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to the advancement of relugolix and RVT-602. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of these product candidates. We cannot be certain that relugolix or RVT-602 will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of products are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market relugolix or RVT-602 in the United States until we receive approval of a new drug application, or NDA, for each, or in any foreign country until they receive the requisite approvals from the appropriate authority in such county. We have not submitted an NDA to the FDA, or any comparable application to any other regulatory authority and do not expect to be in a position to do so for the foreseeable future. Prior to commencing our planned Phase 3 program for the treatment of heavy menstrual bleeding associated with uterine fibroids, we will need to submit our investigational new drug application, or IND, to the FDA, which we expect to occur in 2016. We completed an End of Phase 2 meeting with the FDA for relugolix for this indication in early October 2016. Prior to commencing our planned Phase 3 program for the treatment of endometriosis-associated pain, we will need to complete the End of Phase 2 meeting with the FDA, which we expect to occur in the first quarter of 2017.

Obtaining approval of an NDA or similar 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 relugolix or RVT-602 for many reasons, including:

- we may not be able to demonstrate that relugolix or RVT-602 is effective as a treatment for our target indications to the satisfaction of the FDA or other relevant regulatory authority;
- the relevant regulatory authority may require additional clinical trials, which would increase our costs and prolong our development;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or other relevant regulatory authority for marketing approval;
- the FDA or other relevant regulatory authority may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the contract research organizations, or CROs, that we retain to conduct clinical trials may take actions outside of our control that materially adversely impact our clinical trials;
- the FDA or other relevant regulatory authority may not find the data from preclinical studies and clinical trials sufficient to demonstrate that the clinical and other benefits of these products outweigh their safety risks;
- the FDA or other relevant regulatory authority may disagree with our interpretation of data from our preclinical studies and clinical trials or may require that we conduct additional studies;
- the FDA or other relevant regulatory authority may not accept data generated at our clinical trial sites;
- if our NDA or other foreign application is reviewed by an advisory committee, the FDA or other relevant regulatory authority, as the case may be, may
 have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our
 application(s) or may recommend that the FDA or other relevant regulatory authority, as the case may be, require, as a condition of approval, additional
 preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA or other relevant regulatory authority may require development of a risk evaluation and mitigation strategy, or REMS, or its equivalent, as a condition of approval;



- the FDA or other relevant regulatory authority may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; or
- the FDA or other relevant regulatory authority may change its approval policies or adopt new regulations.

If we are unable to formulate a fixed-dose combination version of relugolix with low-dose estradiol and progestin, the development of relugolix may be delayed and its commercial opportunity could be limited.

A key part of our relugolix clinical development strategy is to formulate a fixed-dose combination with add-back low-dose estradiol and progestin in order to facilitate patient convenience and compliance and minimize side effects. If we are unsuccessful in our attempts to formulate a fixed-dose combination, we expect to instead seek approval for relugolix as monotherapy to be co-administered with commercially available low-dose estradiol and progestin. This would decrease our advantages relative to our competition by requiring patients to take two pills once daily instead of just one pill once daily. If our competitors develop a fixed-dose combination with hormone add-back therapy, and we are unable to do so, then we would be at a competitive disadvantage and this could limit our commercial opportunity. We are not aware of any barriers preventing competitors from developing or achieving regulatory approval of a fixed-dose combination.

Although we plan to conduct Phase 3 clinical trials of relugolix in our target women's health indications with separate administration of relugolix and commercially available low-dose estradiol and progestin products, we intend to conduct bridging studies to support the submission of NDAs for the proposed fixed-dose combination for each of our target women's health indications. Any such bridging study may be unsuccessful or insufficient to support approval of the fixed-dose combination formulation, which would delay and increase the expenses associated with our development program and limit our commercial opportunity.

We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of relugolix or RVT-602.

We expect to spend substantial amounts to complete the development of, seek regulatory approvals for and commercialize relugolix and RVT-602. These expenditures will include costs associated with our license agreement with Takeda. Under the terms of this agreement, we are obligated to cover substantial development costs of relugolix and RVT-602 and make significant royalty payments in connection with the sale of resulting products.

Even with the net proceeds of this offering, we may require additional capital to complete the development and potential commercialization of our product candidates. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our development program or any future commercialization efforts. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts.

Based upon our current operating plan, we believe that the net proceeds from this offering will enable us to fund our operating expenses and capital expenditure requirements through unblinding and release of data for at least one of our Phase 3 programs, which we expect to occur in 2019. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because the length of time and activities associated with successful development of relugolix and RVT-602 are highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of our planned clinical trials for our product candidates;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;

- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or the 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;
- the cost of establishing sales, marketing and distribution capabilities for the products in regions where we choose to commercialize our products on our own; and
- the initiation, progress, timing and results of our commercialization of our product candidates, if approved for commercial sale.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or potentially discontinue operations.

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

We expect that significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements in connection with any collaborations. We do not have any committed external source of funds. To the extent that we raise additional capital by issuing equity securities, our existing shareholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common shareholder. Debt financing and preferred equity financing, if available, may involve the entry into agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

We rely on our agreements with Takeda to provide rights to the core intellectual property relating to our existing product candidates and to supply us with clinical trial material to support development of relugolix. Any termination or loss of significant rights under those agreements would adversely affect our development or commercialization of relugolix and RVT-602.

We have licensed the intellectual property rights covering our current product candidates, relugolix and RVT-602, from Takeda pursuant to the April 2016 license agreement between us and Takeda. If, for any reason, our license agreement is terminated or we otherwise lose those rights, it would adversely affect our business. Our license agreement with Takeda imposes on us obligations relating to exclusivity, territorial rights, development, commercialization, funding, payment, diligence, sublicensing, insurance, intellectual property protection and other matters. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages to Takeda and Takeda may have the right to terminate our license, which would result in us being unable to develop, manufacture and sell relugolix and RVT-602.

Pursuant to the license agreement, we and a Takeda affiliate have entered into an agreement for the manufacture and supply of relugolix. Under this agreement, we are required to obtain from Takeda's affiliate all

of our requirements for relugolix drug substance and drug product to be used under our development plan. The agreement also provides for Takeda's affiliate to reasonably assist us with a technical transfer of the manufacturing process for relugolix to us or our designee. If Takeda's affiliate fails to fulfill its obligations under this agreement to manufacture and supply relugolix to us or to enable the transfer of the manufacturing process for relugolix to us or our designee, our development of relugolix could be significantly delayed or otherwise adversely affected.

We currently have nine employees who are employed by our wholly-owned subsidiary, Myovant Sciences, Inc., and we rely on Roivant Sciences, Inc. to provide various administrative, research and development and other services.

As of September 30, 2016, we had no employees, and our wholly-owned subsidiary, Myovant Sciences, Inc., had nine employees. We rely on the administrative and support and research and development services provided by our affiliate, Roivant Sciences, Inc., a wholly-owned subsidiary of Roivant Sciences Ltd. We and Myovant Sciences, Inc., have entered into a services agreement with Roivant Sciences, Inc. Personnel and support staff that provide services to us under this services agreement are not required to, and we do not expect that they will, have as their primary responsibility the management and administration of our business or act exclusively for us. Under this services agreement, Roivant Sciences, Inc. has the discretion to determine which of its employees will perform services under the agreement.

Roivant Sciences, Inc. has limited financing and accounting and other resources. If Roivant Sciences, Inc. fails to perform its obligations in accordance with the terms of the services agreement, it could be difficult for us to operate our business. In addition, the termination of our relationship with Roivant Sciences, Inc. and any delay in appointing or finding a suitable replacement provider (if one exists) could make it difficult for us to operate our business. Any failure by Roivant Sciences, Inc. to effectively manage our administrative, research and development or other services could harm our business, financial condition and results of operations.

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

As of September 30, 2016, we had no employees, and our wholly-owned subsidiary, Myovant Sciences, Inc., had nine employees. We expect to hire, either directly, through Myovant Sciences, Inc. or through any other current or future subsidiary of ours, additional employees for our managerial, clinical, scientific, operational, sales and marketing teams. We may have operational difficulties in connection with identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate or grow revenue could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize relugolix or RVT-602 and compete effectively will depend, in part, on our ability to effectively manage any future growth.

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

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

We are exposed to the risk that our employees and contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; federal and state healthcare fraud and abuse and health regulatory laws and other similar foreign fraudulent misconduct laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter 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 be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare pro

Our business and operations would suffer in the event of system failures.

Our computer systems, as well as those of Roivant Sciences, Inc. and our CROs and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters (including hurricanes), terrorism, war and telecommunication and electrical failures. 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 preclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of relugolix or RVT-602 or any future product candidate could be delayed.

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

The use of relugolix and RVT-602 in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;

- significant costs to defend the related litigation and 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 candidate;
- 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 insurance we currently carry, and any additional product liability insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for relugolix or RVT-602, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization of any product candidates we develop.

Risks Related to Clinical Development, Regulatory Approval and Commercialization

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

Our product candidates, relugolix and RVT-602, are still in development and will require extensive clinical testing before we are prepared to submit an NDA or other similar application for regulatory approval. Our planned Phase 3 program for the treatment of heavy menstrual bleeding associated with uterine fibroids is subject to the submission of our IND to the FDA, which we expect to occur in 2016. We completed an End of Phase 2 meeting with the FDA for relugolix for this indication in early October 2016. Our planned Phase 3 program for the treatment of endometriosis-related pain is subject to the completion of an End of Phase 2 meeting with the FDA, which we expect to occur in the first quarter of 2017. Further, we cannot predict with any certainty if or when we might submit an NDA for regulatory approval for relugolix or RVT-602 or whether any such application will be approved by the relevant regulatory authority. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA may not agree with our proposed endpoints for any clinical trials of relugolix or RVT-602, which may delay the commencement of our clinical trials. The clinical trial process is also time-consuming. We estimate that our clinical trials of relugolix and RVT-602 will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. The results of early clinical trials of relugolix and RVT-602 therefore may not be predictive of the results of our planned development programs. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse

- The commencement and completion of clinical trials may be delayed by several factors, including:
- failure to obtain regulatory approval to commence a trial;
- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;

- inability to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- slower than expected rates of patient recruitment or failure to recruit suitable patients to participate in a trial;
- failure to manufacture sufficient quantities of a drug candidate for use in clinical trials;
- inability to monitor patients adequately during or after treatment;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- adding a sufficient number of clinical trial sites; or
- clinical sites deviating from trial protocol or dropping out of a trial.

Further, we, the FDA or an institutional review board, or IRB, or other regulatory authority may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including, for example, the FDA's Good Clinical Practice, or GCP, regulations, that we are exposing participants to unacceptable health risks, or if the FDA or other regulatory authority, as the case may be, finds deficiencies in our IND or other submissions or the manner in which the clinical trials are conducted. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of relugolix or RVT-602 could be harmed, and our ability to generate product revenue from relugolix or RVT-602 may be delayed. In addition, any delays in our clinical trials could increase our costs, slow down the approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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

In addition, because we recently acquired worldwide rights, excluding Japan and certain other Asian countries, to relugolix and worldwide rights to RVT-602, we were not involved in the development of relugolix or RVT-602 prior to April 2016. We may experience difficulties in the transition of this product candidate from Takeda and its affiliates to us, which may result in delays in clinical trials as well as problems in our development efforts and regulatory filings, particularly if we do not receive all of the necessary products, information, reports and data from Takeda and its affiliates in a timely manner. Further, we have had no involvement with or control over the preclinical and clinical development of either relugolix or RVT-602 to date. We are dependent on Takeda having conducted such research and development in accordance with the applicable protocol, legal, regulatory and scientific standards, having accurately reported the results of all clinical trials conducted prior to our acquisition of the rights to relugolix and RVT-602 and having correctly collected and interpreted the data from these trials. To the extent any of these has not occurred, expected development time and costs may be increased which could adversely affect any future revenue from this product candidate.

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

Takeda is currently conducting two Phase 3 trials with relugolix in Japan for the treatment of uterine fibroid-associated pain and heavy menstrual bleeding, respectively. If announcements by Takeda are unfavorable with respect to these clinical trials, our clinical development plans may be adversely affected. Further, even if announcements by Takeda are favorable with respect to these clinical trials, our planned Phase 3 clinical trials for relugolix differ from Takeda's clinical trials and investors should not place undue reliance upon any of Takeda's reported data or other clinical development announcements.

The results of our clinical trials may not support our proposed claims for relugolix or RVT-602.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support the effectiveness of relugolix or RVT-602. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, even after promising results in earlier nonclinical 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. The results of preclinical, nonclinical and early clinical studies of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and initial clinical trials. A failure of a clinical trial 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 trials 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 relugolix and RVT-602 and generate product revenue.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites, the eligibility criteria for the study, our ability to obtain and maintain patient consents and the risk that patients enrolled in clinical trials will drop out of the trials before completion. Furthermore, any negative results we may report in clinical trials of our product candidate may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. 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 relugolix and RVT-602, or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compet their actual performance.

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

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

We are aware of several companies that are working to develop drugs that would compete against relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids, endometriosis-associated pain and advanced prostate cancer and against RVT-602 for the treatment of female infertility as part of assisted reproduction. For example, AbbVie in conjunction with Neurocrine Biosciences, is developing a GnRH receptor antagonist, elagolix, as an oral treatment for endometriosis-associated pain and for heavy menstrual bleeding associated with uterine fibroids. AbbVie has initiated a Phase 3 program evaluating elagolix with and without hormone add-back therapy in women with heavy menstrual bleeding associated with uterine fibroids, and AbbVie is expected to commence a Phase 3b trial of elagolix in combination with hormone add-back therapy in women with pain associated with endometriosis by the end of 2016. Further, many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors. Competition may reduce the number and types of patients available to us to participate in clinical trials, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drugs that are more effective or less costly than any product candidate that we may develop.

We will face competition from other drugs currently approved or that will be approved in the future for the treatment of uterine fibroids, endometriosis and advanced prostate cancer as well as infertility in females. Therefore, our ability to compete successfully will depend largely on our ability to:

- · develop and commercialize medicines that are superior to other products in the market;
- · demonstrate through our clinical trials that relugolix or RVT-602 is differentiated from existing and future therapies;
- · attract qualified scientific, product development and commercial personnel;
- · obtain patent or other proprietary protection for our medicines;
- obtain required regulatory approvals;
- · obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicines.

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

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make relugolix or RVT-602 less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in

efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving FDA or other regulatory authority approval for or commercializing medicines before we do, which would have an adverse impact on our business and results of operations.

If we are not able to obtain required regulatory approvals, we will not be able to commercialize relugolix or RVT-602, and our ability to generate product revenue will be materially impaired.

Relugolix and RVT-602 and the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by similar regulatory authorities outside the United States. Failure to obtain marketing approval for relugolix and RVT-602 will prevent us from commercializing them.

We have not received approval from regulatory authorities to market any product candidate in any jurisdiction, and it is possible that none of relugolix, RVT-602 or any product candidates we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us to commence product sales. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States until we receive regulatory approval of an NDA from the FDA.

The time required to obtain approval of an NDA by the FDA is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authority. Prior to submitting an NDA to the FDA or any comparable application to any other foreign regulatory authorities for approval of relugolix, we will need to complete our planned Phase 3 programs, and for approval of RVT-602, we will need to complete additional Phase 2 and Phase 3 clinical trials. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the safety and efficacy of relugolix and RVT-602 for the specified indication. Further, because we are exploring the use of relugolix as a longer-term therapy for the treatment of heavy menstrual bleeding associated with uterine fibroids and of endometriosis-associated pain, we expect to submit data with respect to a large patient population. We expect to rely on third-party CROs and consultants to assist us in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities.

Relugolix and RVT-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 caused by relugolix or RVT-602 could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events are reported in our clinical trials for relugolix or RVT-602 or any future product candidates, our ability to obtain regulatory approval for such product candidates may be negatively impacted. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. Any of these occurrences may harm our business, financial condition and prospects.

Across all relugolix clinical trials, a total of 34 serious adverse events were reported in the more than 1,300 relugolix-treated subjects and patients as of July 10, 2016, of which three were reported by the investigator as

possibly related to relugolix, including an event of abnormal liver function tests (moderate grade), one of cerebral infarction (grade unspecified) and one of embolic stroke (grade 2). In addition, concern has been raised by the FDA about a potential increase in the risk of diabetes and certain cardiovascular diseases in men treated with GnRH agonists.

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 REMS to impose restrictions on its distribution or other risk management measures;
- we may be required to recall a product;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or to conduct additional clinical trials;
- we may be required to implement a REMS or create a Medication Guide outlining the risks of such side effects for distribution to patients;
- 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 or RVT-602.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and even if we obtain approval for a product candidate in one country or jurisdiction, we may never obtain approval for, or commercialize, it in any other jurisdiction, which would limit our ability to realize its full market potential.

Prior to obtaining approval to commercialize a product candidate in any jurisdiction, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by FDA in the United States does not ensure approval by regulatory authorities in any other country or jurisdiction. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign 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 in international markets. If we fail to comply with regulatory requirements in international markets will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.



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

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and current GCP requirements for any clinical trials that we conduct post-approval. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including any requirement to implement a REMS. If relugolix or RVT-602 receives marketing approval, the accompanying label may limit the approved use of our drug, which could limit sales of the product.

The FDA or other regulatory authority may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. Regulatory authorities closely regulate the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Regulatory authorities impose stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to enforcement actions and investigations by the FDA, Department of Justice, and other regulatory agencies alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

The FDA and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of relugolix or RVT-602 or any future product candidate. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

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.

If one of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, thirdparty payors and others in the medical community. If it does not achieve an adequate level of acceptance, we may not generate significant product revenue and 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;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our product together with other medications.

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

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

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

We expect to build a focused sales, distribution and marketing infrastructure to market our product candidates in the United States, if approved. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product launch, which would adversely impact its commercialization. For example, if the commercial launch of relugolix or RVT-602, if approved, for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

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

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

If we are unable to build our own sales force or negotiate a collaborative relationship for the commercialization of our product candidates we may be forced to delay their potential commercialization or

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

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

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

If either relugolix or RVT-602 is approved for commercialization, we intend to enter into agreements with third parties to market it in certain jurisdictions outside the United States. We expect that we will be subject to additional risks related to international operations or entering into international business relationships, including:

- · different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- · compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign reimbursement, pricing and insurance regimes;
- foreign taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

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

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

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain 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 prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or
 providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the
 purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal
 healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or
 specific intent to violate it in order to have committed a violation; in addition, the government may assert that a claim including items or services
 resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal false claims laws, including the civil False Claims Act, impose criminal and civil penalties, including through civil whistleblower or qui tam
 actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false
 or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or knowingly
 making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; in addition, the government may assert
 that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false of fraudulent claim for
 purposes of the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment
 is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government
 information related to certain payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists
 and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the
 government ownership and investment interests held by the physicians described above and their immediate family members and payments or other
 "transfers of value" to such physician owners (covered manufacturers are required to submit reports to the government by the 90th day of each calendar
 year); and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to our business practices, including but
 not limited to, research, distribution sales and marketing arrangements and claims involving healthcare items or services reimbursed by nongovernmental third party payors, including private insurers; 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, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs or similar programs in other countries or jurisdictions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our 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.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval for, and commercialize relugolix or RVT-602 and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of relugolix or RVT-602, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval.

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

- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents payable to the federal government based on each company's market share of prior year total sales of branded products to certain federal healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of
 applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered
 under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs in certain states;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This included further reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025 unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period in which the government may recover overpayments to providers from three to five years. In addition, recently there has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their commercial products.

Moreover, the Drug Supply Chain Security Act, which was enacted in 2012 as part of the Food and Drug Administration Safety and Innovation Act, imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Legislative and regulatory proposals also have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or what the impact of such changes on our business, if any, may be. In addition, increased scrutiny by the 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.

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

Third-party payor coverage and adequate reimbursement 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 product candidates that we develop, will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government health administration authorities and private health insurers. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Third-party payors decide which drugs they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a plan-by-plan basis. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Additionally, a third-party payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Each plan determines whether or not it will provide coverage for a drug, what amount it will pay the manufacturer for the drug, and on what tier of its

formulary the drug will be placed. The position of a drug on a formulary generally determines the co-payment that a patient will need to make to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Even if we do obtain adequate levels of reimbursement, third-party payors, such as government or private healthcare insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for, products. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Increasingly, third-party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We may also be required to conduct expensive pharmacoeconomic studies to justify the coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize any product candidates that we develop.

Additionally, there have been a number of legislative and regulatory proposals to change the healthcare system in the United States and in some foreign jurisdictions that could affect our ability to sell any future drugs profitably. These legislative and regulatory changes may negatively impact the reimbursement for any future drugs, following approval.

Risks Related to Our Dependence on Third Parties

We do not have our own manufacturing capabilities and will rely on Takeda and its affiliates and other third parties to produce clinical and commercial supplies of relugolix and RVT-602, and any future product candidate.

We have no experience in drug formulation or manufacturing and do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. While relugolix and RVT-602 were being developed by Takeda, they were also being manufactured by Takeda. Takeda has retained rights to further develop and commercialize relugolix in Japan and certain other Asian countries, and Takeda is continuing to develop relugolix in Japan. In April 2016, we acquired exclusive, worldwide rights to RVT-602 for all human diseases and conditions. Takeda is no longer developing this compound. We expect that the drug substance transferred from Takeda under our license agreement with Takeda will be sufficient for us to complete our planned Phase 3 programs for relugolix and possibly for RVT-602 as well. However, the drug substance transferred from Takeda may not meet our quality standards and may be disqualified from use in our planned clinical programs. Further, we will be dependent on third parties to help formulate and manufacture a fixed-dose combination of relugolix and low-dose estradiol and progestin. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our product candidates.

We also will rely on third-party manufacturers to supply us with sufficient quantities of relugolix and RVT-602 to be used, if approved, for the commercialization of each. The facilities used by our contract manufacturers

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

- delay or inability to design a fixed-dose combination product of relugolix and low-dose estradiol and progestin;
- failure of the drug substance transferred from Takeda to meet our product specifications and quality requirements;
- · inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- · costs and validation of new equipment and facilities required for scale-up;
- failure to comply with cGMP and similar foreign standards;
- 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 or RVT-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;
- 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;
- 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 lead to clinical trial delays, failure to obtain regulatory approval or impact our ability to successfully commercialize our products. Some of these events could be the basis for FDA or other regulatory authority action, including injunction, recall, seizure, or total or partial suspension of production.

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

We currently do not have the ability to independently conduct pre-clinical studies that comply with the regulatory requirements known as good laboratory practice, or GLP, requirements. We also do not currently have

the ability to independently conduct any clinical trials. We intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance.

We intend to rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be 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 will be required to comply with the GLPs and GCPs, which are 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 in the form of International Conference on Harmonization guidelines for any of our product candidates that are in preclinical and clinical development, respectively. The regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we rely on CROs to conduct our GLP-compliant preclinical and nonclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP pre-clinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process.

While we will have agreements governing their activities, our CROs will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret 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 clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If our relationship with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. 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 intend to 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, 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 United States and other countries with respect to relugolix, RVT-602 and any future product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in-license may fail to result in issued patents with claims that cover relugolix, RVT-602 or any future product candidate in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover relugolix, RVT-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 and companion diagnostic 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, RVT-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 in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent and Trademark Office,

or USPTO, recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business and financial condition.

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

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we 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 the intellectual property rights covering our current product candidates from Takeda. If, for any reason, our license agreement with Takeda is terminated or we otherwise lose those rights, it could adversely affect our business. Our license agreement with Takeda 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 non-compliance 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. Non-compliance 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, RVT-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 patents or other proprietary rights, may delay or prevent the development and commercialization of relugolix, RVT-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 United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter party 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. We have conducted searches for information in support of patent protection and otherwise evaluating the patent landscape for relugolix and RVT-602, and, based on these searches and evaluations to date, we do not believe that there are valid patents which contain granted claims that could be asserted with respect to relugolix or RVT-602. However, we may be incorrect.

There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent 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 United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

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 United States has recently 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 or to enforce patents that we have licensed or 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, RVT-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 United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

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, RVT-602 and any future product candidates, and we expect to collaborate with third parties on the development of relugolix, RVT-602 and any future product candidates, we must, at times, share trade secrets with them. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development 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 this Offering and Our Common Shares

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

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

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

The market price of our common shares is likely to be highly volatile and may be subject to wide fluctuations in response to a variety of factors, including the following:

- any delay in the commencement, enrollment and ultimate completion of clinical trials;
- results of clinical trials of relugolix, RVT-602 or those of our competitors;
- any delay in filing an NDA or similar application for relugolix or RVT-602 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 relugolix, RVT-602 or any future product candidate;
- inability to obtain additional funding;
- regulatory or legal developments in the United States or other countries or jurisdictions applicable to relugolix, RVT-602 or any future product candidate;
- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for relugolix, RVT-602 or any future product candidate, or the inability to do so at acceptable prices;
- introduction of new products, services or technologies by our competitors;

- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- changes in the market valuations of similar companies;
- market conditions in the pharmaceutical and biotechnology sectors, and the issuance of new or changed securities analysts' reports or recommendations;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- significant lawsuits, including patent or shareholder litigation, and disputes or other developments relating to our proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- sales of our common shares by us or our shareholders in the future;
- trading volume of our common shares;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

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

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

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

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

Upon the closing of this offering, Roivant Sciences Ltd. will continue to control a majority of the voting power of our outstanding common shares. As a result, we will be a "controlled company" within the meaning of the NYSE corporate governance requirements. Under these rules, a company of which more than 50% of the voting power for the election of directors is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements:

- that a majority of the board of directors consists of independent directors;
- for an annual performance evaluation of the nominating and corporate governance and compensation committees;

- that we have a nominating and corporate governance committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; and
- that we have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibility.

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

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

Roivant Sciences Ltd. is currently our majority shareholder, and after this offering is completed, we will continue to be controlled by Roivant Sciences Ltd. Upon the closing of this offering, Roivant Sciences Ltd. will beneficially own approximately 63.6% of the voting power of our outstanding common shares, or approximately 61.3% if the underwriters exercise their option to purchase additional common shares in full. Therefore, even after this offering, Roivant Sciences Ltd. will be able to control elections of directors, amendments of our organizational documents, or approval of any merger, amalgamation, sale of assets or other major corporate transaction. Roivant Sciences Ltd.'s interests may not always coincide with our corporate interests or the interests of other shareholders, and it may exercise its voting and other rights in a manner with which you may not agree or that may not be in the best interests of our other shareholders. So long as it continues to own a significant amount of our equity, Roivant Sciences Ltd. will continue to be able to strongly influence and significantly control our decisions.

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

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

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

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

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

Our management will have broad discretion in the application of the net proceeds from this offering and our shareholders will not have the opportunity as part of their investment decision to assess whether the net proceeds are being used appropriately. You may not agree with our decisions, and our use of the proceeds may not yield

any return on your investment. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our failure to apply the net proceeds of this offering effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use our net proceeds from this offering. For a period of six months after the closing of this offering, we have agreed to invest any cash and cash equivalents in a non-interest bearing account, and as a result, such investment will not yield a return.

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

After this offering, based on the 43,590,411 common shares outstanding as of June 30, 2016, there will be 58,523,408 common shares outstanding, assuming no exercise by the underwriters of their option to purchase additional common shares. Sales of a substantial number of our common shares in the public market after this offering, or the perception that these sales might occur, could depress the market price of our common shares and could impair our ability to raise capital through the sale of additional equity securities. Of our issued and outstanding common shares, all of the shares sold in this offering will be freely transferable without restrictions or further registration under the Securities Act of 1933, as amended, or the Securities Act. The remaining 45,523,408 common shares outstanding after this offering will be restricted as a result of securities laws, lock-up agreements or other contractual restrictions that restrict transfers for 180 days after the date of this prospectus. See the section titled "Shares Eligible for Future Sale—Lock-Up Agreements" for a more detailed description of the lock-up period.

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

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

The initial public offering price of our common shares will be substantially higher than the pro forma as adjusted net tangible book value per common share of our common shares. Therefore, if you purchase our common shares in this offering, you will pay a price per common share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. Based on an assumed initial public offering price of \$13.50 per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of \$10.91 per common share, representing the difference between our pro forma as adjusted net tangible book value per common share, after giving effect to this offering, and the assumed initial public offering price. In addition, you will experience further dilution if we issue additional common shares after the closing of this offering pursuant to a warrant we issued to Takeda, exercisable at a price of \$0.000017727 per share, which allows Takeda, together with its affiliates, to maintain a 12% ownership interest in us through April 2017, as further described in the section titled "Certain Relationships and Related Party Transactions—Relationship with Takeda Pharmaceuticals International AG—Warrant." Further, the future exercise of any options to purchase our common shares will cause you to experience additional dilution. See the section titled "Dilution" for additional information.

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

As a public company, and particularly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the NYSE and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel will need to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs.

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

We will be required, pursuant to Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the first fiscal year beginning after the effective date of this offering. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company, as defined in the JOBS Act. We will be required to disclose significant changes made in our internal control procedures on a quarterly basis.

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

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

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

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including exemption from compliance with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of this offering, (b) in which we have total annual gross revenue of at least \$1.0 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common shares that is held by non-affiliates exceeds \$700.0 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

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

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

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

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

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

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

We are organized under the laws of Bermuda. As a result, our corporate affairs are governed by the Bermuda Companies Act 1981, as amended, or the Companies Act, which differs in some material respects from laws typically applicable to U.S. corporations and shareholders, including the provisions relating to interested directors, amalgamations, mergers and acquisitions, takeovers, shareholder lawsuits and indemnification of directors. Generally, the duties of directors and officers of a Bermuda company are owed to the company only. Shareholders of Bermuda companies typically do not have rights to take action against directors or officers of the

company and may only do so in limited circumstances. Shareholder class actions are not available under Bermuda law. The circumstances in which shareholder derivative actions may be available under Bermuda law are substantially more proscribed and less clear than they would be to shareholders of U.S. corporations. The Bermuda courts, however, would ordinarily be expected to permit a shareholder to commence an action in the name of a company to remedy a wrong to the company where the act complained of is alleged to be beyond the corporate power of the company or illegal, or would result in the violation of the company's memorandum of association or bye-laws. Furthermore, consideration would be given by a Bermuda court to acts that are alleged to constitute a fraud against the minority shareholders or, for instance, where an act requires the approval of a greater percentage of the company's shareholders than those who actually approved it.

When the affairs of a company are being conducted in a manner that is oppressive or prejudicial to the interests of some shareholders, one or more shareholders may apply to the Supreme Court of Bermuda, which may make such order as it sees fit, including an order regulating the conduct of the company's affairs in the future or ordering the purchase of the shares of any shareholders by other shareholders or by the company. Additionally, under our bye-laws and as permitted by Bermuda law, each shareholder has waived any claim or right of action against our directors or officers for any action taken by directors or officers in the performance of their duties, except for actions involving fraud or dishonesty. In addition, the rights of our shareholders and the fiduciary responsibilities of our directors under Bermuda law are not as clearly established as under statutes or judicial precedent in existence in jurisdictions in the United States, particularly the State of Delaware. Therefore, our shareholders may have more difficulty protecting their interests than would shareholders of a corporation incorporated in a jurisdiction within the United States.

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

Common shares may be offered or sold in Bermuda only in compliance with the provisions of the Companies Act and the Bermuda Investment Business Act 2003, which regulates the sale of securities in Bermuda. In addition, the Bermuda Monetary Authority must approve all issues and transfers of shares of a Bermuda exempted company. However, the Bermuda Monetary Authority has, pursuant to its statement of June 1, 2005, given its general permission under the Exchange Control Act 1972 and related regulations for the issue and free transfer of our common shares to and among persons who are non-residents of Bermuda for exchange control purposes as long as the shares are listed on an appointed stock exchange, which includes 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.

We have anti-takeover provisions in our bye-laws that may discourage a change of control.

Our bye-laws contain provisions that could make it more difficult for a third party to acquire us without the consent of our board of directors. These provisions provide for:

- a classified board of directors with staggered three-year terms;
- directors only to be removed for cause;
- an affirmative vote of 66²/₃% of our voting shares for certain "business combination" transactions that have not been approved by our board of directors;
- · restrictions on the time period in which directors may be nominated; and
- our board of directors to determine the powers, preferences and rights of our preference shares and to issue the preference shares without shareholder approval.

These anti-takeover defenses could discourage, delay or prevent a transaction involving a change in control of our company and may prevent our shareholders from receiving the benefit from any premium to the market price of our common shares offered by a bidder in a takeover context. Even in the absence of a takeover attempt, the existence of these provisions may adversely affect the prevailing market price of our common shares if the provisions are viewed as discouraging takeover attempts in the future. These provisions could also discourage proxy contests, make it more difficult for you and other shareholders to elect directors of your choosing and cause us to take corporate actions other than those you desire. See the section titled "Description of Share Capital."

The voting power of your common shares may be reduced without your further consent.

Under our amended and restated bye-laws, in the event that any U.S. person holds, directly, indirectly or constructively, 9.5% or more of the total voting power of our issued share capital, excluding any U.S. person that holds, directly, indirectly or constructively, 9.5% or more of the total voting power of issued share capital immediately prior to the closing of this offering, the aggregate votes conferred by the common shares held by such person (or by any person through which such U.S. person indirectly or constructively holds shares) will be reduced by our board of directors to the extent necessary such that the common shares held, directly, indirectly or constructively, by such U.S. person will constitute less than 9.5% of the voting power of all issued and outstanding shares. Roivant Sciences Ltd. and certain of its affiliates will not be subject to these provisions. Further, our board of directors may determine that shares shall carry different or no voting rights as it reasonably determines, based on the advice of counsel, to be appropriate to (1) avoid the existence of any U.S. person who holds 9.5% or more of the total voting power of our issued share capital or (2) avoid adverse tax, legal or regulatory consequences to us, any subsidiary of ours or any holder of our common shares or its affiliates. These provisions may discourage potential investors from acquiring a stake or making a significant investment in our company as well as discourage a takeover attempt, which may prevent our shareholders from receiving the benefit of any such transactions as well as adversely affect the prevailing market price of our common shares if viewed as discouraging takeover attempts in the future.

We may become subject to unanticipated tax liabilities and higher effective tax rates.

We are incorporated under the laws of Bermuda, where we are not subject to any tax. We may, however, 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 non-Bermudan tax liability could materially adversely affect our results of operations. For example, we expect that Myovant Sciences GmbH will be the principal operating company for conducting our business and the entity that will hold our intellectual property rights in relugolix and RVT-602. The establishment of this Swiss entity as our principal operating company and the transfer of our intellectual property rights to this entity may result in a higher overall effective tax rate.

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

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

Significant judgment is required in evaluating our tax positions and determining our provision for income taxes. During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. For example, our effective tax rates could be adversely affected by changes in foreign currency exchange rates or by changes in the relevant tax, accounting and other laws, regulations, principles and interpretations. As we intend to operate in numerous countries and taxing jurisdictions, the application of tax laws can be subject to diverging and sometimes conflicting interpretations by tax authorities of these jurisdictions. It is not uncommon for taxing authorities in different countries to have conflicting views, for instance, with respect to, among other things, the manner in which the arm's length standard is applied for transfer pricing purposes, or with respect to the valuation of intellectual property. In addition, tax laws are dynamic and subject to change as new laws are passed and new interpretations of the law are issued or applied. In particular, there is uncertainty as to any future U.S. tax legislation on corporate tax rates but also the U.S. tax consequences of income derived from intellectual property held overseas in low tax jurisdictions.

If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arms' length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, potentially resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our 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, the United States, Bermuda and other jurisdictions as well as being affected by certain changes currently proposed by the Organisation for Economic Co-operation and Development and their action plan on Base Erosion and Profit Shifting. Such changes may become more likely as a result of recent economic trends in the jurisdictions in which we operate, particularly if such trends continue. If such a situation 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 generally accepted accounting principles; and (7) challenges to the transfer pricing policies related to our structure.

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

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest, and gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. 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 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 gains on the sale of our common shares. In addition, special information reporting may be required. See the section titled "Material Bermuda and U.S. Federal Income Tax Considerations—U.S. Federal Income Tax Considerations— Passive Foreign Investment Company Rules."

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets (which, assuming we are not a "controlled foreign corporation," or a CFC, under Section 957(a) of the Internal Revenue Code of 1986, as amended, or the Code, for the year being tested, may be determined 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) from time to time. Our status may also depend, in part, on how quickly we utilize the cash proceeds from this offering in our business. We believe that we were not a CFC prior to this offering in the current taxable year which will end on March 31, 2017. Based on this belief, with respect to the taxable year beginning in 2016 and foreseeable future taxable years, we presently do not anticipate that we will be a PFIC based upon the expected value of our assets, including any goodwill, and the expected nature and composition of our income and assets. Our status as a PFIC is a factintensive determination made on an annual basis and we cannot provide any assurances regarding our PFIC status for the current or future taxable years.

In the event that we receive passive income in the future that would cause us to be a PFIC, we would expect to evaluate and may implement alternative structures and arrangements including structures and arrangements intended to mitigate the possibility that we will be classified as a PFIC. The failure or inability to implement such structures or arrangements may have an adverse impact on the determination of whether we are classified as a PFIC.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

• the timing of and our ability to obtain and maintain regulatory approval of relugolix and RVT-602;

- our ability to successfully commercialize relugolix and RVT-602, if approved;
- the rate and degree of market acceptance of relugolix and RVT-602, if approved;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing;
- our expectation that the net proceeds from this offering will be sufficient to enable us to conduct our planned clinical development of relugolix and RVT-602, including through unblinding and release of data for at least one of our Phase 3 programs, which we expect to occur in 2019;
- our ability to maintain intellectual property protection for relugolix and RVT-602;
- our ability to identify and develop new product candidates;
- our ability to identify, recruit and retain key personnel;
- our use of proceeds from this offering;
- our financial performance; and
- · developments and projections relating to our competitors or our industry.

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

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

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

INDUSTRY AND MARKET DATA

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

USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of 13,000,000 common shares in this offering will be approximately \$160.7 million, or approximately \$185.2 million if the underwriters exercise their option to purchase additional common shares in full, based upon an assumed initial public offering price of \$13.50 per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase or decrease in the assumed initial public offering price of \$13.50 per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, would increase or decrease the net proceeds to us from this offering by approximately \$12.1 million, assuming that the number of common shares offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of common shares we are offering. Each increase or decrease of 1.0 million in the number of common shares we are offering at the assumed initial public offering price of \$13.50 per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions would increase or decrease the net proceeds to us from this offering by approximately \$12.6 million, assuming the assumed initial public offering price stays the same.

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

- approximately \$25.0 million to \$33.0 million to fund our planned Phase 3 clinical program for relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids;
- approximately \$30.0 million to \$40.0 million to fund our planned Phase 3 clinical program for relugolix for the treatment of endometriosis-associated pain;
- approximately \$40.0 million to \$50.0 million to fund our planned Phase 3 clinical program for relugolix for the treatment of advanced prostate cancer;
- approximately \$3.0 million to \$5.0 million to fund a Phase 1 healthy-volunteer study in women followed by a planned proof-of-concept Phase 2 trial for RVT-602 for the treatment of female infertility as part of assisted reproduction; and
- the remainder to fund working capital and general corporate purposes, which may include research and development of relugolix and RVT-602 for other indications.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. We believe the net proceeds from this offering, allocated as set forth above, will enable us to conduct each of the indicated planned clinical programs or trials, as applicable, including through unblinding and release of data for at least one of our Phase 3 programs, which we expect to occur in 2019; however, the amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of and results from preclinical studies and clinical trials, as well as any collaborations that we may enter into with third parties, and any unforeseen cash needs.

We believe opportunities may exist from time to time to expand our current business through the acquisition or in-license of complementary product candidates. While we have no current agreements or commitments for any specific acquisitions or in-licenses at this time, we may use a portion of the net proceeds for these purposes.

Our management will have broad discretion in the application of the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations and the anticipated growth of our business. Pending these uses, for a period of six months after the closing of this offering, we plan to invest these net proceeds in a non-interest bearing account. Thereafter, we may choose to invest these net proceeds in short-term, interest bearing obligations, investment-grade instruments,

certificates of deposit or direct or guaranteed obligations of the United States. The goal with respect to the investment of these net proceeds is capital preservation and liquidity so that such funds are readily available to fund our operations.

We believe that the net proceeds from this offering will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through unblinding and release of data for at least one of our Phase 3 programs, which we expect to occur in 2019. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

DIVIDEND POLICY

We have never declared or paid any dividends on our common shares. We anticipate that we will retain all of our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Any decision to declare and pay dividends in the future will be made at the sole discretion of our board of directors and will depend on, among other things, our results of operations, cash requirements, financial condition, contractual restrictions and other factors that our board of directors may deem relevant. In addition, pursuant to Bermuda law, a company may not declare or pay dividends 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.

CAPITALIZATION

The following table sets forth our cash and capitalization as of June 30, 2016:

- on an actual basis; and
- on a pro forma as adjusted basis to give effect to:
 - the issuance and sale of 13,000,000 common shares in this offering at an assumed initial public offering price of \$13.50 per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us;
 - an aggregate of 160,273 common shares issued to Takeda in August and September 2016 upon the automatic exercise of a warrant we issued to Takeda at an exercise price of \$0.000017727 per share, which was initiated by the grant of stock options for an aggregate of 1,175,311 common shares;
 - the issuance of an additional 1,772,724 common shares to Takeda upon the closing of this offering pursuant to the automatic exercise of a warrant we issued to Takeda, based upon the sale and issuance of 13,000,000 common shares to investors in this offering at an assumed initial public offering price of \$13.50 per common share, which is the midpoint of the price range set forth on the cover page of this prospectus;
 - offsetting increases of \$26,095,460 to each of accumulated deficit and additional paid-in capital to account for the aggregate issuance of 1,932,997 common shares to Takeda (calculated by multiplying such shares by the assumed initial public offering price of \$13.50 per common share, which is the midpoint of the price range set forth on the cover page of this prospectus); and
 - the reclassification of deferred initial public offering costs of \$523,681 from assets to additional paid-in capital.

The following information is illustrative only of our capitalization following the closing of this offering and will change based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with the sections titled "Use of Proceeds," "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes appearing elsewhere in this prospectus.

		As of June 30, 2016		
	Actual		Pro Forma As Adjusted(1)	
Cash	\$		\$ 160	0,715,000
Shareholders' (deficit) equity:				
Common shares, \$0.000017727 par value; 564,111,242 shares authorized, 43,590,411 shares issued and outstanding, actual; 564,111,242 shares authorized, 58,523,408 shares issued and outstanding, pro forma as				
adjusted	\$	773	\$	1,037
Common shares subscribed		(660)		(660)
Additional paid-in capital	12	,029,070	198	8,315,585
Accumulated deficit	(20	,627,277)	(46	6,722,737)
Total shareholders' (deficit) equity	(8	,598,094)	151	1,593,225
Total capitalization	\$ (8	,598,094)	\$ 151	1,593,225

(1) Each \$1.00 increase or decrease in the assumed initial public offering price of \$13.50 per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, would increase or decrease the pro forma as adjusted amount of each of cash, additional paid-in capital, total shareholders' (deficit) equity and total capitalization by approximately \$12.1 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. Each increase or decrease of 1.0 million in the number of common shares we are offering at the assumed initial public offering price of \$13.50 per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions, would increase or decrease each of cash, additional paid-in capital, total shareholders' (deficit) equity and total capitalization on a pro forma as adjusted basis by approximately \$12.6 million.

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

- an indeterminate number of capital shares that may be issued after the closing of this offering pursuant to a warrant we issued to Takeda, which allows Takeda, together with its affiliates, to maintain a 12% ownership interest in us, as determined after such exercise, through April 2017, unless earlier terminated upon a change in control, as further described in the section titled "Certain Relationships and Related Party Transactions—Relationship with Takeda Pharmaceuticals International AG—Warrant;" and
- 3,384,667 common shares reserved for future issuance under our 2016 Equity Incentive Plan, as amended, of which stock options for an aggregate of 1,175,311 common shares, with a weighted-average exercise price of \$3.17 per share, were granted in August and September 2016, as well as any automatic increases in the number of common shares reserved for future issuance under this plan.

DILUTION

If you invest in our common shares in this offering, your interest will be diluted to the extent of the difference between the initial public offering price per common share and the pro forma as adjusted net tangible book value per common share of our common shares immediately after this offering.

As of June 30, 2016, we had a pro forma net tangible book deficit of \$(9.1) million, or \$(0.20) per common share. Pro forma net tangible book value per common share is determined by dividing our total tangible assets less total liabilities by the number of outstanding common shares, after giving effect to: (1) an aggregate of 160,273 common shares issued to Takeda in August and September 2016 upon the automatic exercise of a warrant we issued to Takeda at an exercise price of \$0.000017727 per share, which was initiated by the grant of stock options for an aggregate of 1,175,311 common shares; and (2) the issuance of an additional 1,772,724 common shares to Takeda upon the closing of this offering pursuant to the automatic exercise of a warrant we issued to Takeda, based upon the sale and issuance of 13,000,000 common shares to investors in this offering at an assumed initial public offering price of \$13.50 per common share, which is the midpoint of the price range set forth on the cover page of this prospectus.

After giving effect to the issuance and sale of 13,000,000 common shares in this offering at an assumed initial public offering price of \$13.50 per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2016 would have been \$151.6 million, or \$2.59 per common share. This represents an immediate increase in the pro forma as adjusted net tangible book value of \$2.79 per common share to our shareholders, and an immediate dilution in the pro forma as adjusted net tangible book value of \$10.91 per common share to investors purchasing our common shares in this offering. The following table illustrates this per common share dilution:

Assumed initial public offering price per common share		\$13.50
Pro forma net tangible book deficit per common share as of June 30, 2016	\$(0.20)	
Increase in pro forma net tangible book value per common share attributable to new investors participating in this offering	2.79	
Pro forma as adjusted net tangible book value per common share after this offering		2.59
Dilution per common share to investors participating in this offering		\$10.91

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$13.50 per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value as of June 30, 2016 by \$0.21 per common share, and would increase (decrease) dilution to investors in this offering by \$0.79 per common share, assuming that the number of common shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions.

Similarly, each increase (decrease) of 1.0 million shares in the number of common shares we are offering would increase (decrease) our pro forma as adjusted net tangible book value as of June 30, 2016 by \$0.17 per common share and would (decrease) increase dilution to investors in this offering by \$0.17 per common share, assuming the assumed initial public offering price remains the same, and after deducting underwriting discounts and commissions. The pro forma as adjusted information is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

If the underwriters exercise their option in full to purchase an additional 1,950,000 common shares in this offering, the pro forma as adjusted net tangible book value per common share after the offering would be \$2.90 per common share, the increase in the pro forma as adjusted net tangible book value per common share to our shareholders would be \$3.10 per common share and the dilution to new investors purchasing common shares in this offering would be \$10.60 per common share.

The following table sets forth as of June 30, 2016, on the pro forma as adjusted basis described above, the differences between the number of common shares purchased from us, the total consideration paid and the weighted average price per common share paid by our shareholders, including an aggregate of 160,273 common shares issued to Takeda in August and September 2016 and 1,772,724 common shares issuable to Takeda upon the closing of this offering pursuant to the automatic exercise of a warrant we issued to Takeda at an exercise price of \$0.000017727 per share, and by investors purchasing our common shares in this offering at an assumed initial public offering price of \$13.50 per common share, which is the midpoint of the price range set forth on the cover page on this prospectus, before deducting underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purc	hased	Total Consideration		Average Price Per Common
	Number	Percent	Amount	Percent	Share
Existing shareholders	45,523,408	78%	\$	— %	\$ —
New investors	13,000,000	22	175,500,000	100	13.50
Total	58,523,408	100%	\$175,500,000	100%	

Weighted

Each \$1.00 increase or decrease in the assumed initial public offering price of \$13.50 per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the total consideration paid by new investors by \$12.1 million, and increase or decrease the percent of total consideration paid by new investors by less than a quarter of a percentage point, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same.

The table and discussion above exclude:

- an indeterminate number of capital shares that may be issued after the closing of this offering pursuant to a warrant we issued to Takeda, which allows Takeda, together with its affiliates, to maintain a 12% ownership interest in us, as determined after such exercise, through April 2017, unless earlier terminated upon a change in control, as further described in the section titled "Certain Relationships and Related Party Transactions—Relationship with Takeda Pharmaceuticals International AG—Warrant;" and
- 3,384,667 common shares reserved for future issuance under our 2016 Equity Incentive Plan, as amended, of which stock options for an aggregate of 1,175,311 common shares, with a weighted-average exercise price of \$3.17 per share, were granted in August and September 2016, as well as any automatic increases in the number of common shares reserved for future issuance under this plan.

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

SELECTED CONSOLIDATED FINANCIAL DATA

The following tables set forth our selected consolidated financial data for the periods indicated. We derived the consolidated statement of operations data for the period from February 2, 2016 (date of inception) through March 31, 2016 and the consolidated balance sheet data as of March 31, 2016 from our audited consolidated financial statements appearing elsewhere in this prospectus. Our consolidated statement of operations data for the three months ended June 30, 2016 and the consolidated balance sheet data as of June 30, 2016 are derived from our unaudited consolidated financial statements appearing elsewhere in this prospectus. We have prepared the unaudited consolidated financial statements on the same basis as the audited consolidated financial statements and have included, in our opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. The data should be read together with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes appearing elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future, and our operating results for the period ended March 31, 2016 and the three months ended June 30, 2016 are not indicative of the results that may be expected for a full fiscal year or any other future period. Our fiscal year ends on March 31.

	Period from February 2, 2016 (Date of Inception) to March 31, 2016	Three Months Ended June 30, 2016
Consolidated Statement of Operations Data:		
Operating expenses:		
Research and development	\$ —	\$ 14,573,014
General and administrative	1,656,788	2,561,878
Total operating expenses	1,656,788	17,134,892
Other (expense) income:		
Changes in the fair value of the warrant liability		(1,832,543)
Loss before provision for income tax	(1,656,788)	(18,967,435)
Income tax expense		3,054
Net loss and comprehensive loss	\$ (1,656,788)	\$(18,970,489)
Net loss per common share—basic and diluted(1)	\$ (0.04)	\$ (0.47)
Weighted average shares outstanding—basic and diluted(1)	37,231,342	40,771,548
Pro forma net loss per common share—basic and diluted (unaudited)(2)		\$ (0.45)
Pro forma weighted average common shares outstanding—basic and diluted (unaudited)(2)		42,544,277

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

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

Consolidated Balance Sheet Data:	As of March 31, 2016	As of June 30, 2016
Cash	\$ —	\$ —
Total assets	·	523,681
Total liabilities	222,650	9,121,775
Accumulated deficit	(1,656,788)	(20,627,277)
Total shareholders' deficit	(222,650)	(8,598,094)

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

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

Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for women's health diseases and other endocrine-related disorders. Our lead product candidate is relugolix, an oral, once-daily, small molecule that acts as a gonadotropin-releasing hormone, or GnRH, receptor antagonist. We are advancing relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids, endometriosis-associated pain and advanced prostate cancer. Relugolix has been evaluated in over 1,300 subjects to date, in Phase 1 and multiple large, randomized Phase 2 clinical trials, some of which are ongoing. These trials have produced favorable results in each indication. In these trials, relugolix was shown to be generally well tolerated and to successfully suppress estrogen and progesterone levels in women and testosterone levels in men. The suppression of estrogen and progesterone levels in women has been shown to effectively treat the symptoms of uterine fibroids and endometriosis, and the suppression of testosterone levels in men has been shown to effectively treat advanced prostate cancer.

We plan to initiate three multinational Phase 3 clinical programs for relugolix, one in the first quarter of 2017 in women with heavy menstrual bleeding associated with uterine fibroids, a second in the first half of 2017 in women with endometriosis-associated pain, and a third in the first quarter of 2017 in men with advanced prostate cancer. We completed an End of Phase 2 meeting with the FDA for relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids in early October 2016, and expect to submit our IND, including Phase 3 protocols, for this indication to the FDA in 2016. The commencement of our Phase 3 program in women with endometriosis-associated pain is subject to the completion of an End of Phase 2 meeting with the FDA, which we expect to occur in the first quarter of 2017. We expect to report top-line data from each of these Phase 3 programs in 2019. We plan to develop our second product candidate, RVT-602, for the treatment of female infertility as part of assisted reproduction. In the second half of 2017, we expect to initiate a Phase 1 healthy-volunteer study in women followed by a Phase 2 proof-of-concept trial for RVT-602.

We were incorporated in February 2016 and our operations to date have been limited to organizing and staffing our company, acquiring the rights to relugolix and RVT-602 and preparing for and advancing our product candidates into clinical development. To date, we have not generated any revenue. As of June 30, 2016, we had an accumulated deficit of \$20,627,277. For the period from February 2, 2016 (date of inception) to March 31, 2016 and for the three months ended June 30, 2016 we recorded net losses of \$1,656,788 and \$18,970,489, respectively.

License Agreement with Takeda Pharmaceuticals International AG

In April 2016, we entered into a license agreement with Takeda in which we were granted an exclusive, royalty-bearing license to develop and commercialize relugolix and RVT-602 and products containing relugolix and RVT-602. The territory for our exclusive license for relugolix covers all countries worldwide, excluding Japan and certain other Asian countries, which we collectively refer to as the Takeda Territory, to which Takeda retains exclusive rights. The territory for our exclusive license for RVT-602 covers all countries worldwide. We

also granted to Takeda an exclusive, royalty-bearing license in the Takeda Territory to develop and commercialize relugolix and products containing relugolix for all human diseases and conditions. We will pay a fixed, high single-digit royalty on net sales of relugolix or RVT-602 products in our territory, subject to certain agreed reductions, and Takeda will pay us a royalty at the same high single-digit rate on net sales of relugolix products for prostate cancer in the Takeda Territory, subject to certain agreed reductions. See the section titled "Business—License Agreement with Takeda Pharmaceuticals International AG" for additional information.

In connection with this license agreement with Takeda, we issued 5,077,001 common shares, then equal to 12% of our outstanding share capital, to Takeda pursuant to a subscription agreement, and also issued Takeda a warrant which allows Takeda, together with its affiliates, to maintain a 12% ownership of us through April 29, 2017, the one-year anniversary of the issuance of the warrant, unless earlier terminated as a result of a change in control. We also entered into an investor rights agreement with Takeda and a manufacture and supply agreement with a Takeda affiliate. See the sections titled "Certain Relationships and Related Party Transactions—Relationship with Takeda Pharmaceuticals International AG" and "—Investor Rights Agreement" for further information regarding these agreements and the warrant.

Services Agreement with Roivant Sciences, Inc.

In July 2016, we and our wholly-owned subsidiary, Myovant Sciences, Inc., entered into a services agreement with Roivant Sciences, Inc., a wholly-owned subsidiary of Roivant Sciences Ltd., or the Services Agreement, effective April 29, 2016, pursuant to which Roivant Sciences, Inc. provides us with services in relation to the identification of potential product candidates, project management of clinical trials and other development, administrative and financial activities. Under the terms of the Services Agreement, we are obligated to pay or reimburse Roivant Sciences, Inc. for the costs it, or third parties acting on its behalf, incur(s) in providing services to us. In addition, we are obligated to pay to Roivant Sciences, Inc. a pre-determined mark-up, currently equal to 10%, on costs incurred by it in connection with any general and administrative and support services as well as research and development services. Following the closing of this offering, we expect that our reliance on Roivant Sciences, Inc. will decrease over time as we, Myovant Sciences, Inc. and any other future subsidiary of ours continue to hire the necessary personnel to manage the development and potential commercialization of relugolix. See the section titled "Certain Relationships and Related Party Transactions—Relationship with Roivant Sciences, Inc.—Services Agreement" for additional information.

Financial Operations Overview

Revenue

We have not generated any revenue, and we do not expect to generate any revenue from the sale of any products unless or until we obtain regulatory approval of and commercialize relugolix or RVT-602.

Research and Development Expense

Since our incorporation, our operations have primarily been limited to the license of the rights to relugolix and RVT-602 and products containing these compounds. Our research and development expenses for the three months ended June 30, 2016 were \$14,573,014 and consisted primarily of in-process research and development expenses of \$13,117,000, which consisted of \$7,740,000 for the estimated fair value of the 5,077,001 common shares issued to Takeda and \$5,377,000 for the estimated fair value of the warrant liability, as well as share-based compensation expense and costs allocated to us under the Services Agreement, including employee-related services and third-party costs. Following the closing of this offering, we expect to significantly increase our research and development efforts as we initiate our Phase 3 programs for relugolix. Research and development expenses will include:

- employee-related expenses, such as salaries, share-based compensation, benefits and travel expense for the research and development personnel that we plan to hire;
- costs allocated to us under the Services Agreement;

- expenses incurred under agreements with contract research organizations, or CROs, as well as consultants that conduct preclinical studies designed to assist with the lead optimization of our product candidate;
- manufacturing costs in connection with conducting preclinical studies;
- costs for sponsored research; and
- depreciation expense for assets used in research and development activities.

Research and development activities will continue to be central to our business model. Product candidates in later stages of clinical development, such as 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 trials. We expect our research and development expenses to be significant over the next several years as we increase personnel and compensation costs and commence our potential Phase 3 programs, initiate a Phase 1 healthy-volunteer study in women followed by a Phase 2 proof-of-concept trial for RVT-602 and prepare to seek regulatory approval for our product candidates. It is difficult to determine with certainty the duration and completion costs of any clinical trial we may conduct.

The duration, costs and timing of clinical trials of relugolix, RVT-602 and any other product candidates will depend on a variety of factors that include, but are not limited to:

- the number of trials required for approval;
- the per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trial is conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- the potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up;
- the timing and receipt of regulatory approvals; and
- the efficacy and safety profile of the product candidate.

In addition, the probability of success for relugolix, RVT-602 and any other product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability.

General and Administrative Expense

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

We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities and increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, lawyers and accountants, among other expenses. Additionally, we anticipate increased costs associated with being a public company, including expenses related to services associated with maintaining compliance with NYSE rules and SEC requirements, insurance and investor relations costs. In addition, if relugolix or RVT-602 obtains regulatory approval for marketing, we expect that we would incur expenses associated with building a sales and marketing team.

Results of Operations from February 2, 2016 (Date of Inception) to March 31, 2016 and for the Three Months Ended June 30, 2016

The following table sets forth our results of operations for the period from February 2, 2016 (date of inception) to March 31, 2016 and for the three months ended June 30, 2016.

	Period from February 2, 2016 (Date of Inception) to March 31, 2016	Three Months Ended June 30, 2016	
Operating expenses:			
Research and development	\$ —	\$ 14,573,014	
General and administrative	1,656,788	2,561,878	
Total operating expenses	1,656,788	17,134,892	
Other (expense) income:			
Changes in the fair value of the warrant liability		(1,832,543)	
Income tax expense		3,054	
Net loss and comprehensive loss	\$ (1,656,788)	\$ (18,970,489)	

Research and Development Expenses

We did not incur any research and development expenses for the period from February 2, 2016 (date of inception) to March 31, 2016.

Research and development expenses were \$14,573,014 for the three months ended June 30, 2016, and consisted primarily of in-process research and development expenses of \$13,117,000, which were related to our acquisition of the rights to our product candidates and consisted of \$7,740,000 for the estimated fair value of the 5,077,001 common shares issued to Takeda and \$5,377,000 for the estimated fair value of warrant liability. The remainder consisted of share-based compensation expense of \$974,642 allocated to us by Roivant Sciences Ltd. and costs billed to us under the Services Agreement of \$476,374, including personnel expenses and third-party costs associated with the preparation of our clinical and other research programs.

General and Administrative Expenses

General and administrative expenses were \$1,656,788 for the period from February 2, 2016 (date of inception) to March 31, 2016, and consisted primarily of share-based compensation expense of \$987,066 and personnel expenses of \$441,522 allocated to us from Roivant Sciences, Inc. and Roivant Sciences Ltd. for services provided to us by their employees and \$164,116 of legal fees and consulting services associated with the formation of our company and corporate matters.

General and administrative expenses were \$2,561,878 for the three months ended June 30, 2016, and consisted of share-based compensation expense of \$1,645,860, primarily related to share-based compensation expense allocated to us by Roivant Sciences, Inc. and Roivant Sciences Ltd., and costs of \$555,186 billed to us under the Services Agreement, including personnel expenses, overhead allocations and third-party costs. The remainder consisted primarily of legal and professional fees of \$278,660 and other personnel related-expenses of \$82,172.

Changes in the Fair Value of the Warrant Liability

The change in the fair value of the warrant liability was \$1,832,543 as the fair value of the warrant liability increased to \$6,975,000 at June 30, 2016 from \$5,377,000 at April 29, 2016, the date of issuance of the warrant to Takeda, primarily due to changes in the assumptions regarding probabilities of successful financing events used to estimate the fair value of the liability, partially offset by \$234,543 related to the fair value of the warrant exercised during the three months ended June 30, 2016.

Liquidity and Capital Resources

Overview

For the period from February 2, 2016 (date of inception) to March 31, 2016 and for the three months ended June 30, 2016, we had net losses of \$1,656,788 and \$18,970,489, respectively. As of June 30, 2016, we had no cash and had never generated any revenue. These factors raise substantial doubt about our ability to continue as a going concern.

We expect to continue to incur significant and increasing operating losses at least for the next several years. We do not expect to generate product revenue unless and until we successfully complete development and obtain regulatory approval for relugolix and RVT-602 or any other product candidate. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our planned clinical trials and our expenditures on other research and development activities. We anticipate that our expenses will increase substantially as we:

- commence our Phase 3 programs of relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids, endometriosis-related pain and advanced prostate cancer;
- commence a Phase 1 healthy-volunteer study in women followed by a Phase 2 proof-of-concept trial for RVT-602 for the treatment of female infertility as part of assisted reproduction;
- seek to identify, acquire, develop and commercialize additional product candidates;
- integrate acquired technologies into a comprehensive regulatory and product development strategy;
- maintain, expand and protect our intellectual property portfolio;
- hire scientific, clinical, quality control and administrative personnel;
- add operational, financial and management information systems and personnel, including personnel to support our drug development efforts;
- · seek regulatory approvals for any product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any drug candidates for which we may obtain regulatory approval; and
- begin to operate as a public company.

We intend to use the proceeds of this offering primarily to fund the development of relugolix for the treatment of uterine fibroids, endometriosis and advanced prostate cancer. These funds will not be sufficient to enable us to complete all necessary development and commercially launch relugolix. Accordingly, we will be required to obtain further funding through other public or private offerings of our capital stock, debt financing, collaboration and licensing arrangements or other sources. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of relugolix or potentially discontinue operations.

Until such time, if ever, as we can generate substantial product revenue from sales of relugolix, RVT-602 or any future product candidate, we expect to finance our cash needs through a combination of equity offerings, debt financings and potential collaboration, license or development agreements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common shareholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our 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 for the period from February 2, 2016 (date of inception) to March 31, 2016 and for the three months ended June 30, 2016:

	Period from February 2, 2016 (Date of Inception) to March 31, 2016		Three Months Ended June 30, 2016	
Net cash used in operating activities	\$		\$ _	
Net cash used in investing activities			—	
Net cash provided by financing activities		—	—	

Operating Activities

For the period from February 2, 2016 (date of inception) to March 31, 2016, no cash was used in operating activities. The net loss for the period of \$1,656,788 was offset by an increase in our accrued expenses primarily attributable to legal and professional fees and consulting services and an allocation of personnel expenses by Roivant Sciences Ltd. and Roivant Sciences, Inc. associated with the formation of our company and corporate matters.

For the three months ended June 30, 2016, no cash was used in operating activities. The net loss for the period of \$18,970,489 was primarily offset by \$13,117,000 of non-cash in-process research and development expenses related to the acquisition of the rights to our product candidates, \$2,620,502 non-cash share-based compensation, \$1,832,543 non-cash changes in the fair value of the warrant liability and \$1,153,378 allocation of personnel expenses by Roivant Sciences Ltd. and Roivant Sciences, Inc. associated with the preparation of our clinical and other research programs, the formation of our company and corporate matters, and \$247,066 other expenses.

Investing Activities

For the period from February 2, 2016 (date of inception) to March 31, 2016 and for the three months ended June 30, 2016, no cash was used in investing activities.

Financing Activities

For the period from February 2, 2016 (date of inception) to March 31, 2016 and for the three months ended June 30, 2016, no cash was provided by financing activities.

Outlook

Based on the expected net proceeds from this offering, our research and development plans and our timing expectations related to the commencement of our Phase 3 programs for relugolix, we expect that the net proceeds from this offering will enable us to fund our operating expenses and capital expenditure requirements through unblinding and release of data for at least one of our Phase 3 programs, which we expect to occur in 2019. However, we have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect.

Contractual Obligations

As of June 30, 2016, we did not have any ongoing material financial commitments, such as lines of credit or guarantees that we expect to affect our liquidity over the next several years.

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 under SEC rules.

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Company Valuation

To estimate certain expenses and record certain transactions, it is necessary for us to estimate the fair value of our common shares. Given the absence of a public trading market, and in accordance with the American Institute of Certified Public Accountants' Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, our board of directors exercises reasonable judgment and considers numerous objective and subjective factors to determine the best estimate of the fair value of our common shares. See the section titled "—Share-Based Compensation."

Share-Based Compensation

We recognize share-based compensation expense related to stock options and restricted stock awards granted to employees based on the estimated fair value of the awards on the date of grant, net of forfeitures. We estimate the grant date fair value, and the resulting share-based compensation expense, using the Black-Scholes option-pricing model. The grant date fair value of the share-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards.

We recognize share-based compensation expense related to stock options granted to non-employees issued in exchange for services based on the estimated fair value of the awards on the date of grant, net of forfeitures.



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

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

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

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

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

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

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

In addition to the Black-Scholes assumptions, we estimate our forfeiture rate based on an analysis of our actual forfeitures and will continue to evaluate the adequacy of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover behavior and other factors. The impact from any forfeiture rate adjustment would be recognized in full in the period of adjustment and if the actual number of future forfeitures differs from our estimates, we might be required to record adjustments to share-based compensation in future periods.

A significant component of total share-based compensation expense relates to the Roivant Sciences Ltd. common share awards and options issued by Roivant Sciences Ltd. to its employees and employees of Roivant Sciences, Inc. Share-based compensation expense is allocated to us by Roivant Sciences Ltd. based upon the relative percentage of time utilized by Roivant Sciences, Inc. employees on our matters. The fair value of the Roivant Sciences Ltd. common share awards are determined on the date of grant and that fair value is recognized over the requisite service period. As Roivant Sciences Ltd. is a non-public entity and its common shares are not publicly traded, the common share awards and options are classified as a Level 3 measurement within the fair value hierarchy due to their unobservable nature. Significant judgment and estimates were used to estimate the fair value of these awards and options, as they are not publicly traded. Roivant Sciences Ltd. common share awards and options are subject to specified vesting schedules and requirements (a combination of time-based, performancebased and corporate event-based vesting terms, including targets for post-IPO market capitalization and future financing events of Roivant Sciences Ltd.). We estimated the fair value of each option on the date of grant using the Black-Scholes closed-form option-pricing model.

Prior to this offering, the fair value of our common shares was estimated on each grant date by our board of directors. In order to determine the fair value of our common shares, our board of directors considered, among other

things, timely valuations of our common shares prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Given the absence of a public trading market for our common shares, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common shares, including (1) our business, financial condition and results of operations, including related industry trends affecting our operations; (2) our forecasted operating performance and projected future cash flows; (3) the illiquid nature of our common shares; (4) the rights and privileges of our common shares; (5) market multiples of our most comparable public peers and (6) market conditions affecting our industry. Since the initial fair value of common shares at April 29, 2016, our probabilities of successful financing events and the hiring our chief executive officer have caused an increase in our estimate of the fair value of our common shares.

In connection with this initial public offering and after preliminary discussions with the underwriters, we reassessed the fair value of: (1) 1,128,222 restricted common shares issued to our Principal Executive Officer in June 2016 with a fair value of \$1.52 per common share; (2) 602,743 common shares underlying stock options granted in August 2016 to our employees and consultants with an exercise price of \$2.38 per common share; and (3) 572,568 common shares underlying stock options granted in September 2016 to our employees and directors with a weighted-average exercise price of \$4.00 per common share. As a result, we determined that the reassessed fair value of the restricted common shares was \$4.95 per common share and the reassessed fair value of the common shares underlying the stock options granted in August and September 2016 was \$13.50 per common share, which is the midpoint of the price range set forth on the cover page of this prospectus. This reassessment will increase share-based compensation expense commencing in the three months ended September 30, 2016. As of September 30, 2016, we expect to have \$20.7 million of total unrecognized share-based compensation cost, which we expect to recognize over a weighted-average period of 3.68 years. We determined that the amount of share-based compensation related to the June 2016 grant was not material to the three months ended June 30, 2016.

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

Warrant Liability

We record the warrant liability at its estimated fair value as a liability in our consolidated balance sheets. We remeasure the estimated fair value of the warrant liability each reporting period and record the changes in the estimated fair value in our consolidated statement of operations as other (expense) income. We measure the warrant liability at fair value based on significant inputs not observable in the market, which causes it to be classified as a Level 3 measurement within the fair value hierarchy. The valuation of the warrant liability uses assumptions and estimates we believe would be made by a market participant in making the same valuation. We assess these assumptions and estimates on an ongoing basis as additional data impacting the assumptions and estimates are obtained. Changes in the fair value of the warrant liability related to updated assumptions and estimates are recognized as other expenses in our consolidated statements of operations.

The warrant liability may change significantly as additional data is obtained, impacting our assumptions regarding probabilities of successful financing events used to estimate the fair value of the liability. In evaluating this information, considerable judgment is required to interpret the market data used to develop the assumptions and estimates. The estimates of fair value may not be indicative of the amounts that could be realized in a financing event. Accordingly, the use of different market assumptions or different valuation techniques may have a material effect on the estimated fair value amounts, and such changes could materially impact the our results of operations in future periods.

Research and Development Expense

We expense research and development costs 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. Payments for a product license prior to regulatory approval of the product and payments for milestones achieved prior to regulatory approval of the product are expensed in the period incurred as research and development. Milestone payments made in connection with regulatory approvals are capitalized and amortized to cost of revenue over the remaining useful life of the asset. Research and development expenses primarily consist of the intellectual property and research and development materials acquired, certain costs charged by Roivant Sciences, Inc. under the Services Agreement and expenses from third parties who conduct research and development activities on our behalf. We expense in-process research and development projects acquired as asset acquisitions which have not reached technological feasibility and which have no alternative future use. Clinical study costs are accrued over the service periods specified in the contracts and adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred.

As the intellectual property and inventory we acquired from Takeda had no alternative future use on the date of acquisition, we recorded them as research and development expense at April 29, 2016, the date we entered into the license agreement with Takeda, which consisted of the estimated fair value of the common shares transferred to Takeda and the estimated fair value of warrant liability. Significant judgment and estimates were used to estimate the fair value of common shares and warrant liability, as they are not publicly traded and are considered Level 3 measurement within the fair value hierarchy. The estimation of the fair value of the common shares considered discounted cash flow analyses and relevant industry and comparable public company data.

Income Taxes

We account for income taxes in accordance with ASC 740, Income Taxes. Under the assets-and-liability method of ASC 740, 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. Under ASC 740, 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.

We account for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, we recognize the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of June 30, 2016, we did not have any significant uncertain tax positions.

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board, or FASB, issued ASU No. 2014-15, *Presentation of Financial Statements—Going Concern* (*Subtopic 205-40*): *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ASU No. 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Specifically, ASU No. 2014-15 provides a definition of the term substantial doubt and requires an assessment for a period of one year after the date that the financial statements are issued. It also requires certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans and requires an express statement and other disclosures when substantial doubt is not alleviated. The new standard will be effective for reporting periods ending after December 15, 2016, with early adoption permitted. We do not expect the adoption of ASU No. 2014-15 will significantly impact our consolidated financial statements and related disclosures.

In November 2015, the FASB, issued ASU No. 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes.* This amendment will simplify the presentation of deferred tax assets and liabilities on the balance sheet and require all deferred tax assets and liabilities to be treated as non-current. ASU No. 2015-17 is effective for fiscal years, and interim periods within those fiscal years beginning after December 15, 2016, with early adoption permitted. We adopted ASU No. 2015-17. The adoption of ASU No. 2015-17 did not have a significant impact on our consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, which is a comprehensive new lease standard that amends various aspects of existing accounting guidance for leases. The core principle of ASU No. 2016-02 will require lessees to present the assets and liabilities that arise from leases on their balance sheets. ASU No. 2016-02 is effective for annual periods beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted. We are currently evaluating the new standard and its impact on our consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. ASU No. 2016-09 makes several modifications to Topic 718 related to the accounting for forfeitures, employer tax withholding on share-based compensation, and the financial statement presentation of excess tax benefits or deficiencies. ASU No. 2016-09 also clarifies the statement of cash flows presentation for certain components of share-based awards. The standard is effective for interim and annual reporting periods beginning after December 15, 2016, with early adoption permitted. We expect to adopt this guidance when effective and are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

JOBS Act

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107(b) of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Quantitative and Qualitative Disclosures about Market Risk

We did not have any cash or other financial instruments as of June 30, 2016.

BUSINESS

Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for women's health diseases and other endocrine-related disorders. Our lead product candidate is relugolix, an oral, once-daily, small molecule that acts as a gonadotropin-releasing hormone, or GnRH, receptor antagonist. We are advancing relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids, endometriosis-associated pain and advanced prostate cancer. Relugolix has been evaluated in over 1,300 subjects since 2007, in Phase 1 and multiple large, randomized Phase 2 clinical trials conducted in Japan, North America and the United Kingdom, some of which are ongoing. These trials have produced favorable results in each indication. In these trials, relugolix was shown to be generally well tolerated and to successfully suppress estrogen and progesterone levels in women and testosterone levels in men, consistent with its known mechanism of action.

We plan to initiate two multinational Phase 3 clinical programs for relugolix, one in the first quarter of 2017 in women with heavy menstrual bleeding associated with uterine fibroids and the other in the first half of 2017 in women with endometriosis-associated pain. We completed an End of Phase 2 meeting with the U.S. Food and Drug Administration, or FDA, for relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids in early October 2016, and expect to submit our investigational new drug application, or IND, including Phase 3 protocols, to the FDA in 2016. The commencement of our Phase 3 program in women with endometriosis-associated pain is subject to an End of Phase 2 meeting with the FDA, which we expect to occur in the first quarter of 2017. Based on a completed End of Phase 2 meeting with the FDA, we also plan to initiate a multinational Phase 3 clinical program for relugolix in men with advanced prostate cancer in the first quarter of 2017. We expect to report top-line data from each of these Phase 3 programs in 2019. We plan to develop our second product candidate, RVT-602, for the treatment of female infertility as part of assisted reproduction. In the second half of 2017, we expect to initiate a Phase 1 healthy-volunteer study in women followed by a Phase 2 proof-of-concept trial for RVT-602. We intend to develop relugolix in additional indications and augment our current pipeline through the acquisition and in-licensing of complementary, clinical-stage product candidates that we believe can be developed and commercialized in a capital-efficient manner.

Relugolix is an oral, once-daily, small molecule that acts as a GnRH receptor antagonist that binds to and inhibits receptors in the anterior pituitary gland. Inhibition of GnRH receptors decreases the release of the gonadotropins, luteinizing hormone, or LH, and follicle-stimulating hormone, or FSH, thereby decreasing the down-stream production of estrogen and progesterone by the ovaries in women and testosterone by the testes in men. This is a clinically-validated mechanism of action, and there is a commercially available injectable GnRH receptor antagonist for the treatment of advanced prostate cancer. The suppression of estrogen and progesterone levels has been shown to effectively treat the symptoms of uterine fibroids and endometriosis, and the suppression of testosterone levels has been shown to effectively treat advanced prostate cancer.

We believe relugolix has the potential to be a best-in-class oral GnRH receptor antagonist for the treatment of heavy menstrual bleeding associated with uterine fibroids and endometriosis-associated pain and both a first-in-class and best-in-class oral GnRH receptor antagonist for the treatment of advanced prostate cancer. We believe relugolix, as a once-daily oral therapy, has the potential to provide a substantial improvement over the current standards of care provided by injectable GnRH agonists and antagonists for women and men. In addition to its ease of administration, relugolix has been observed to offer advantages based on its mechanism of action as a GnRH antagonist rather than a GnRH agonist. In studies conducted to date, relugolix resulted in a rapid decline in LH and FSH, and therefore rapidly suppressed estrogen and progesterone production by the ovaries or testosterone production by the testes. Hormone suppression was achieved more quickly compared with the GnRH agonists, which initially stimulate these hormones and cause a flare or worsening of symptoms. Unlike GnRH agonists such as leuprolide, relugolix is not a depot, or slow-release, formulation and hormone levels return to baseline more rapidly after it is discontinued, providing more control for patients and their physicians. For example, a more

rapid return of hormone levels to baseline could be advantageous in the management of a concurrent illness, the restoration of fertility in women desiring to attempt pregnancy and the restoration of sexual function and energy levels in men.

We are developing relugolix to be co-administered with low-dose estradiol and progestin as add-back therapy in our target women's health indications to minimize mineral density loss, a known side effect of estrogen suppression, and improve tolerability. Estradiol is a major estrogen and progestin is a synthetic progestational agent. We intend to commercialize relugolix, if approved, in our target women's health indications as a fixed-dose combination product, which is a once-daily, single pill containing both relugolix and low-dose estradiol and progestin. We believe relugolix with add-back therapy has the potential to be used longer-term, unlike the currently approved GnRH agonist therapies. The low-dose estradiol and progestin add-back therapy we plan to use is approximately one-fifth of the dose used in traditional, combined oral contraceptive pills. This low dose is well-known to minimize bone mineral density loss in a hypoestrogenic state.

In April 2016, we entered into a license agreement with Takeda Pharmaceuticals International AG, or Takeda, through which we acquired the worldwide rights, excluding Japan and certain other Asian countries, to develop and commercialize relugolix. In multiple large, randomized Phase 2 clinical trials conducted by Takeda, relugolix has been shown to be generally well tolerated and to effectively suppress estrogen and progesterone levels in women and testosterone levels in men, consistent with its known mechanism of action. Takeda is currently conducting two Phase 3 trials evaluating relugolix in Japan for the treatment of uterine fibroid-related pain and heavy menstrual bleeding, respectively. Takeda expects to report top-line data from each of these trials in the second half of 2017 and, if these trials are successful, Takeda plans to seek regulatory approval of relugolix for these indications in Japan in 2018. We expect to submit Takeda's Phase 3 data as part of our new drug application, or NDA, to the FDA for relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids.

In the first quarter of 2017, we plan to initiate a multinational Phase 3 program, composed of two replicate clinical trials, for relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids. We completed an End of Phase 2 meeting with the FDA for this indication in early October 2016, and expect to submit our IND, including Phase 3 protocols, to the FDA in 2016. In the first half of 2017, we also plan to initiate a multinational Phase 3 program, composed of two replicate clinical trials, for relugolix for the treatment of endometriosis-associated pain. The commencement of our Phase 3 program in women with endometriosis-associated pain is subject to an End of Phase 2 meeting with the FDA, which we expect to occur in the first quarter of 2017.

In a double-blind, placebo-controlled Phase 2 clinical trial in 216 women conducted in Japan from 2011 to 2012, relugolix, administered at doses of 10 mg, 20 mg or 40 mg once daily for 12 weeks, markedly decreased menstrual blood loss associated with uterine fibroids. To be included in the trial, women were required to have a baseline menstrual period blood loss score of at least 120 as measured by the Pictorial Blood Assessment Chart, or PBAC, a method for evaluation of menstrual blood loss in clinical trials. A normal menstrual period has a PBAC score of approximately 70. A treatment responder was defined as a woman with a sum of PBAC scores from week 6 through week 12 of less than 10. Of the women enrolled in the relugolix 40 mg once-daily arm, 83.6% were responders and had marked decrease in menstrual blood loss. No women in the placebo arm responded. The result was statistically significant for each treatment arm versus placebo, with the greatest benefit observed at a dose of 40 mg once daily (p<0.0001). P-value is a conventional statistical method for measuring the statistical significance of clinical results. A p-value of 0.05 or less represents statistical significance, meaning there is a less than 1-in-20 likelihood that the observed results occurred by chance. There was a clear dose-dependent response across relugolix treatment arms, including estradiol suppression and the primary efficacy endpoint for heavy menstrual bleeding.

In a double-blind, placebo-controlled Phase 2 clinical trial in 487 women with endometriosis conducted in Japan from 2011 to 2013, relugolix was administered at doses of 10 mg, 20 mg or 40 mg once daily for 12 weeks. The primary endpoint was the change in pelvic pain from week 8 to week 12 as assessed by visual

analogue scale, or VAS, a patient-reported scale for the quantification of pain. The decline in pain was statistically significant between each dose arm and placebo, with the greatest benefit observed at a dose of 40 mg once daily (p<0.0001). There was a clear dose-dependent relationship across treatment arms.

Uterine fibroids and endometriosis represent large women's health markets with significant unmet medical need. We estimate approximately 19.0 million women in the United States have uterine fibroids, approximately 5.0 million of whom suffer from symptoms of the disease. Of these women, we estimate approximately 60%, or 3.0 million women in the United States, are inadequately treated by current medical therapy and require further treatment. We estimate approximately 7.5 million women in the United States have endometriosis, approximately 6.0 million of whom suffer from symptoms of the disease. Of these women, we estimate approximately 20%, or 1.2 million women in the United States, are inadequately treated by oral contraceptives and require further treatment.

Neither heavy menstrual bleeding associated with uterine fibroids nor endometriosis-associated pain has any curative medical solution. Current medical therapies include non-steroidal anti-inflammatory drugs, or NSAIDs, oral contraceptives and GnRH agonists, as well as danazol for endometriosis only. In moderate-to-severe cases of both diseases, medical therapies have been shown to be generally ineffective or the clinical benefit is hampered by a trade-off between efficacy and safety profiles, with drugs such as GnRH agonists limited to short-term use. Heavy menstrual bleeding associated with uterine fibroids is a leading cause of hysterectomy, resulting in approximately 250,000 hysterectomies per year in the United States alone. Further, approximately 100,000 endometriosis-related hysterectomies in women of reproductive age are performed in the United States each year. Complications arising from hysterectomy are common, with 17% to 25% of women experiencing post-surgical complications, including ureteral injury, bowel injury, bladder injury, hemorrhage or infection. Other surgical procedures such as myomectomy, or surgical removal of the fibroids, and laparoscopic procedures for endometriosis are commonly performed. We believe an oral therapy that could be used longer-term has the potential to enable women to avoid surgical intervention that may result in postoperative complications or complications with future pregnancy or even preclude the potential for future pregnancy.

An End of Phase 2 meeting in October 2015 for relugolix for the treatment of advanced prostate cancer confirmed that there are no additional clinical trials or nonclinical studies required to support the initiation of a Phase 3 trial, which we intend to initiate in the first quarter of 2017. In two randomized Phase 2 clinical trials in 228 men with advanced prostate cancer conducted in North America and the United Kingdom from 2014 to 2016, relugolix, administered orally for 24 weeks, demonstrated an ability to decrease testosterone to very low levels, commonly referred to as castration levels, and to reduce levels of prostatespecific antigen, or PSA, a key prostate cancer biomarker. These results for relugolix were consistent with those for leuprolide acetate, or leuprolide, a GnRH agonist typically used in ADT, and for degarelix, an injectable GnRH antagonist. Unlike GnRH agonists, relugolix, when orally administered once daily, was shown in these trials to rapidly decrease testosterone levels. In addition, testosterone levels returned to baseline more rapidly after discontinuation of relugolix than after discontinuation of leuprolide or degarelix.

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 United States. According to the National Cancer Institute, approximately 2.9 million men are currently living with prostate cancer in the United States, and approximately 180,000 men are newly diagnosed in the United States each year. Current treatments used when men are first diagnosed with prostate cancer generally include combinations of surgery and radiation therapy. If the disease recurs or spreads beyond the prostate, androgen deprivation therapy, or ADT, is initiated to lower testosterone and block androgen receptor signaling, which helps shrink the cancer. Prostate cancer that recurs and responds to ADT is referred to as advanced prostate cancer. Approximately 650,000 men with advanced prostate cancer are treated with GnRH agonists each year in the United States.

As part of our license agreement with Takeda, we also acquired the worldwide rights to RVT-602, our second product candidate. RVT-602 is an oligopeptide kisspeptin analog. Kisspeptin is a naturally-occurring

peptide in humans that plays a key role in egg maturation and ovulation by increasing the release of LH and FSH through the stimulation of GnRH secretion. In the second half of 2017, we plan to initiate a Phase 1 healthy-volunteer study in women followed by a Phase 2 proof-of-concept clinical trial for RVT-602 for the treatment of female infertility as part of assisted reproduction. 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-LH/FSH axis. We believe RVT-602 may mimic natural physiology by inducing the release of LH during assisted reproduction, thereby enhancing the likelihood of successful egg maturation and ovulation at the right time during the cycle without the potential for the uncommon but serious side effects associated with current hormone-stimulation treatment options. We believe RVT-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.

The following chart represents our current product candidate pipeline:

	Product Candidate	Indication	Phase 1	Phase 2	Phase 3	Upcoming Milestones	Myovant Commercial Rights
	Relugolix with Add-	Uterine Fibroids— Heavy Menstrual Bleeding				Phase 3 Initiation in First Quarter of 2017 ¹	Global, Excluding Takeda Territory ⁵
Myovant	Back Therapy	Endometriosis— Pain				Phase 3 Initiation in First Half of 2017 ²	Global, Excluding Takeda Territory ⁵
	Relugolix	Advanced Prostate Cancer				Phase 3 Initiation in First Quarter of 2017 ³	Global, Excluding Takeda Territory ⁵
	RVT-602	Female Infertility as part of Assisted Reproduction ⁴				Phase 1 Initiation in Second Half of 2017	Global

1 2

Subject to the submission of our IND to the FDA, which we expect to occur in 2016. Subject to our End of Phase 2 meeting with the FDA, which we expect to occur in the first quarter of 2017.

An End of Phase 2 meeting confirmed that there are no additional clinical trials or nonclinical studies required to support the initiation of a Phase 3 trial.

3 4 RVT-602 has been evaluated in Phase 1 and Phase 2a clinical trials conducted by Takeda in men for the treatment of prostate cancer and hypogonadotropic hypogonadism, or a state of low testosterone levels. We plan to initiate a Phase 1 healthy-volunteer study in women followed by a Phase 2 proof-of-concept trial.

5 Takeda Territory includes Japan, China, Hong Kong, Indonesia, Korea, Malaysia, Philippines, Singapore, Taiwan, Thailand and Vietnam, including, in each case, the territories and possessions of each of the foregoing.

The following chart represents the anticipated near-term milestones for Takeda's development of relugolix in Japan:

	Product Candidate	Indication	Phase 1	Phase 2	Phase 3	Upcoming Milestones	Takeda Commercial Rights
Takeda		Uterine Fibroids— Pain				Top-line Data in Third Quarter of 2017	Takeda Territory ¹
	Relugolix	Uterine Fibroids— Heavy Menstrual Bleeding				Top-line Data in Fourth Quarter of 2017	Takeda Territory ¹

1 Takeda Territory includes Japan, China, Hong Kong, Indonesia, Korea, Malaysia, Philippines, Singapore, Taiwan, Thailand and Vietnam, including, in each case, the territories and possessions of each of the foregoing.

Our Strategy

Our goal is to be the leading global biopharmaceutical company focused on the innovative treatment of women's health diseases and other endocrinerelated disorders in areas of high unmet medical need, and improve the lives of millions of patients suffering from these diseases. The key elements of our strategy to achieve this goal include the following:

- *Rapidly advance relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids and endometriosis-associated pain.* In the first quarter of 2017, we plan to initiate two replicate multinational Phase 3 trials for relugolix with add-back therapy in women with heavy menstrual bleeding associated with uterine fibroids. In the first half of 2017, we plan to initiate two replicate multinational Phase 3 trials for relugolix co-administered with add-back therapy in women with endometriosis-associated pain. We completed an End of Phase 2 meeting with the FDA for relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids in early October 2016, and expect to submit our IND, including Phase 3 protocols, to the FDA in 2016. The commencement of our Phase 3 program in women with endometriosis-associated pain is subject to an End of Phase 2 meeting with the FDA, which we expect to occur in the first quarter of 2017. We expect to report top-line data from each of these Phase 3 programs in 2019. If the results of these planned Phase 3 trials are favorable, we intend to submit NDAs to the FDA in 2019 and may submit comparable submissions to other regulatory authorities to obtain marketing approval for relugolix for the treatment of heavy menstrual bleeding associated pain, respectively. Takeda is currently conducting two Phase 3 trials in Japan for relugolix for the treatment of uterine fibroid-related pain and heavy menstrual bleeding, respectively, and if the results are favorable, Takeda intends to apply for marketing approval in Japan.
- *Rapidly advance relugolix for the treatment of advanced prostate cancer.* In the first quarter of 2017, we plan to initiate a multinational Phase 3 clinical trial for relugolix in men with advanced prostate cancer. We expect to report top-line data from this Phase 3 trial in 2019. If the results of this planned Phase 3 trial are favorable, we intend to submit an NDA to the FDA and may submit comparable submissions to other regulatory authorities to obtain marketing approval for relugolix for the treatment of advanced prostate cancer.
- Advance clinical development of RVT-602. In the second half of 2017, we plan to initiate a Phase 1 healthy-volunteer study in women followed by a Phase 2 proof-of-concept clinical trial of RVT-602 to assess the potential of this oral kisspeptin analog as a treatment to enhance egg maturation in women as part of assisted reproduction, such as in vitro fertilization, or IVF, with a decreased risk of the uncommon but serious side effects associated with current hormone stimulation treatment options.

- *Expand development of relugolix for additional indications.* We intend to explore the development of relugolix for additional indications, including polycystic ovary syndrome and precocious puberty.
- Acquire or in-license additional clinical- or commercial-stage product candidates for the treatment of women's health diseases or endocrine-related disorders in a capital efficient manner. In addition to relugolix and RVT-602, we intend to identify, acquire, develop and commercialize novel, clinical- or commercial-stage product candidates with clinically-validated mechanisms of action in a capital-efficient manner.
- *Maximize the commercial potential of our product candidates.* We plan to independently commercialize our product candidates, including relugolix and RVT-602, in the United States and selectively in other territories. Takeda plans to commercialize relugolix in Japan and certain other Asian countries. We may opportunistically seek additional strategic collaborations to maximize the commercial opportunities for our product candidates outside of the United States.

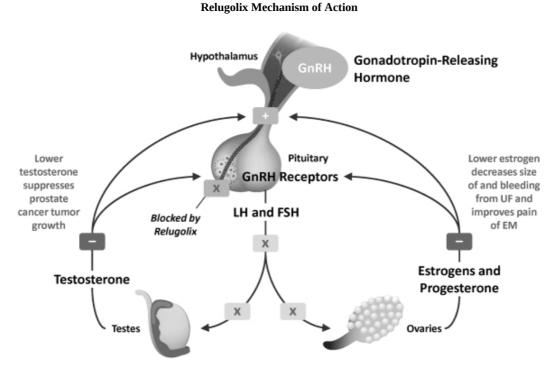
Relugolix

Relugolix is an oral, once-daily, small molecule that acts as a potent antagonist of the GnRH receptor and has a long half-life. The half maximal inhibitory concentration, or IC₅₀, of relugolix, a measure of its potency, is 0.12 nanomolar, or nM, and the half-life, or the time when approximately 50% of relugolix is cleared from the body, is 37 to 42 hours. Relugolix binds to receptors in the anterior pituitary gland to inhibit the release of the gonadotropins, LH and FSH, decreasing the production of estrogen and progesterone in the ovaries, and testosterone in the testes. GnRH antagonists such as relugolix exhibit a classical competitive and reversible blockade of GnRH receptors on the cell membrane of the gonadotropic cells in the pituitary and result in rapid lowering of hormone levels. By contrast, approved agents such as GnRH agonists first stimulate the GnRH receptors, thereby initially increasing hormone levels, which can result in an initial worsening of clinical symptoms, known as hormonal flare. After this initial increase, the pituitary eventually becomes desensitized to the stimulation due to down-regulation of the GnRH receptors, ultimately resulting in a decrease in gonadotropin secretion and hormone levels.

In women, both LH and FSH regulate the secretion of estrogen and progesterone from the ovaries. Suppression of gonadotropin secretion using GnRH antagonists may be an effective treatment for hormone-dependent gynecological diseases such as uterine fibroids or endometriosis due to the direct and immediate inhibition of GnRH action. Lowering estrogen levels in women has been shown to decrease bleeding from, and the size of, uterine fibroids and reduce the pain associated with endometriosis. GnRH antagonists, such as relugolix, rapidly downregulate the gonadotropin-gonadal axis without the transient increase of gonadotropin secretion and the resulting flare associated with use of GnRH agonists such as leuprolide. Once treatment with relugolix is discontinued, estrogen and progesterone levels have been shown to return to baseline within four weeks, on average.

In men, LH stimulates the production of testosterone by the testes. Testosterone is a strong growth factor for prostate cancer. ADT with a GnRH agonist such as leuprolide is the most commonly used treatment to reduce testosterone levels in advanced prostate cancer. GnRH agonists, when administered continuously, have been shown to suppress testosterone secretion by down-regulating gonadotropin secretion from the pituitary, and thereby slow prostate cancer growth. However, the agonists initially stimulate hormonal production and require co-administration with an anti-androgen such as bicalutamide to prevent flare of symptoms in many men, a treatment known as complete androgen blockade. In contrast, GnRH antagonists directly inhibit production of LH, rapidly decrease testosterone levels, do not result in flare of symptoms and do not require co-administration with an anti-androgen. In men, this rapid decrease in testosterone to very low levels, or chemical castration, coupled with the absence of an initial testosterone flare, may allow men to avoid exacerbation of bone pain, increase in urinary symptoms or development of neurologic evidence of disease. Furthermore, once treatment with relugolix is discontinued, testosterone levels have been shown to return to baseline within four weeks, on average.

We believe oral administration of GnRH antagonists may offer flexibility in dosing duration and regimen for both men and women without the inconvenience or potential discomfort of injectable depot formulations. Additionally, hormone levels have been observed to return to baseline more rapidly after discontinuing oral relugolix compared to GnRH agonist depot formulations.



Potential Advantages of Relugolix

We believe relugolix has the potential to be a best-in-class oral GnRH receptor antagonist for the treatment of heavy menstrual bleeding associated with uterine fibroids and endometriosis-related pain and both a first-in-class and best-in-class oral GnRH receptor antagonist for the treatment of advanced prostate cancer. We believe relugolix may offer significant advantages over currently approved injectable therapies, as well as therapies in late-stage clinical development, based on the following:

- Demonstrated Clinical Benefit with a Favorable Safety Profile. Relugolix has been evaluated in over 1,300 subjects to date, in Phase 1 and multiple large, randomized Phase 2 clinical trials, some of which are ongoing. In these trials, relugolix has demonstrated clinical benefit for the treatment of symptoms associated with uterine fibroids and endometriosis and advanced prostate cancer, and was observed to be generally well tolerated, consistent with its mechanism of action.
- Once-Daily, Oral Administration. Based on the existing clinical data, we believe relugolix is the only oral GnRH antagonist in development with the potency and half-life necessary to suppress estrogen and progesterone levels in women and testosterone levels in men with once-daily dosing for our target women's health indications and advanced prostate cancer, respectively. Additionally, we believe once-daily administration of relugolix, if approved, would provide significant advantages over therapies requiring twice-daily doses, such as greater convenience for patients and increased compliance leading to potentially better outcomes.

- *Rapid Onset of Action.* In clinical trials conducted to date, relugolix was observed to directly and rapidly decrease the release of LH and FSH and suppress estrogen and progesterone in women and testosterone in men. Further, clinical data to date suggest that relugolix suppresses hormone levels in less than a week and without causing a symptomatic hormonal flare generally associated with GnRH agonists, which take up to three to four weeks to lower hormone levels.
- *Rapid Reversal of Hormone Suppression.* In a Phase 2 trial, relugolix has been shown to allow hormone levels to return to baseline more rapidly than the GnRH antagonist depot formulation, degarelix, after discontinuation. The option of rapid return to baseline hormone levels may be an advantage for patients wanting to eliminate any unwanted effects of hormone suppression. For example, women can quickly discontinue treatment for fertility needs, if desired. The ability to reverse effects may also be beneficial in the treatment of prostate cancer by enabling the more rapid return of testosterone levels during intermittent, as opposed to continuous, testosterone suppression with ADT.
- Longer-Term Treatment with Add-Back Therapy. We plan to commercialize relugolix, if approved, for the treatment of heavy menstrual bleeding associated with uterine fibroids and endometriosis-associated pain as a fixed-dose combination of relugolix with low-dose estradiol and progestin add-back therapy to minimize bone mineral density loss and other hypoestrogenic symptoms, such as hot flash, commonly associated with GnRH agonists and antagonists. We believe this strategy of suppressing estrogen levels with an oral GnRH antagonist and then adding back the appropriate dose of estradiol and progestin to minimize bone mineral density loss may allow longer-term use in women, and thereby potentially avoiding invasive surgical procedures.
- *Fixed-Dose Combination.* We are developing relugolix to be co-administered with hormone add-back therapy in a single pill, taken once daily. We believe that a fixed-dose combination therapy offers the potential to enhance patient compliance. In addition, we believe that a fixed-dose combination may potentially improve patient outcomes by ensuring that the add-back therapy is always taken to address known class side effects, such as bone mineral density loss and hot flash. Finally, we believe that a fixed-dose combination product may offer a meaningful commercial benefit by distinguishing from competitive products that cannot be administered as one combination pill, once daily.

Women's Health Indications

Uterine Fibroids Overview

Uterine fibroids are non-cancerous tumors composed of smooth muscle and fibrous connective tissue that develop in or on the walls of the uterus. In addition to an individual's genetic predisposition, estrogens, progesterone and human growth hormone all play important roles in the regulation of fibroid growth. Although uterine fibroids are benign tumors that are often asymptomatic, 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 social embarrassment.

Uterine fibroids are among the most common reproductive tract tumors in women. We estimate approximately 5.0 million women in the United States suffer from symptomatic uterine fibroids, approximately 3.0 million of whom are inadequately treated by current medical therapy and require further treatment.

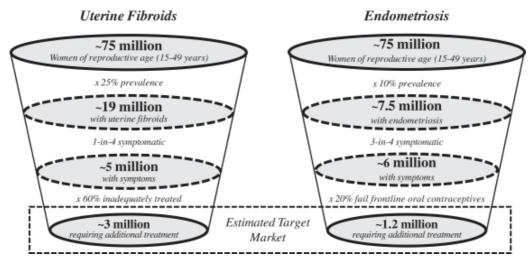
Endometriosis Overview

Endometriosis is a gynecological medical condition in which cells from the lining of the uterus grow outside the uterine cavity, most commonly on the ovaries. The uterine cavity is normally lined with endometrial cells that are under the influence of estrogen and progesterone, which cause the cells to grow, differentiate and shed on a monthly basis. Endometriosis lesions outside the uterus exhibit a pattern of hormonal responsiveness similar to

that of the lining of the uterus. During the menstrual cycle, the lesions grow, differentiate and shed into the abdomen, thereby inducing a cascade of inflammatory events that may lead to non-menstrual pelvic pain, pain during menstruation, painful intercourse and, in some cases, infertility.

According to the Endometriosis Foundation, endometriosis affects an estimated 1-in-10 women during their reproductive years. We estimate that approximately 6.0 million women in the United States suffer from symptomatic endometriosis, approximately 1.2 million of whom are inadequately treated by oral contraceptives and require additional treatment.

United States Epidemiology



Treatment Landscape for Women's Health Indications

Uterine Fibroids

The current approach to treating uterine fibroids includes both medical and surgical options. The choice of treatment approach 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 and GnRH agonists. GnRH agonists are used for short-term therapy and may involve low-dose estradiol and progestin hormone add-back therapy to minimize bone mineral density loss generally associated with GnRH agonists. 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 or complications with future pregnancy or even 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 United States alone.

Lowering estrogen levels decreases the size of uterine fibroids and associated bleeding. Two classes of drugs commonly used for the treatment of heavy menstrual bleeding associated with uterine fibroids in the United States: oral contraceptives, which include estrogen and/or progesterone, and GnRH agonists. The current standard of care for the treatment of patients with mild symptoms includes the use of oral contraceptives or

NSAIDs which are generally prescribed at the time of initial diagnosis. These therapeutic options, however, often do not provide sufficient relief to patients with moderate-to-severe symptoms, who require additional treatment to relieve excessive bleeding and pain.

Leuprolide, marketed as Lupron by AbbVie, is currently the only GnRH agonist approved by the FDA for the management of endometriosis and the preoperative treatment of patients with anemia caused by uterine fibroids, when co-administered with iron. Leuprolide is also marketed as Leuplin by Takeda in Japan for the treatment of uterine fibroid-related pain and heavy menstrual bleeding. In each case, leuprolide is only indicated for short-term use of six months or less due to the bone mineral density loss associated with longer-term use. Ulipristal acetate, or ulipristal, a selective progesterone receptor modulator, is marketed by Gedeon Richter in Europe as Esmya and as Fibristal in Canada for preoperative treatment of moderate-to-severe symptoms of uterine fibroids. Esmya recently received approval from the European Medicines Agency, or EMA, for the long-term management of uterine fibroid-related symptoms.

Endometriosis

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. In more severe cases, GnRH agonists are used for short-term treatment and may involve hormone add-back therapy, similar to the use of GnRH agonists for the treatment of uterine fibroids. The FDA has approved Lupaneta Pack, or leuprolide administered with norethindrone acetate, or NETA, 5 mg, to treat pain associated with endometriosis while minimizing bone mineral density loss. For many patients, surgical intervention is ultimately undertaken to relieve pain. After treatment with hormone therapy or conservative surgery, such as ablation of endometriotic lesions, recurrence of endometriosis and related symptoms is common. Approximately 100,000 endometriosis-related hysterectomies are performed each year in the United States.

Other Treatments in Development for Women's Health Indications

AbbVie, in conjunction with Neurocrine Biosciences, is developing an oral GnRH receptor antagonist, elagolix, as a treatment for moderate-to-severe endometriosis-associated pain and for heavy menstrual bleeding associated with uterine fibroids. AbbVie has reported data from two Phase 3 trials in endometriosis and expects to receive FDA marketing approval for that indication in 2018.

In January 2015, AbbVie announced results from its first Phase 3 trial for elagolix in 872 women with moderate-to-severe endometriosis-associated pain. Elagolix doses of 150 mg once daily and 200 mg twice daily were evaluated, and both met the trial's co-primary endpoints (p<0.001) of reducing scores of non-menstrual pelvic pain and menstrual pain at three and six months, as measured by the Daily Assessment of Endometriosis Pain scale (previously referred to as the modified Biberoglu and Behrman Score). This scale is a daily questionnaire about menstrual and non-menstrual pelvic pain and painful intercourse administered to patients using an electronic diary. Responder rates at six months for menstrual pain or non-menstrual pelvic pain, respectively, were 23.1% and 34.9% for placebo, 42.1% and 45.7% for elagolix 150 mg once daily, and 75.3% and 62.1% for elagolix 200 mg twice daily. The most common adverse events were hot flash, headache, nausea and fatigue. Women in the placebo arm had a 0.53% increase in bone mineral density at six months, compared with a 0.32% and 2.64% loss in bone mineral density at six months in the elagolix 150 mg once-daily and 200 mg twice-daily arms, respectively.

In February 2016, AbbVie announced top-line results from its second, similarly designed Phase 3 trial for elagolix. After six months of continuous treatment, both doses of elagolix (150 mg once daily and 200 mg twice daily) met the trial's co-primary endpoints of reducing scores of non-menstrual pelvic pain and menstrual pain associated with endometriosis, at three and six months, as measured by the Daily Assessment of Endometriosis Pain scale. Responder rates from this second Phase 3 trial were consistent with results from AbbVie's first Phase



3 trial. Women in the placebo arm had a 0.49% increase in bone mineral density at six months, compared with a 0.71% and 2.45% loss in bone mineral density at six months in the elagolix 150 mg once-daily and 200 mg twice-daily arms, respectively.

AbbVie has initiated a Phase 3 program evaluating elagolix 300 mg twice daily, with and without hormone add-back therapy with estradiol and NETA, or E2/NETA, compared with placebo in women with heavy menstrual bleeding associated with uterine fibroids. In addition, AbbVie is expected to commence a Phase 3b trial of elagolix in combination with E2/NETA in women with pain associated with endometriosis by the end of this year.

AbbVie recently reported data from a Phase 2b trial evaluating elagolix 300 mg twice daily and elagolix 300 mg twice daily in combination with E2/NETA compared with placebo in women with heavy menstrual bleeding associated with uterine fibroids. A responder was defined as a woman with a blood loss less than 80 mL with at least a 50% improvement in blood loss from baseline, as assessed by the alkaline hematin method. In this trial, 91.9% of women in the 300 mg twice-daily arm and 79.0% of women in the 300 mg twice daily in combination with E2/NETA arm responded compared to 26.6% of women in the placebo arm. In this six-month Phase 2b trial, bone mineral density loss was 3.59% in the elagolix 300 mg twice-daily arm and 0.12% in the elagolix 300 mg twice-daily in combination with E2/NETA arm compared to bone mineral density increase of 0.78% in the placebo arm.

ObsEva SA, or ObsEva, is developing OBE2109, an oral GnRH antagonist for the treatment of endometriosis and uterine fibroids. ObsEva in-licensed OBE2109 from Kissei Pharmaceutical Company, Ltd., a Japanese company, and is initiating a Phase 2 clinical trial evaluating multiple doses in women with endometriosis and may start a Phase 3 study in women with uterine fibroids in the first quarter of 2017. ObsEva has not publicly discussed using hormone add-back therapy as part of its current clinical trial design.

Allergan owns the rights to ulipristal in the United States. In May 2016, Allergan announced results from one of two Phase 3 clinical trials evaluating the efficacy and safety of ulipristal in uterine fibroids. The trial included 101 women randomized to ulipristal at 5 mg or 10 mg once daily, or 56 to placebo for a 12-week course, or one cycle, followed by a 12-week treatment-free period. The study met all co-primary and secondary endpoints with both ulipristal arms achieving significant results over placebo. The co-primary endpoints were percentage of patients with absence of uterine bleeding and time to absence of uterine bleeding. The most common side effects of ulipristal treatment in this study were hypertension, increased blood creatine phosphokinase, hot flash and acne. Allergan expects to report results of their second Phase 3 clinical trial in late 2016 and is expected to file an NDA with the FDA in 2017. Ulipristal is only being evaluated in the United States as a cyclic therapy for short-term use due to concerns related to endometrial effects. Other side effects of ulipristal include hot flash, headache, functional ovarian cysts, vertigo, nausea, acne, sweating, muscle pain and tiredness.

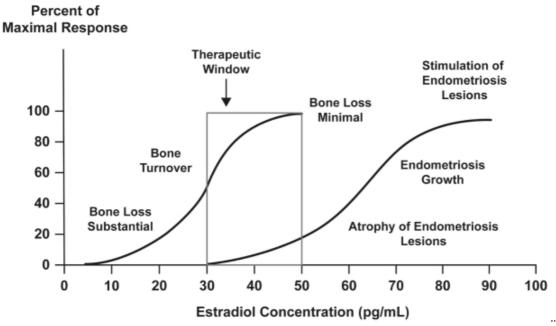
Our Solution for Women's Health Indications

Our goal is to develop and commercialize relugolix for women with uterine fibroids or endometriosis as a once-daily, fixed-dose combination of relugolix and low-dose estradiol and progestin, with the same dose for each indication. We believe a once-daily, single-pill fixed-dose combination product would offer substantial improvement to the current injectable depot GnRH agonists that are the current standard of care for the treatment of uterine fibroids and endometriosis. For example, we believe relugolix with add-back therapy has the potential for longer-term use in women because treatment duration will not be limited by bone mineral density loss, a common side effect associated with GnRh agonists.

Several randomized clinical trials have validated the approach of suppressing estrogen levels with a GnRH agonist and adding back low-dose estrogen and/or progestin to improve safety and tolerability. These results are consistent with the "estrogen hypothesis," which suggests that different tissue types have different sensitivities to



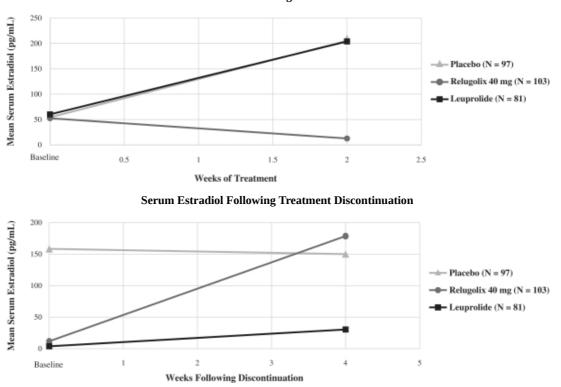
estrogen. Takeda conducted or funded two trials supporting this hypothesis, one from 1993 to 1997 and a second from 1997 to 2000. Third-party investigators completed a third trial supporting this hypothesis in 2013. As shown in the diagram below, we believe that at estradiol concentrations between 30-50 pg/mL, the majority of symptomatic benefits associated with estrogen suppression are preserved, while side effects, including bone mineral density loss, are minimized. We believe that relugolix administered as a once-daily, single-pill fixed-dose combination product with hormone add-back therapy will achieve this estradiol target in a majority of women. With the hormone add-back therapy, we intend to maximize clinical benefit with an acceptable safety profile to provide women with the option of longer-term medical therapy as an alternative to invasive surgical procedures.



Source: Barbieri, Am J Obstet Gyn, 1992

Relugolix has been shown to rapidly suppress estrogen and progesterone levels in women, avoiding the initial increase in these hormones and the accompanying flare of clinical symptoms, such as an increase in menstrual bleeding, frequently observed following initiation of treatment with a GnRH agonist. Further, relugolix may allow hormone levels to return to baseline more rapidly than degarelix, after the drug is discontinued. The option of rapid return to baseline hormone levels may be a significant advantage for patients wanting to eliminate any unwanted effects of hormone suppression. An oral, once-daily GnRH receptor antagonist such as relugolix may provide patients and their physicians with more control. For example, more rapid return of hormonal levels to baseline could be advantageous in the management of a concurrent illness, the restoration of fertility for women desiring to attempt pregnancy or the restoration of sexual function and energy levels in men. Accordingly, we believe there is a significant opportunity to both improve clinical outcomes and address known safety and tolerability issues generally associated with GnRH agonists.

The following graphs show mean serum estradiol concentrations following initiation and discontinuation of administration of placebo, relugolix 40 mg or leuprolide treatment. The first graph shows the mean serum estradiol at baseline, which in this analysis was immediately prior to the start of treatment, and at two weeks after the start of treatment. In this analysis, the mean serum estradiol concentration in women treated with relugolix, which as a GnRH antagonist directly suppresses estradiol levels, decreased after two weeks of treatment. The mean estradiol concentration in women treated with leuprolide, which as a GnRH agonist first stimulates and then suppresses estradiol levels, remained similar to the mean estradiol concentration observed in women administered placebo after two weeks of treatment. The second graph shows the mean serum estradiol at baseline, which in this analysis was at the end of a 24-week treatment period, and at four weeks after the discontinuation of treatment. The baseline shows that both relugolix and leuprolide suppressed estradiol to very low levels after 24 weeks of treatment. In this analysis, relugolix was observed to have faster reversal of estradiol suppression as compared to leuprolide, resulting in a mean serum estradiol concentration is milar to the mean serum estradiol concentration of treatment. Estradiol levels in women of reproductive age fluctuate between 50 pg/mL and 275 pg/mL during the normal menstrual cycle. No statistical comparisons were conducted. This analysis of serum estradiol concentrations was performed by third-party investigators in connection with Takeda's completed Phase 2 trial for relugolix for the treatment of endometriosis-related pelvic pain described below.



Serum Estradiol Following Treatment Initiation

Phase 3 Clinical Development for Women's Health Indications

In the first quarter of 2017, we plan to initiate a multinational Phase 3 program, composed of two replicate clinical trials, for relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids. We completed an End of Phase 2 meeting with the FDA for this indication in early October 2016, and expect to

submit our IND, including Phase 3 protocols, to the FDA in 2016. In the first half of 2017, we also plan to initiate a multinational Phase 3 program, composed of two replicate clinical trials, for relugolix for the treatment of endometriosis-associated pain. In 2007, Takeda submitted an IND for relugolix (also known as TAK-385) to the FDA for the treatment of endometriosis and, in May 2016, Takeda transferred this IND to us. We expect to hold an End of Phase 2 meeting with the FDA in the first quarter of 2017 to request confirmation that there are no additional clinical trials or nonclinical studies required to support the initiation of our Phase 3 program for endometriosis and that our planned trials, if successful, will be sufficient to support the submission of an NDA in that indication.

Takeda Phase 3 Clinical Development for Uterine Fibroids

Takeda is currently conducting two Phase 3 trials with relugolix in Japan for the treatment of uterine fibroid-associated pain and heavy menstrual bleeding, respectively. The first trial is a multicenter, randomized, double-blind study evaluating relugolix 40 mg once daily for 12 weeks versus placebo in 64 women having at least moderate pain symptoms associated with uterine fibroids. The primary endpoint is the proportion of women with a maximum Numerical Rating Scale score, or score on a patient reported assessment of pain, of one or less during the 28 days before the final dose of study drug at week 12. The second study is a multi-center, randomized, double-blind non-inferiority study to evaluate the efficacy and safety of relugolix in 288 women with symptomatic uterine fibroids. Relugolix 40 mg once daily will be administered for 24 weeks, compared with leuprolide administered by subcutaneous injection every four weeks at a dose of 1.88 mg or 3.75 mg. The primary endpoint will be the proportion of women who receive a total score of less than 10 on the PBAC, the same endpoint used in the Phase 2 trial.

Preliminary data from these trials are currently anticipated in the second half of 2017. These Phase 3 data will be available to us, and may be used to support our NDA. If Takeda's Phase 3 program for uterine fibroid-related pain and heavy menstrual bleeding is successful, Takeda plans to seek regulatory approval of relugolix in Japan for the treatment of uterine fibroid-related pain and heavy menstrual bleeding in 2018. Prior to our acquisition of the rights to develop and commercialize relugolix, if approved, for the treatment of heavy menstrual bleeding associated with uterine fibroids in the United States, Takeda had not submitted an IND for relugolix to the FDA for this indication. We will be solely responsible for obtaining FDA approval for relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids.

Our Planned Phase 3 Program for Uterine Fibroids

Our two proposed replicate Phase 3 clinical trials in women with heavy menstrual bleeding associated with uterine fibroids will randomize women to one of three arms using 1:1:1 randomization. Women will receive treatment with relugolix 40 mg once daily co-administered with commercially available low-dose hormone add-back therapy for 24 weeks, relugolix 40 mg once daily monotherapy for 12 weeks followed by relugolix 40 mg once daily co-administered with hormone add-back therapy for an additional 12 weeks, or placebo once daily for a period of 24 weeks. All patients completing the initial 24-week period will be offered an active treatment extension with relugolix 40 mg once daily co-administered with hormone add-back therapy for an additional 24-week period, or a total treatment period of 48 weeks, to evaluate the safety of long-term treatment. Each of the two replicate trials is expected to enroll approximately 390 women, with 130 women in each active treatment arm and 130 women in the placebo arm.

The primary efficacy endpoint for these trials is expected to be the percentage of responders with less than 80 mL uterine blood loss per menstrual cycle and at least a 50% reduction from baseline to last month of treatment in menstrual blood volume as measured by the alkaline hematin method, a quantitative measurement of menstrual blood loss. The secondary efficacy endpoints are expected to include the change from baseline in hemoglobin, the reduction in uterine and fibroid volume and pain reduction. Safety, including bone mineral density changes as measured by dual-energy x-ray absorptiometry, will be assessed. If the results of these trials are favorable, we intend to submit an NDA to the FDA in 2019. We expect the safety database at the time of

NDA submission to be sufficient to support dosing for 12 months or longer. We will conduct a bridging study to demonstrate bioequivalence of the fixed-dose combination of relugolix with low-dose estradiol and progestin to co-administered relugolix with low-dose estradiol and progestin. We may conduct additional clinical trials to further support the commercial potential of relugolix in uterine fibroids in the United States and other major markets.

The following graphic represents the anticipated trial design for each of our two replicate Phase 3 trials for relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids:

Relugolix 40 mg/day + Add-Back Therapy (N = 130)Women with WEEK 48 WEEK 24 Relugolix Relugolix Heavy Menstrual 40 mg/day + 40 mg/day Bleeding Extension Study: (N = 130)Add-Back Associated with Co-Primary Relugolix 40 mg/day Therapy Completing Uterine Fibrosis Endpoints² + Add-Back Therapy¹ 12 Weeks 12 Weeks Patients Eligible (N = 390)for Active Placebo Treatment (N = 130)Extension

Anticipated Phase 3 Trial Design for Relugolix for the Treatment of Heavy Menstrual Bleeding Associated with Uterine Fibroids

Double-Blind Treatment: 24 Weeks

Commercially available low-dose estradiol and progestin.

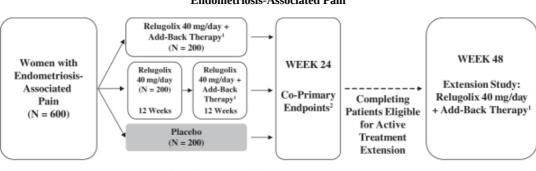
²The percentage of women with less than 80 mL uterine blood loss per menstrual cycle and at least a 50% reduction in menstrual blood volume from baseline to last month of treatment as measured by the alkaline hematin method.

Our Planned Phase 3 Program for Endometriosis

Our two proposed replicate Phase 3 clinical trials in women with endometriosis-associated pain will randomize women to one of three arms using 1:1:1 randomization. Women will receive treatment with relugolix 40 mg once daily co-administered with commercially-available, low-dose hormone add-back therapy for 24 weeks, relugolix 40 mg once daily monotherapy for 12 weeks followed by relugolix 40 mg once daily co-administered with hormone add-back therapy for an additional 12 weeks, or placebo once daily for a period of 24 weeks. All women completing the initial 24-week period will be offered an active treatment extension with relugolix 40 mg once daily co-administered with hormone add-back therapy for an additional 24 weeks, or a total treatment period of 48 weeks, to evaluate the safety of long-term treatment. Each of the two replicate trials is expected to enroll approximately 600 women, with 200 women in each active treatment arm and 200 women in the placebo arm.

The co-primary efficacy endpoints for these trials is expected to be the percentage of responders with reductions in non-menstrual pelvic pain and menstrual pain, as assessed by an endometriosis-specific patient questionnaire administered daily. Secondary endpoints will include additional questionnaires assessing endometriosis-specific pain and quality of life, and the use of pain medications to treat endometriosis. Safety, including bone mineral density changes as measured by dual-energy x-ray absorptiometry, will be assessed. If the results of these trials are favorable, we intend to submit an NDA to the FDA in 2019. We expect the safety database at the time of NDA submission to be sufficient to support dosing for 12 months or longer. If not already completed for the uterine fibroid indication, we will conduct a bridging study to demonstrate bioequivalence of the fixed-dose combination of relugolix with low-dose estradiol and progestin to co-administered relugolix with low-dose estradiol and progestin. We may conduct additional clinical trials to further support the commercial potential of relugolix in endometriosis in the United States and other major markets.

The following graphic represents the anticipated trial design for each of our two replicate Phase 3 trials for relugolix for the treatment of endometriosisassociated pain:



Anticipated Phase 3 Trial Design for Relugolix for the Treatment of Endometriosis-Associated Pain

Double-Blind Treatment: 24 Weeks

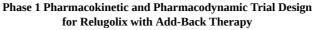
¹Commercially available low-dose estradiol and a progestin. ²Reduction in dysmenorrhea, or painful menstruation, and non-menstrual pelvic pain as assessed using the Symptoms of Endometriosis Scale, a daily patient

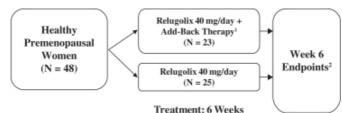
questionnaire for the assessment of endometriosis-associated pain, scored on the Numeric Rating Scale, a universal pain screening scale which asks patients to indicate the intensity of pain on a scale of 0-10.

Phase 1 Pharmacokinetic and Pharmacodynamic Trial for Relugolix with Add-Back Therapy

We recently completed a six-week Phase 1 clinical trial in 48 healthy premenopausal women, evaluating the pharmacokinetics and pharmacodynamics of relugolix 40 mg administered with and without add-back therapy. The add-back therapy used in this Phase 1 clinical trial, 1 mg estradiol and 0.5 mg norethindrone acetate, is the same low-dose estradiol and progestin add-back therapy that we intend to use in each of our planned Phase 3 trials. In this Phase 1 clinical trial, the plasma concentrations of relugolix and add-back therapy were measured, as well as LH, FSH, estradiol, and progesterone levels. Early biomarkers of bone mineral density loss were also assessed.

The following graphic represents the trial design for our Phase 1 pharmacokinetic and pharmacodynamics trial for relugolix with add-back therapy:



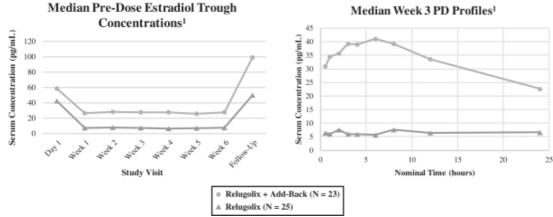


¹ Commercially available low-dose estradiol and progestin.

Primary endpoints include steady-state pharmacokinetic parameters of relugolix, estradiol, norethindrone and ethinyl estradiol; area under the concentration-time curve; predose concentration, average concentration, maximum concentration, time to maximum concentration and elimination half-life of relugolix. Secondary endpoints include safety and tolerability parameters and hot flash.

Estradiol levels were sampled before doses of relugolix to determine the median trough plasma concentrations of estradiol in women receiving relugolix with or without add-back therapy. The median pre-dose estradiol trough levels are depicted below in graph on the left. The median pharmacokinetic profiles of estradiol at week 3 in women receiving relugolix with or without hormone add-back therapy are presented below in the graph on the right. These data demonstrate that the trough levels are above the desired target minimum estradiol concentration of 20 pg/mL. The pharmacokinetic profile of estradiol demonstrates the achievement of estradiol levels throughout the day in the target range of 20 to 50 pg/mL.

In this Phase 1 clinical trial, this hormone add-back therapy achieved estradiol levels above 20 pg/mL, the level demonstrated to protect women from bone mineral density loss, yet generally below 50 pg/mL, which we believe will maximize the benefit of low estrogen levels on the heavy menstrual bleeding associated with uterine fibroids and endometriosis-associated pain. We believe this strategy of maximal estrogen suppression coupled with adding back low-dose estradiol and progestin may preserve much of relugolix's clinical benefit while minimizing bone mineral density loss and improving tolerability, thereby potentially enabling longer-term use.



¹ Data shown are preliminary and subject to further analysis.

Existing Clinical Data in Women's Health Indications

Uterine Fibroids

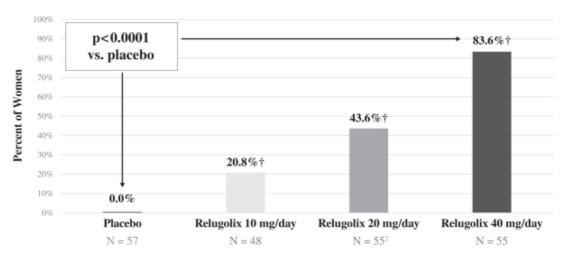
Takeda completed a Phase 2 clinical trial (TAK-385/CCT-001) in women with uterine fibroids in Japan. A total of 216 women were randomized to relugolix at doses of 10 mg, 20 mg or 40 mg once daily administered orally, or placebo, each administered for 12 weeks. The following graphic represents the trial design for TAK-385/CCT-001:

Relugolix 10 mg/day (N = 48)Relugolix 20 mg/day WEEK 12 WEEK 16 (N = 56)Women with Uterine Fibroids Primary (N = 216)Endpoint² Relugolix 40 mg/day (N = 211)Follow-up (N = 55)Placebo (N = 57)

Trial Design for Completed Phase 2 Trial for Relugolix for the Treatment of Heavy Menstrual Bleeding Associated with Uterine Fibroids

The Phase 2 trial demonstrated dose-dependent decreases in menstrual blood loss and an increase in mean blood hemoglobin concentration, and suggested a reduction in fibroid and uterine volumes as compared with placebo. To be included in the trial, women were required to have a baseline PBAC score of at least 120, confirming heavy menstrual bleeding, in addition to uterine fibroids confirmed by ultrasound, magnetic resonance imaging, computed tomography or laparoscopy. A responder for the primary endpoint analysis was defined as a patient with a sum of PBAC scores from week 6 through week 12 of less than 10. In the relugolix 40 mg once-daily dose arm, 83.6% of women were responders and had marked decrease in menstrual blood loss compared with 0% in the placebo arm (p<0.0001). Further, in the 40 mg once-daily arm, 72.7% of women achieved amenorrhea from week 6 through week 12 compared with 0% in the placebo, the benefit was greatest at the 40 mg once-daily dose. Secondary efficacy endpoints, including mean change in myoma volume, uterine volume, and hemoglobin, also demonstrated dose-dependent clinical benefit. Women in the 40 mg once-daily treatment arm experienced decreases in myoma and uterine volume at 12 weeks of 48.8% and 50.7%, respectively, compared to patients receiving placebo. Further, women receiving 40 mg relugolix once-daily experienced a mean increase in hemoglobin at 12 weeks of 0.72 g/dL compared to patients receiving placebo. Mean estradiol levels were fully suppressed below the assay lower limit of quantification of 10 pg/mL at a dose of 40 mg once daily (<10 pg/mL in 75% of patients). On the basis of the findings observed in this trial, we believe 40 mg once-daily relugolix to be an appropriate dose for Phase 3 evaluation in heavy menstrual bleeding associated with uterine fibroids.

¹Premenopausal females aged 20 years or older with a diagnosis of UF, with a total PBAC score ≥120. ²Decrease in menstrual blood loss as measured by percent of patients with a total PBAC score from week 6 to week 12 of <10.



Percent of Women with Markedly Decreased Blood Loss at End of Treatment Period¹ (Primary Endpoint of PBAC <10)

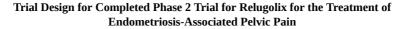
1 Data shown is from the relugolix CCT-001 study using PBAC method of assessing blood loss during week 6 to week 12.

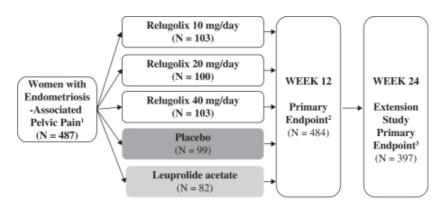
² 56 patients were randomized to relugolix 20mg/day; 55 were included in the analysis.

† Statistically significant difference with p<0.001 observed for each relugolix treatment arm versus placebo.

Endometriosis

In a Phase 2 clinical trial (TAK-385/CCT-101) with an extension study (TAK-385/OCT-101) of women with endometriosis, 487 women were randomized to relugolix at doses of 10 mg, 20 mg or 40 mg administered orally once daily for 12 weeks, to placebo for 12 weeks, or to leuprolide, 3.75 mg administered subcutaneously every four weeks for 12 weeks. The following graphic represents the trial design for TAK-385/CCT-101 and TAK-385/OCT-101:

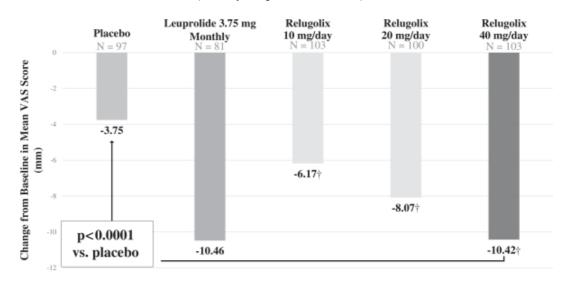




¹Premenopausal females aged 20 years or older with diagnosis of endometriosis within the past five years. ²Change in VAS score for pelvic pain. ³Safety measures, including bone mineral density loss, and adverse events.

The trial demonstrated dose-dependent decreases from baseline in pelvic pain. Pelvic pain, including both non-menstrual pelvic pain and menstrual pain, was assessed by VAS score. The primary endpoint was the change

from baseline in mean VAS score for pelvic pain from week 8 through week 12. The mean pelvic pain VAS scores at baseline for the four groups ranged between 14.6 mm to 15.6 mm. The mean change from baseline in the VAS score was -10.42 mm in the relugolix 40 mg arm versus -3.75 mm in the placebo arm (p<0.0001). All doses were significantly better than placebo, with the greatest benefit observed at the highest dose evaluated, 40 mg once daily. The mean change from baseline in the VAS score for the leuprolide arm was -10.46 mm, which was similar to that of the relugolix 40 mg arm. Secondary efficacy endpoints also demonstrated clinical benefit. Secondary efficacy endpoints included individual VAS scores for non-menstrual pelvic pain, menstrual pain and painful intercourse during the treatment period; the modified Biberoglu and Behrman score for pelvic pain, a commonly used endometriosis-specific patient questionnaire; use of analgesics to treat pelvic pain; proportion of women achieving amenorrhea, or the absence of menstrual blood loss; and quality of life using the endometriosis health profile-30 questionnaire. Clinical improvement was observed on all pain endpoints, including dose-dependent responses in mean VAS score for dysmenorrhea, mean modified Biberoglu and Behrman score for pelvic pain and mean modified Biberoglu and Berhman score for dysmenorrhea. In the 40 mg once-daily treatment arm, mean changes on these endpoints were -29.7, -0.325, and -1.16, respectively, compared to -5.21, -0.178, and -0.172 for patients receiving placebo. The proportion of days in which the women used analgesics and the amount of menstrual bleeding both decreased, while the proportion of women who achieved amenorrhea increased in a time-dependent manner depending on relugolix dose level. The effects of relugolix on pelvic pain were maintained and estradiol levels suppressed for the duration of the study in the 397 women who enrolled in the extension study and received an additional 12 weeks of treatment, or a total of 24 weeks of treatment. On the basis of the efficacy findings observed in this trial, we believe 40 mg once-daily relugolix to be an appropriate dose for Phase 3 evaluation in endometriosis-associated pain. Four weeks after treatment discontinuation, median estradiol levels had returned to above baseline levels in the relugolix 40 mg arm (137 pg/mL), whereas median levels in the leuprolide arm remained suppressed (11 pg/mL).



Change from Baseline in Patient-Reported Pelvic Pain Score at End of Treatment¹ (Primary Endpoint of VAS Score)

¹ Data shown is from the relugolix 12-week CCT-101 study, data measured from the VAS score over the last four weeks of treatment † Statistically significant difference with p<0.05 observed for each relugolix treatment arm versus placebo.</p>

The table below sets forth what we believe to be key characteristics of the product candidates, relugolix and elagolix.

		Relugolix ¹		Elagolix ²		
Observed Half-life		37 - 42 hours		2 - 6 hours		
Observed Potency ³	1	IC ₅₀ = 0.12 nM		IC ₅₀ = 1.5 nM		
Phase 3 Dose Frequency	Uterine Fibroids4: Endometriosis5:	Once daily (planned) Once daily (planned)	Uterine Fibroids4: Endometriosis5:	Twice daily Once or twice daily		
Phase 3 Dose by Indication	Uterine Fibroids4: Endometriosis5:	40 mg once daily (planned) 40 mg once daily (planned)	Uterine Fibroids4: Endometriosis5:	300 mg twice daily 150 mg once daily, or 200 mg twice daily		
Dose at Which Maximum Estrogen Suppression Observed		40 mg once daily		200 mg - 300 mg twice daily		
Use of Add-back Therapy in Phase 3	Uterine Fibroids ⁴ . Phase 3 clinical trials planned to start first quarter of 2017 with add-back therapy Endometriosis ⁵ : Phase 3 clinical trials planned start first half of 2017 with add-back therapy		Uterine Fibroids4: Endometriosis5:	Phase 3 clinical trials with and without add-back therapy started in 2016 Not in initial Phase 3 trials; Phase 3b with add-back therapy expected to start in 2016		
Food Effect	Yes: Dosed on em	y stomach once daily Yes: Dosed on er		pty stomach up to twice daily		
Clinical Trials Ongoing in Prostate Cancer		cal trials ongoing; Phase 3 clinical to start in first quarter of 2017	No			

Key Characteristics of Relugolix and Elagolix

¹ Based on the results of clinical trials to date and our Phase 3 development plan for relugolix.

² Based on publicly available nonclinical and clinical data to date and Phase 3 development plan for elagolix.
³ IC₅₀ is a quantitative measure of the drug concentration needed to inhibit a given biological process by half; a lower IC₅₀ indicates a more potent drug.

⁴Target indication of heavy menstrual bleeding associated with uterine fibroids.

5 Target indication of endometriosis-associated pain.

Relugolix, administered at a once daily dose of 40 mg, was observed in clinical trials to suppress estrogen levels below the limit of detection in most women. At these very low estrogen levels, for example less than 20 pg/mL, relugolix also decreases bone mineral density to a level that is unsafe for long-term clinical use. The decrease in bone mineral density was also observed with doses of elagolix and leuprolide that maximally suppress estrogen levels. In the Phase 2 endometriosis study in Japanese women of relugolix 40 mg once daily, bone mineral density at the lumbar spine decreased 4.9% over 24 weeks of treatment. Leuprolide 3.75 mg monthly injections decreased bone mineral density by 4.4% in the same time period. In this same Phase 2 endometriosis study, the placebo group had a bone mineral density decrease of 0.2%. In a Phase 2 study of elagolix 300 mg administered twice daily to North American women with uterine fibroids, bone mineral density decreased 3.6% over six months of treatment. In this study, the placebo group had a bone mineral density increase of 0.8%.

Suppressing estrogen levels to low levels provides a consistent baseline upon which to add back low-dose estradiol and progestin in a controlled fashion. In our Phase 1 clinical trial for relugolix with and without add-back therapy, this hormone add-back therapy achieved estradiol levels above 20 pg/mL, the level demonstrated to protect women from bone mineral density loss, yet generally below 50 pg/mL, which we believe will maximize the benefit of low estrogen levels on the heavy menstrual bleeding associated with uterine fibroids and endometriosis-associated pain. We believe this strategy of maximal estrogen suppression coupled with adding back low-dose estradiol and progestin may preserve much of relugolix's clinical benefit while minimizing bone mineral density loss and improving tolerability, thereby potentially enabling longer-term use.

Based on the existing clinical data, we believe relugolix is the only oral GnRH antagonist in development with the potency and half-life necessary to suppress estrogen and progesterone levels in women and testosterone levels in men with once-daily dosing for our target women's health indications and advanced prostate cancer, respectively.

Advanced Prostate Cancer

Overview

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 United States. According to the National Cancer Institute, approximately 2.9 million men are currently living with prostate cancer in the United States, and approximately 180,000 men are newly diagnosed each year. 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 98.9%.

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, or 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 either: 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. The cure rate following surgery, depending on the stage of the cancer, is about 70% overall and, following radiation, about 50% to 60%. Approximately 25% to 30% of men will, therefore, progress to advanced disease, excluding those with metastatic disease at the time of diagnosis.

First-line treatment for advanced prostate cancer typically involves treatment with androgen deprivation therapies, or ADT, which are therapies that drastically 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, or removal of the testes which produce testosterone, can be successful in delaying prostate cancer progression. More than 80% of patients with advanced prostate cancer initially respond to ADT with varying degrees of tumor regression or stabilization. The duration and depth of response to ADT is presumably dependent on the underlying tumor biology and burden. Thus, patients with metastatic prostate cancer, or prostate cancer that has spread to other parts of the body, respond for an average of two years before any biochemical evidence of castration resistance occurs. By contrast, patients with biochemical-only evidence of progressive disease may respond to ADT for five years or more. As men with prostate cancer progress, they remain on ADT while other therapies are added, typically until death.

Treatment Landscape for Advanced Prostate Cancer

Currently, most men with prostate cancer in developed countries receive medical rather than surgical castration. GnRH agonists, such as long-acting leuprolide depot injections, are the current standard-of-care for achieving medical castration, causing long-term desensitization and down regulation of the LH-gonadal axis. Approximately 650,000 men with advanced prostate cancer are treated with GnRH agonists each year in the United States. GnRH agonists may be associated with mechanism-of-action limitations. For example, overstimulation of GnRH receptors on the pituitary promotes an initial testosterone surge that not only delays the onset of testosterone suppression, but also may result in a potentially detrimental initial exacerbation of clinical symptoms such as bone pain in advanced disease, known as a clinical or hormonal flare. Importantly, testosterone surges, also known as microsurges, can also occur following repeated administration of GnRH agonists.

In 2008, degarelix (marketed as Firmagon), an injectable GnRH antagonist, was approved by the FDA as an alternative form of ADT. In 2009, degarelix was approved by the European Medicines Agency for the treatment

of patients with advanced prostate cancer. As a GnRH antagonist, degarelix achieves, within the first one to two weeks of administration, suppression of testosterone to castration levels and a corresponding decrease in PSA levels with no initial agonist activity. Recent nonclinical research and an independent third-party meta-analysis of multiple trials evaluating ADT, suggest that GnRH antagonists, such as degarelix, may have an additional advantage on cardiac safety. In the meta-analysis, among men with pre-existing cardiovascular disease, the risk of cardiac events within one year of initiating therapy was significantly lower among men treated with a GnRH antagonist compared with GnRH agonists; however, such differences require confirmation in future prospective studies. We believe degarelix has not achieved significant market acceptance because of the need for monthly depot injections in large aggregate volumes. We are not currently aware of any other GnRH antagonist in clinical development as an ADT for prostate cancer.

Our Solution for Advanced Prostate Cancer

When compared to a GnRH agonist such as leuprolide, we believe relugolix may offer several potential advantages based on its oral administration, rapid onset of testosterone suppression within four days, absence of clinical hormonal flare, no need for anti-androgen therapy to protect the patient from flare symptoms, and rapid return to baseline testosterone levels after the last dose, which may result in more rapid improvements in quality of life, such as higher energy levels and restored sexual function. This may be particularly beneficial to men undergoing intermittent, rather than continuous, ADT.

When compared to an injectable GnRH antagonist such as degarelix, we believe relugolix may offer several advantages, while retaining the same benefits of GnRH antagonist pharmacology compared with GnRH agonists. In particular, relugolix is designed to be administered orally, rather than as a painful monthly injection, and may provide a more rapid return to baseline testosterone levels after the last dose.

Our Phase 3 Clinical Development Plan for Advanced Prostate Cancer

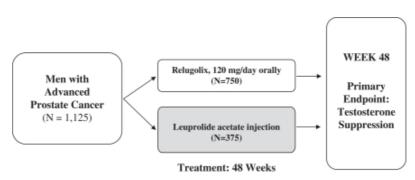
We intend to initiate a Phase 3 trial for relugolix for the treatment of advanced prostate cancer in the first quarter of 2017. In 2013, Takeda submitted an IND to the FDA for relugolix (also known as TAK-385) for the treatment of advanced prostate cancer and, in May 2016, Takeda transferred this IND to us. An End of Phase 2 meeting in October 2015 confirmed that there are no additional clinical trials or nonclinical studies required to support the initiation of a Phase 3 trial. Moreover, we believe that this Phase 3 trial, if successful, will be sufficient to support the filing of an NDA. The European Scientific Advice procedure and an End of Phase 2 meeting with the Japanese health authority have also been completed.

Our planned Phase 3 trial in men with advanced prostate cancer who require ADT will randomize men 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. We plan to enroll approximately 1,125 men into this trial, with approximately 750 men enrolled into the active treatment arm and 375 men into the leuprolide arm using a 2:1 randomization scheme. Based on FDA discussions, we are only required to conduct one Phase 3 trial with a single relugolix arm to gain approval in the United States; however, we plan to include a leuprolide arm to gain approval in other major markets where the demonstration of non-inferiority to leuprolide is required.

The primary efficacy endpoint accepted by the FDA will be testosterone suppression (£ 50 ng/dL) from week 5, day 1 through week 48, day 7. Relugolix must demonstrate that the lower bound of the 95% confidence interval of the percent of patients achieving testosterone suppression is at least 90%. The secondary efficacy endpoint will be PSA reduction as a percentage change from baseline. Testosterone reduction is an approvable endpoint in the United States and several other hormonal therapies have been approved based on this endpoint. If the results of this trial are favorable, we intend to submit an NDA to the FDA. We may conduct additional clinical trials to further support the commercial potential of relugolix in prostate cancer in the United States and other major markets.

The following graphic represents the anticipated trial design for our Phase 3 clinical trial for relugolix for the treatment of advanced prostate cancer:

Anticipated Phase 3 Trial Design for Relugolix for the Treatment of Advanced Prostate Cancer



Existing Clinical Data

In a Phase 1 study of healthy men, relugolix at daily doses of 80 mg to 180 mg for up to 28 days achieved and maintained serum testosterone at castration levels of \pounds 50 ng/dL (N = ~15/arm). Less testosterone suppression was observed at daily doses of 40 mg and 60 mg for up to 14 days (N = 6/arm). Data from this study guided the selection of the relugolix doses used in Takeda's Phase 2 clinical trials for relugolix for the treatment of advanced prostate cancer.

In 2014, two Phase 2 clinical trials of relugolix (C27002 and C27003) in men with advanced prostate cancer requiring ADT were initiated. Study C27002, which remains ongoing, enrolled patients with advanced prostate cancer, including either: 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. In this open-label, parallel group study, men in North America were enrolled to receive oral relugolix at a daily dose of 80 mg or 120 mg (after a single oral loading dose of 320 mg) (N = 50 in each arm) or to receive GnRH agonist therapy (leuprolide 22.5 mg administered subcutaneously every 12 weeks, N = 25) for up to 48 weeks. Study C27003, which is completed, enrolled men in North America or the United Kingdom requiring six months ADT as neoadjuvant and adjuvant therapy to external beam radiation therapy. Patients were randomized to relugolix 120 mg once daily (after a single oral loading dose of 320 mg) (N = 65) or to degarelix 80 mg intramuscularly every four weeks (N = 38) for 24 weeks (after a single loading dose of 240 mg).

Trial Design for Phase 2 Trials for Relugolix for the Treatment of Advanced Prostate Cancer

Study	Relugolix vs. Lupron C27002	Relugolix vs. Degarelix C27003
No. of 125 men (with hormone-sensitive advanced prostate cancer)		103 men (receiving neoadjuvant/adjuvant therapy to external beam radiotherapy)
Location (Date)	North America (2014 - ongoing)	North America United Kingdom (2014 - 2015)
Design	80 mg or 120 mg relugolix or leuprolide 22.5 mg 12-week depot injection	120 mg relugolix or degarelix 80 mg 4-week depot injection
Treatment Duration 48 weeks plus 48-week safety extension		24 weeks with 12 weeks of follow-up
Analyses Interim analysis performed after Performed ~75 patients treated for at least 24 weeks		Final analysis

In study C27002, a pre-specified interim analysis was conducted after a combined 75 patients completed at least 24 weeks of treatment in either of the two relugolix arms. Results from the interim analysis demonstrated that both doses of oral, once daily relugolix, 80 mg and 120 mg, rapidly reduced testosterone levels below the castration threshold (£50 ng/dL) and maintained these levels through at least 48 weeks. These data are comparable to testosterone levels achieved by leuprolide 22.5 mg every 3 months, although no statistical comparisons were conducted between the two arms.

Phase 2 Trials for Relugolix for the Treatment of Advanced Prostate Cancer

Sustained Castration Rates1 in Phase 2 Trials

Mean percentage of men achieving <50 ng/dL testosterone

		Study C27002		Study C27003 Final Analysis		
Time point	Ь	nterim Analysi	s			
	Relugolix 80 mg ² N = 39	Relugolix 120 mg ² N = 36	Lupron 22.5 mg ³ N = 20	Relugolix 120 mg ² N = 65	Degarelix 80 mg ⁴ N = 38	
24 weeks (95% CI)	92% (79.1, 98.4)	92% (77.5, 98.2)	95% (75.1, 99.9)	93% (77.9, 99.2)	85% (62.1, 96.8)	
48 weeks (95% CI)	90% (75.8, 97.1)	92% (77.5, 98.2)	95% (75.1, 99.9)	N/A	N/A	

1 At each visit after week 4 through end of the treatment period.

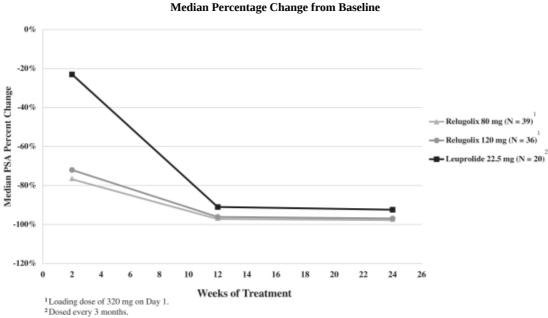
2 Loading dose of 320 mg on day 1.

3 Dosed every 3 months.

4 Loading dose of 240 mg on day 1, then dosed every month.

CI = Confidence Interval

After two weeks of treatment, the median percent change in PSA for the relugolix 120 mg arm was 72.0%, compared to 23.0% in the leuprolide arm. PSA reductions in the relugolix arms were sustained through 24 weeks of treatment. In the relugolix 120 mg arm, 83% of patients achieved a PSA reduction from baseline of at least 50%, compared to 20% of patients in the leuprolide group.



PSA Reduction in Phase 2 Trials Median Percentage Change from Baseli

PSA Reduction in Phase 2 Trials

Percentage of subjects with 350% or 390% reduction from baseline

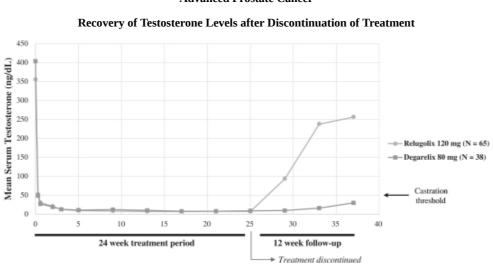
		Study C27002				
Crit	eria	Relugolix 120 mg ¹ N = 36	Leuprolide 22.5 mg ² N = 20			
% of subjects (N)	≥50% PSA reduction	83% (N=30)	20% (N=4)			
with PSA Reduction at 4 weeks	≥90% PSA reduction	8% (N=3)	0% (N=0)			

1 Loading dose of 320 mg on day 1.

2 Dosed every three months.

Study C27003 demonstrated rapid and sustained suppression of testosterone levels for the 24 week treatment duration. Importantly, in this study, the testosterone recovery following the last dose of treatment was more rapid in the relugolix arm than in the degarelix arm. Baseline testosterone levels were similar between the

two arms (356 ng/dL and 404 ng/dL in the relugolix and degarelix groups, respectively), but at 12 weeks after discontinuing therapy, the median testosterone levels were 257 ng/dL and 30 ng/dL, respectively. No statistical comparisons were made between the two arms.



Phase 2 Trial (C27003) for Relugolix for the Treatment of Advanced Prostate Cancer

On the basis of the efficacy findings observed in these two Phase 2 trials, we believe relugolix 120 mg once daily (following a single loading dose of 360 mg) to be an appropriate dose for Phase 3 evaluation in men with advanced prostate cancer.

Completed Phase 1 Clinical and Preclinical Studies of Relugolix

Phase 1 Clinical Trials

Phase 1 clinical trials with relugolix conducted in 862 healthy adults in the United States, Japan and the United Kingdom demonstrated similar pharmacokinetic profiles after single and multiple dosing across these populations. In healthy, premenopausal women receiving single and multiple doses of relugolix, median LH, FSH and estradiol concentrations were suppressed in a dose-dependent manner when compared with subjects receiving placebo. The duration of suppression appeared to increase with increasing single doses of relugolix ranging from 10 mg to 80 mg. In healthy men, relugolix achieved and maintained testosterone at castration levels (£ 50 ng/dL) at daily doses of 80 mg to 180 mg for up to 28 days of dosing. Less robust testosterone suppression was observed at daily doses of 40 mg and 60 mg. The following chart summarizes the Phase 1 clinical trials completed by Takeda for relugolix:

Summary of Relugolix Phase 1 Clinical Trials

TAK-385_101: A Double-Blind, Randomized, Placebo-Controlled, Sequential-Panel, Ascending Single- and Multiple-Dose Study to Evaluate the Effect of TAK-385 on Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics in Healthy Premenopausal Women

•	Subject	Number of	
Location (Date)	Description	Subjects	Key Findings
United States	Healthy	N = 120	Generally well tolerated following single doses of 1 mg to 80 mg and 14-day once-daily
(2007-2008)	premenopausal	(99 relugolix / 21	doses of 10 mg to 40 mg
	women	placebo)	 Frequency of adverse events was similar between placebo and relugolix with no apparent dose relationship
			 Dosing with food reduced absorption of relugolix
			Relugolix suppressed mean concentrations of endogenous LH, FSH, and estradiol following
			repeat doses in dose-dependent manner

TAK-385/CPH-001: A Phase I, Double-Blind, Randomized, Placebo-Controlled, Sequential-Panel, Ascending Single- and Multiple-Dose Study to Evaluate the Effect of TAK-385 on Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics in Healthy Premenopausal Women

	Subject		
Location (Date)	Description	Number of Subjects	Key Findings
Japan (2007-2008)	Healthy premenopausal women	N = 144 (120 relugolix / 24 placebo)	 Generally well tolerated following single doses of 1 mg to 80 mg and 14-day once-daily doses of 10 mg to 40 mg

TAK-385_102: A Phase 1, Open-label Study to Evaluate the Pharmacokinetic Drug-Drug Interaction Between Multiple Doses of TAK-385 and a Panel of Cytochrome P-450 Substrates Administered Concomitantly as an Indiana Cocktail in Healthy Subjects

	Subject				
Location (Date)	Description	Number of Subjects		Key Findings	
United States	Healthy subjects	N = 16	•	Multiple dosing with 20 mg oral once-daily relugolix for 7 days does not have a relevant	
(2008)				effect on the pharmacokinetic profile of substrates for drug metabolizing enzymes	
				CYP1A2, CYP2C9, CYP2D6, and CYP3A4	

TAK-385/CPH-010: An Open-Label, Drug-Drug Interaction Study to Evaluate the Effects of Multiple Oral Doses of Erythromycin on the Pharmacokinetics of a Single Oral Dose of TAK-385 in Healthy Adult Male and Female Subjects

	Subject		
Location (Date)	Description	Number of Subjects	Key Findings
Japan	Healthy subjects	N = 20	• When 20 mg single-dose relugolix was administered in combination with erythromycin, the
(2012)			plasma exposure of relugolix was increased ~6-fold, likely as a result of increased oral
			bioavailability and/or absorption
			The incidence of adverse events known to occur due to the pharmacological effect of

relugolix was higher in the combination period than that in the relugolix only period

• All adverse events were mild and recovered without any treatment

C27001: A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Single and Multiple Dose, Inpatient and Outpatient Study in Healthy Men to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy for Testosterone Lowering of TAK-385, an Oral Gonadotropin-Releasing Hormone (GnRH) Antagonist

	Subject			
Location (Date)	Description	Number of Subjects		Key Findings
United Kingdom	Healthy men	N = 176	•	Sustained, lower-threshold medical castration of <50 ng/dL was consistently achieved with
(2011-2012)		(128 relugolix / 48		once-daily 80 mg, 160 mg, or 180 mg relugolix for 28 days, and rapid reductions in serum
		placebo)		testosterone were achieved by using a loading dose approach (320 mg or 360 mg).
			•	Single and multiple doses administered were generally well tolerated

TAK-385_106: A Randomized, Double-Blind, Placebo- and Positive-Controlled (Open-Label Moxifloxacin), 4-Arm Parallel-Group Study to Evaluate the Effect of TAK-385 on Cardiac Repolarization in Healthy Subjects Subject

	bubjeet				
Location (Date)	Description	Number of Subjects	Key Findings		
United States	Healthy subjects	N = 280	• Single doses of 60 mg and 360 mg relugolix had no effect on cardiac repolarization (QTc		
(2013)		(140 relugolix/	interval)		
		70 placebo/	 Both doses were generally well tolerated in healthy subjects 		
		70 moxifloxacin)			
C27005: An Open-label, Drug-Drug Interaction Study to Evaluate the Effects of Multiple Oral Doses of Fluconazole and Atorvastatin on the					
Pharmacokinetics of a Single Oral Dose of TAK-385 in Healthy Subjects					
	0.1.				

	Subject				
Location (Date)	Description	Number of Subjects	Key Findings		
United States	Healthy subjects	N = 40	Fluconazole or atorvastatin did not result in a clinically relevant change in relugolix		
(2014)			exposure, suggesting CYP3A inhibition is not the dominant mechanism of the previously		
			observed interaction with erythromycin in TAK-385/CPH-010, rather increased oral		
			bioavailability due to P-glycoprotein inhibition		

TAK-385-1009: An Open-Label, Single-Centre, Two-Part, Phase 1, Mass Balance Study to Assess the Absorption, Distribution, Metabolism, Excretion, and Absolute Bioavailability of Orally Administered [14C]-TAK-385 in Healthy Male Subjects

	Subject				
Location (Date)	Description	Number of Subjects	Key Findings		
United Kingdom	Healthy males	N = 12	•	After oral administration of a radiolabeled dose of relugolix, the majority of radioactivity	
(2014)				was recovered in the feces as a metabolite, with little in the urine.	
			•	There were no major circulating relugolix metabolites	
				Oral availability of value of $v_{\rm random}$ of $v_{\rm random}$	

Oral availability of relugolix was determined to be ~12%

TAK-385-1010: An Open-label, Randomized, Three-Way Crossover Study Evaluating the Relative Bioavailability and Effect of Food on TAK-385 Tablet Formulations in Healthy Subjects

	Subject			
Location (Date)	Description	Number of Subjects		Key Findings
United States	Healthy subjects	N = 54	•	Relative bioavailability of two new tablet formulations was similar compared to existing
(2015)				tablet formation
			•	Dosing with food reduced absorption of relugolix

Preclinical Studies

In a series of in vitro and in vivo pharmacological studies conducted by Takeda, relugolix was observed to be a potent and highly selective antagonist for human GnRH receptor. Administration of elagolix in targeting the human GnRH receptor resulted in reductions in reproductive organ weights of male mice, suggesting that relugolix suppressed blood testosterone levels. Orally administered relugolix suppressed the hypothalamic-pituitary axis in castrated cynomolgus monkeys at doses of 1 mg/kg and higher.

In nonclinical pharmacokinetic studies, oral relugolix showed rapid absorption and elimination, with low oral bioavailability. Oral bioavailability is a measure of absorption and is the fraction of an administered dose that reaches the systemic circulation of unchanged drug, one of the principal pharmacokinetic properties of drugs. Relugolix has been evaluated for safety in single-dose studies in rats and monkeys and in repeat-dose toxicity studies in mice, rats and monkeys. Genotoxicity, carcinogenicity, reproductive toxicity and phototoxicity studies have also been performed. No safety issues have been identified from nonclinical studies that would preclude the continued development of relugolix in humans. Studies conducted to date have shown that relugolix is not mutagenic or clastogenic (a mutagenic agent giving rise to or inducing disruption or breakages of chromosomes) and it was not observed to be carcinogenic in two-year mouse and rat toxicity studies.

Summary of Pharmacokinetic and Safety Data for Relugolix

As of July 2015, Takeda had completed or had ongoing 15 Phase 1 or Phase 2 clinical trials for relugolix in a total of 1,839 subjects. Of these, 1,309 subjects, including 792 women and 517 men, had been administered relugolix. Overall, relugolix has been generally well tolerated in the Phase 1 and 2 trials. No safety issues of concern were identified that preclude the continued development of relugolix based on assessments of adverse events, physical examinations, vital sign measurements, clinical laboratory values and electrocardiogram findings. Importantly, in a dedicated study evaluating the impact of relugolix on electrocardiograms, relugolix did not prolong the corrected QT interval. Relugolix treatment results in rapid, dose-dependent suppression of estradiol in women and testosterone in men. The predominant half-life is 37 to 42 hours. Relugolix has low oral bioavailability (average 11.6%), presumably due to intestinal efflux by the Permeability-glycoprotein, or P-gp, transporter. Relugolix is highly metabolized, and there are no major circulating metabolites. Clinical drug-drug interaction studies suggest the exposure of relugolix is increased by P-gp inhibitors. Food was shown to decrease the extent of relugolix absorption. The pharmacokinetics and pharmacodynamics of relugolix have been evaluated and appear similar in American and Japanese volunteers, despite the lower mean body mass index observed in Japanese volunteers.

The overall safety profile of relugolix in clinical studies was consistent with its known mechanism of action as a GnRH receptor antagonist, including bone mineral density loss, hot flash, headache, loss of energy, mood swings, decreased libido and decreased muscle mass. The majority of adverse events have been mild and resolved without treatment.

In the Phase 2 trial of women with uterine fibroids and heavy menstrual bleeding, the most common treatment-emergent adverse events in the relugolix 40 mg once-daily arm, occurring in at least 10% of women included hot flash, nasopharyngitis, abnormal bleeding from the uterus, abnormally heavy menstrual bleeding, headache and genital hemorrhage. In the Phase 2 trial of women with pelvic pain and endometriosis, the most common treatment-emergent adverse events in the relugolix 40 mg once-daily arm, occurring in at least 10% of women included hot flash, headache and genital hemorrhage. In the Phase 2 trial of women with pelvic pain and endometriosis, the most common treatment-emergent adverse events in the relugolix 40 mg once-daily arm, occurring in at least 10% of women included hot flash, abnormal

bleeding from the uterus, nasopharyngitis, and abnormally heavy menstrual bleeding. The majority of events of abnormal bleeding from the uterus, abnormally heavy menstrual bleeding and genital hemorrhage in both trials were reported in the first 28 days as estradiol and progesterone levels were falling. A very high proportion of women in each study achieved amenorrhea, including 72.7% in the uterine fibroids trial and 73.4% in the endometriosis trial. The common adverse events observed with relugolix in women with uterine fibroids or endometriosis were generally consistent with its mechanism of action and those observed with leuprolide.

In an interim analysis of the Phase 2 prostate cancer study C27002, the most common treatment-emergent adverse events occurring in at least 10% of men with advanced prostate cancer in the relugolix 80 mg or 120 mg once-daily arms, or leuprolide arm, included hot flash, alanine aminotransferase increase, fatigue, cataract, aspartate aminotransferase increase, diabetes mellitus, hyperhidrosis, muscle spasm, injection site reaction, frequent daytime urination and weight decrease. The common adverse events observed with relugolix in men with prostate cancer were generally consistent with its mechanism of action and those observed with leuprolide.

Across all relugolix clinical trials, a total of 34 serious adverse events were reported in the more than 1,300 relugolix-treated subjects and patients as of July 10, 2016, of which three were reported by the investigator as possibly related to relugolix, including an event of abnormal liver function tests (moderate grade), one of cerebral infarction (grade unspecified) and one of embolic stroke (grade 2). Three deaths (grade 5 events) have occurred in patients treated with relugolix; all deaths occurred in the prostate cancer study, C27002, and were assessed as unrelated to relugolix.

Bone mineral density decreases were observed at 12 and 24 weeks in premenopausal women treated with relugolix 40 mg once daily and were similar to those observed with leuprolide (3.75 mg subcutaneously administered every four weeks) over the same duration, consistent with the near complete estrogen suppression observed in the trials. Specifically, in the Phase 2 trial for relugolix for the treatment of uterine fibroids, the mean loss in bone mineral density in the relugolix 40 mg once-daily arm was 2.3% at week 12.

The following tables show the incidence of adverse events occurring in greater than 10% of women and the bone mineral density loss following administration of placebo, relugolix 40 mg or leuprolide in the Phase 2 trial for relugolix for the treatment of endometriosis.

Adverse Events	Week 12 Analysis of Safety Population Number (%) of Patients Reporting Event							
Adverse Events	Placebo (N = 97)	Relugolix 40 mg/day ¹ (N=103)	Leuprolide (N = 81)					
Irregular Menstrual Bleeding	4 (4.1%)	25 (24.3%)	32 (39.5%)					
Heavy Menstrual Bleeding	4 (4.1%)	13 (12.6%)	9 (11.1%)					
Hot Flashes	8 (8.2%)	54 (52.4%)	34 (42.0%)					
Nasopharyngitis	21 (21.6%)	22 (21.4%)	15 (18.5%)					

Mean Bone Mineral Density Loss at 24 weeks	Placebo (N = 75)	Relugolix 10 mg/day ¹ (N = 81)	Relugolix 20 mg/day ¹ (N = 77)	Relugolix 40 mg/day ¹ (N = 88)	Leuprolide (N = 64)
LIUSS III AT HUCKS	0.2%	1.6%	2.6%	4.9%	4.4%

¹Relugolix administered without low-dose hormonal add-back therapy.

On the basis of the efficacy findings observed in this trial, we believe relugolix 40 mg once daily to be an appropriate dose for Phase 3 evaluation in women with heavy menstrual bleeding associated with uterine fibroids or endometriosis-associated pain. The purpose of co-administration with low-dose estradiol and progestin as add-back therapy, is to prevent bone mineral density loss and increase tolerability by ameliorating hot flash and other symptoms consistent with a hypoestrogenic state while maintaining the improvement in clinical symptoms, in support of longer-term dosing.

RVT-602

Overview

As part of our license agreement with Takeda, we acquired the worldwide rights to RVT-602, our second product candidate, which has been evaluated in over 150 men. RVT-602 is an oligopeptide kisspeptin analog. Kisspeptin 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. In the second half of 2017, we plan to initiate a Phase 1 healthy volunteer study in women followed by a Phase 2 proof-of-concept clinical trial for RVT-602 for the treatment of female infertility in women as part of assisted reproduction, such as IVF. We expect to submit an IND, or other comparable application, to the FDA or foreign regulatory authorities in the first

half of 2017. 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-LH/FSH axis. We believe RVT-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.

Female Infertility and Assisted Reproduction

Kisspeptin plays a key role in egg maturation and ovulation by increasing the release of LH and FSH through the stimulation of GnRH secretion. During the process of egg maturation, FSH stimulates an ovarian follicle, the sac which contains the developing egg, to grow and the egg within it to develop. When the egg is appropriately mature, a surge of LH occurs. Approximately 24 to 36 hours after the LH surge, the follicle bursts releasing the egg into the Fallopian tube. When hormonal imbalances occur, the processes of egg maturation and ovulation can be disrupted, decreasing a woman's chances for pregnancy and resulting in female infertility.

A major cause of female infertility is hormone imbalance, with approximately 85% related to hypothalamic-pituitary dysfunction. Fertility specialists use a group of medications, including GnRH agonists, to temporarily correct ovulatory problems and increase a woman's chance for pregnancy. IVF is a method of assisted reproduction that involves surgically removing an egg from the woman's ovary and combining it with sperm in a laboratory dish. If the egg is fertilized, resulting in an embryo, the embryo is transferred to the woman's uterus. Every assisted reproduction cycle includes the following essential steps as part of the ultimate goal of pregnancy: (1) maturation of the ovarian follicles, which control the release of an egg in the ovaries, with preparations of LH and FSH; (2) prevention of premature ovulation by treating with a GnRH agonist to prevent release of LH; (3) triggering egg maturation at the appropriate time with human chorionic gonadotropin or a GnRH agonist; (4) egg retrieval and fertilization; and (5) transplantation of fertilized egg followed by biochemical tests for pregnancy.

Current Treatment Landscape for Assisted Reproduction

Current treatments used in assisted reproduction cycles include preparations of FSH and LH administered to stimulate multiple follicles and eggs to grow and mature, followed by a GnRH agonist to prevent premature ovulation. At the right time, human chorionic gonadotropin or a GnRH agonist is administered as an injection to stimulate ovulation of the mature egg. Ovarian hyperstimulation syndrome, or OHSS, results from an abnormal enlargement of the ovarian follicles following egg maturation and stimulation with human chorionic gonadotropin or GnRH agonists (step 3 in the assisted reproduction cycle). Severe OHSS is characterized by ovarian enlargement, accumulation of fluid in the abdomen, nausea and vomiting, fluid in the chest cavity, and can even result in kidney and lung failure and death.

Our Solution

We believe RVT-602, an analog of the naturally-occurring kisspeptin peptide in humans, may mimic natural physiology by inducing the LH 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 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. OHSS is thought to occur as a result of the non-physiologic elevations in LH that occur as a result of egg maturation triggered with human chorionic gonadotropin and to a lesser extent the GnRH receptor agonists.

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 LH, kisspeptin analogs, such as RVT-602, may have the

potential to trigger egg maturation without causing OHSS. A recently published investigator-sponsored trial 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 encouraging results validate the potential use of these agents as a safe alternative to the standard egg maturation trigger in every assisted reproduction protocol. To our knowledge, RVT-602 is the only kisspeptin analog in clinical development and thus has the potential to become a safe alternative egg-maturation trigger in this space.

Our Phase 2 Clinical Development Plan

RVT-602 was initially developed by Takeda as an ADT for prostate cancer and, with a different dosing regimen, as a treatment for hypogonadotropic hypogonadism, or a state of low testosterone levels in men. Both acute and continuous administrations of RVT-602 have been studied in human males. Phase 1 trials demonstrated that RVT-602 in single doses as low as 1 µg given by subcutaneous injection was a potent stimulus of LH and testosterone concentrations, while continuous infusion of RVT-602 ultimately results in reversible suppression of testosterone. Over 150 men have been treated to date. In April 2016, we acquired exclusive, worldwide rights to RVT-602 for all human diseases and conditions. Takeda is no longer developing this compound. Although RVT-602 may have potential as a treatment for prostate cancer and hypogonadotropic hypogonadism. We believe RVT-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.

To explore this hypothesis, in the second half of 2017, we plan to initiate a Phase 1 single-ascending dose safety and pharmacokinetic/pharmacodynamic study in healthy female volunteers. This is expected to be followed by an open-label proof-of-concept Phase 2 study in women undergoing IVF. The objective of the Phase 2 study will be to further evaluate the safety of RVT-602 in women undergoing assisted reproduction, particularly with respect to the occurrence of OHSS.

Pharmacokinetic and Safety Data for RVT-602

RVT-602 has been studied in five Phase 1 trials, conducted between June 2008 and September 2011, involving men aged 50 to 79 who were either healthy or had prostate cancer. The pharmacokinetics of single and repeated doses of RVT-602 or as administered by infusion is predictable as a function of dose, and is stable over time. Single doses as low as 1 µg potently stimulate LH and testosterone release in healthy males, while repeated higher doses or continuous subcutaneous infusion rapidly down regulate the pituitary-testicular axis. The overall safety profile was favorable. Non-severe or non-serious adverse events included hot flash, loose stools, diarrhea, dizziness, orthostatic hypotension, headache and injection site reactions.

In vitro and in vivo pharmacological studies have shown that RVT-602 is a potent agonist of kisspeptin receptors. Continuous subcutaneous administration of RVT-602 was effective in lowering plasma testosterone levels in rats, dogs, monkeys and humans, suggesting that it has potential as an ADT in advanced prostate cancer, while low-dose and intermittent RVT-602 therapy may be effective as a stimulatory agent for secondary hypogonadotropic hypogonadism, as well as for late onset hypogonadism, in humans.

Safety pharmacology studies showed that there were no effects on the cardiovascular, respiratory and central nervous systems, with the exception of a slight and transient decrease in body temperature in rats at the subcutaneous dose of 3 mg/kg and higher. In toxicity studies, subcutaneous doses of RVT-602 were well tolerated in rats and dogs. In rats, subcutaneous treatment with RVT-602 resulted in localized atrophy of the seminiferous tubules at single or repeated doses as low as 0.003 mg/kg, and this lesion did not resolve 13 weeks after cessation of treatment. The RVT-602-induced focal atrophy in the rat testis appears to be species-specific, as such changes were not noted in dogs. Similar species specificity has been observed for GnRH agonists. RVT-602 is not mutagenic or clastogenic.

The overall safety profile to date and the observed effects on the pituitary-gonadal axis in animals and humans support the continued development of RVT-602. We believe that RVT-602 may promote ovulation in a physiologic manner during IVF without the life-threatening side effect of OHSS. Therefore, we plan to explore the utility of RVT-602 for the treatment of female infertility as part of assisted reproductive technology, such as IVF, specifically as a potential replacement for human chorionic gonadotropin.

License Agreement with Takeda Pharmaceuticals International AG

In April 2016, we entered into a license agreement with Takeda, or the Takeda Agreement. Pursuant to the Takeda Agreement, Takeda granted to us an exclusive, royalty-bearing license under certain patents and other intellectual property controlled by Takeda to develop and commercialize the compound TAK-385, which we now refer to as relugolix, and the compound TAK-448, which we now refer to as RVT-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 non-exclusive license in the Takeda Territory to manufacture relugolix and to conduct development of relugolix for prostate cancer, solely for our territory. The territory for our exclusive license for RVT-602 covers all countries worldwide. Our license includes a right of reference to regulatory materials related to relugolix and RVT-602 controlled by Takeda.

Under the Takeda 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 non-exclusive rights to conduct development and manufacturing as described above. We also granted to Takeda a non-exclusive license in our territory to manufacture relugolix and RVT-602 and to conduct development of relugolix for uterine fibroids and endometriosis, in each case solely for 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 RVT-602 in our territory and all activities related to the development of relugolix through the receipt of regulatory approval for prostate cancer in the Takeda Territory. Pursuant to the terms of the Takeda 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 RVT-602 in our territory, as well as to develop and obtain regulatory approval of relugolix for prostate cancer in Japan and the United States. We are solely responsible, at our expense, for all activities related to the commercialization of relugolix and RVT-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 for prostate cancer in the Takeda Territory following receipt of regulatory approval.

We will pay Takeda a fixed, high single-digit royalty on net sales of relugolix and RVT-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 Agreement, there was no upfront payment and there are no payments upon the achievement of clinical development or marketing approval milestones.

During the period commencing on the effective date of the Takeda Agreement and ending two years after the first commercial sale of product containing relugolix in a major market country, we and Roivant Sciences Ltd., have both agreed that we will not, directly or indirectly, and will cause all of our respective affiliates (other than any affiliate that is a public company) not to, alone or with others, research (or fund any research), develop, make, use, sell, offer for sale, or import any competing product in our territory or the Takeda Territory or enter into any agreement with any third party with respect to a license or other acquisition of rights relating to any competing product in our territory or the Takeda Territory. For these purposes, a competing product is (1) any small molecule oral GnRH receptor antagonist (other than a product containing relugolix) for uterine fibroids, endometriosis or prostate cancer, and (2) any product containing RVT-602 for prostate cancer in the Takeda Territory. If, during such period, we or any of our non-public affiliates is acquired by a third party that is developing or commercializing a competing product, then we must divest our interest or terminate the development or commercialization of the competing product or cause our affiliate to do so.

The Takeda 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 Agreement for the other party's uncured material breach, challenge to the patents licensed under the Takeda Agreement or insolvency. Takeda may terminate the Takeda 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 trials 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.

In connection with the Takeda Agreement, we issued 5,077,001 common shares, then equal to 12% of our outstanding share capital, to Takeda pursuant to a subscription agreement, and also issued Takeda a warrant to enable them to maintain its 12% ownership of us through the one-year anniversary of the warrant, unless earlier terminated as a result of our change in control. We also entered into an investor rights agreement with Takeda. Please see the sections titled "Certain Relationships and Related Party Transactions—Relationship with Takeda Pharmaceuticals International AG" and "—Investor Rights Agreement" for further information regarding these agreements and the warrant.

Sales and Marketing

We do not have our own marketing, sales or distribution capabilities. In order to commercialize our product candidates, if approved for commercial sale, we must either develop a sales and marketing infrastructure or collaborate with third-parties that have sales and marketing experience. We plan to directly commercialize our product candidates in the United States. In other markets for which commercialization may be less capital efficient for us, we may selectively pursue strategic collaborations with third parties in order to maximize the commercial potential of our product candidates.

Manufacturing

We have no experience in drug formulation or manufacturing and do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. While

relugolix was being developed by Takeda, it was also being manufactured by Takeda. In June 2016, we and Takeda's affiliate, Takeda Pharmaceutical Company Limited, or Takeda Limited, entered into an agreement for the manufacture and supply of relugolix. Under this agreement, Takeda Limited will supply to us and we will obtain from Takeda Limited all of our requirements for relugolix drug substance and drug product to be used under our development plans for all indications. If we request, Takeda Limited will assist us with a technical transfer of the manufacturing process for relugolix to us or our designee and we will pay the expenses related to such transfer.

We expect that the existing drug substance transferred from Takeda to us under the Takeda Agreement will be sufficient for us to complete our planned Phase 3 programs for relugolix. If relugolix is approved by the FDA for commercial use, we also will rely on Takeda or other third-party manufacturers to supply us with sufficient commercial quantities of relugolix. In addition, we expect that the RVT-602 drug substance transferred from Takeda to us under the Takeda Agreement will be sufficient for us to complete our planned Phase 3 program for RVT-602. We intend to contract with a third party to fill, finish, supply, store and distribute the drug product for this program, if necessary. If we are unable to continue our relationship with Takeda or initiate a new relationship with one or more other third-party manufacturers, we could experience delays in our commercialization efforts as we locate and qualify new manufacturers.

Relugolix is a small molecule that can be manufactured using commercially available technologies. We acquired data from Takeda related to the chemical synthesis and manufacturing of relugolix, and we expect that we will be able to contract with third-party manufacturers for commercial supplies of relugolix on a cost-efficient basis based on our understanding of the simple structure and synthesis of the compound.

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 under current Good Manufacturing Practice, or cGMP, conditions. cGMP is a regulatory standard for the production of pharmaceuticals to be used in humans.

Competition

We consider relugolix's most direct competitor for the treatment of heavy menstrual bleeding associated with uterine fibroids and endometriosis-associated pain to be elagolix, a GnRH receptor antagonist in development at AbbVie that is currently in Phase 3 development. ObsEva is also developing an oral GnRH antagonist, OBE2109, for the treatment of endometriosis and uterine fibroids. ObsEva is initiating a Phase 2 clinical trial evaluating multiple doses in women with endometriosis and may start a Phase 3 study in women with uterine fibroids in the first quarter 2017. Further, Allergan is developing ulipristal, a selective progesterone receptor modulator, in the United States for uterine fibroids and expects to file an NDA with the FDA in 2017. We believe the development of multiple GnRH receptor antagonists by other biopharmaceutical firms adds further validation to the therapeutic relevance of GnRH as a target for the treatment of women's health diseases and other endocrine-related disorders.

In addition to other GnRH receptor antagonists in active development, we are aware of many 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.

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

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

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

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for relugolix, RVT-602 and any of our future product candidates, novel discoveries, product development technologies and know-how; to operate without infringing on the proprietary rights of others; and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing or in-licensing U.S. and foreign patents and patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trademarks, trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position.

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

Following our execution of the Takeda Agreement, as of June 30, 2016, by virtue of the license of patent rights under the Takeda 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 RVT-602. For relugolix, we are the exclusive worldwide licensee, excluding the Takeda Territory. As they relate to relugolix, these patents and patent applications cover the relugolix molecule and analogs thereof as a composition of matter, the use of relugolix to treat sex-hormone dependent prostate cancer or hysteromyoma (uterine fibroids), as well as methods of manufacturing. The patent family directed to the relugolix composition of matter and methods of use naturally expires in 2024, subject to any extension of patent term that may be available in a particular country. The patent applications directed to methods of manufacturing, if issued, would naturally expire in 2033 subject to any adjustment or extension of patent term that may be available in a particular country. For example, we expect the term of the composition of matter patent to relugolix will be extended up to about five years, or 2029, under the provisions of the Hatch-Waxman Act.

For RVT-602, we are the exclusive worldwide licensee of multiple U.S. patents and patent applications as well as patents and patent applications in numerous foreign jurisdictions. These patents and patent applications cover the RVT-602 molecule as a composition of matter, and its use in treating advanced prostate cancer, as well as certain sustained release formulations containing RVT-602. The patent family directed to the RVT-602 composition of matter and method of use naturally expires in 2028 in the U.S. and in 2026 ex-U.S., subject to any extension of patent term that may be available in a particular country. The patent applications directed to the

sustained release formulations of RVT-602, if issued, would naturally expire in 2030 and 2031, subject to any adjustment or extension of patent term that may be available in a particular country. For example, in the United States, we expect the term of the composition of matter patent to RVT-602 will be extended up to about three years, or 2031, under the provisions of the Hatch-Waxman Act.

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

Furthermore, we rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality 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 are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

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

Government Regulation

FDA Drug Approval Process

In the United States, pharmaceutical 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 at any time during the product development process may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs warning or untitled letters, imposition of a clinical hold, withdrawal of approval, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

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

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

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

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

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

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations, including GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol and subsequent protocol amendments must be submitted to the FDA as part of the IND.

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

temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their www.clinicaltrials.gov website.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess pharmacological actions, side effects associated with increasing doses and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine metabolism, pharmacokinetics, the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 clinical trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug 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 trials to demonstrate the efficacy of the drug. A single Phase 3 clinical trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

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 United States. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, and the manufacturer and sponsor under an approved NDA are also subject to annual product and establishment user fees. These fees are typically increased annually. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes 12 months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision.

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 may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

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

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and

may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a risk evaluation and mitigation strategy, or REMS, 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. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. 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 indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs. Such supplements are typically reviewed within 10 months of receipt.

Post-Approval Requirements

Once an NDA is approved, a product may be subject to certain post-approval requirements. 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.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, 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 cGMPs after approval. 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 cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. 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 mandatory revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;

- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- · product seizure or detention, or refusal to permit the import or export of products; or injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Foreign Regulation

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

Other Healthcare Laws

Although we currently do not have any products on the market, our 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.

The federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer or a party acting on its behalf to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and beneficiaries on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations of this law are punishable by up to five years in prison, and can also result in criminal fines, civil money penalties and exclusion from part

Moreover, 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.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent or not provided as claimed. Persons and entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. Penalties for federal civil False Claims Act violations may include up to three times the actual damages sustained by the government, plus mandatory civil penalties of between \$5,500 and \$11,000 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal False Claims Act is a civil statute, False Claims Act violations may also implicate various federal criminal statutes.

HIPAA created new federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute a person or entity does not need 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.

Also, 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. Additionally, to the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws.

HIPAA, as amended by HITECH, and their implementing regulations, including the final omnibus rule published on January 25, 2013, mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and criminal penalties.

The Affordable Care Act imposed, among other things, new annual reporting requirements for covered manufacturers for certain payments and other transfers of value provided to physicians and teaching hospitals, as

well as certain ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of \$150,000 per year and up to an aggregate of \$1 million per year for "knowing failures." Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices or require the tracking and reporting of gifts, compensation or other remuneration to physicians.

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

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

Health Reform

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

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

We continue to evaluate the effect that the Affordable Care Act will have on our business. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product candidate.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. These included reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025 unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, the Drug Supply Chain Security Act, imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing, which will be phased in over several years beginning in 2016. Among the requirements of this legislation, manufacturers will be required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Coverage and Reimbursement

Sales of our product candidates, once 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 health 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 unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product. Sales of our product candidates, and any future product candidates, will be paid by third-party payors. Additionally, the market for our product candidates, and any future product candidates, will be paid by third-party payors' formularies without prior authorization, step therapy, or other limitations such as approved lists of treatments for which third-party payors' formularies without prior authorization, step therapy, or other limitations such as approved lists of treatments for which 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 be a time-consuming process.

Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs and increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls and transparency requirements, restrictions on reimbursement and requirements for substitution of 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 could reduce or eliminate utilization of our products and have an adverse effect on our sales, results of operations and financial condition. In addition, state and federal healthcare reform measures have been and will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures.

Employees

As of September 30, 2016, we had no employees, and our wholly-owned subsidiary, Myovant Sciences, Inc., had nine employees, including seven who are engaged in research and development activities. The employees of Myovant Sciences, Inc. provide services to us pursuant to an intercompany services agreement between us and Myovant Sciences, Inc.

Facilities

Our registered office is located at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda, and we also have business operations at Park Place, 55 Par-La-Ville Road, Hamilton HM11, Bermuda. In anticipation of conducting extensive research and development and building out the functions, personnel and facilities necessary for commercialization of relugolix and RVT-602, if approved, we have established an indirect, wholly-owned subsidiary, Myovant Sciences GmbH, with its principal offices in Basel, Switzerland. We expect that Myovant Sciences GmbH will be the principal operating company for conducting our business and the entity that will hold our intellectual property rights in relugolix and RVT-602.

Our wholly-owned subsidiary, Myovant Sciences, Inc., leases approximately 11,689 square feet of office space in Brisbane, California on a month to month basis for clinical research and development operations and administrative functions. Our affiliate, Roivant Sciences GmbH, leases office space in Basel, Switzerland and our controlling shareholder, Roivant Sciences Ltd., leases office space in Hamilton, Bermuda for business development, intellectual property management and other administrative functions. We anticipate that Myovant Sciences GmbH will sublease space from Roivant Sciences GmbH in Basel, from which we will conduct business development, intellectual property management, commercial preparation and clinical research and development activities. Our affiliate, Roivant Sciences, Inc., leases office space in New York, New York and Durham, North Carolina for clinical and non-clinical research and development operations and finance operations. We do not anticipate that Myovant Sciences, Inc. will separately sublease space in New York or North Carolina, and the clinical research and development and other activities in those locations will be carried out by Roivant Sciences, Inc. at our direction in accordance with our services agreement with Roivant Sciences, Inc. See "Certain Relationships and Related Party Transactions—Relationship with Roivant Sciences, Inc.—Services Agreement" for additional information regarding this agreement. We intend to add new facilities or expand our existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Legal Proceedings

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

MANAGEMENT

Directors and Executive Officers

The following table sets forth information concerning our executive officers, including their ages as of September 30, 2016:

Name	Age	Position
Executive Officers		
Lynn Seely, M.D.*	57	Principal Executive Officer and Director
Frank Karbe*	48	Principal Financial and Accounting Officer
Marianne L. Romeo**	48	Head, Global Transactions & Risk Management
Non-Employee Directors		
Mark Altmeyer	56	Director
Wayne DeVeydt(1)(2)	46	Director
Keith Manchester, M.D.(2)(3)	47	Director
Vivek Ramaswamy	31	Director
Kathleen Sebelius(1)(2)(3)	68	Director

* Employee of our wholly-owned subsidiary, Myovant Sciences, Inc. Such employee provides services to us pursuant to an intercompany services agreement between us and Myovant Sciences, Inc.

** Co-employee of our controlling shareholder, Roivant Sciences Ltd., and our affiliate, Axovant Sciences Ltd.

(1) Member of the audit committee. Mr. DeVeydt serves as the chair of this committee.

(2) Member of the compensation committee. Ms. Sebelius serves as the chair of this committee.

(3) Member of the nominating and corporate governance committee. Dr. Manchester serves as the chair of this committee.

Lynn Seely, M.D. has served as our Principal Executive Officer and as the President and Chief Executive Officer of Myovant Sciences, Inc. since May 2016. From March 2005 to October 2015, Dr. Seely served as Chief Medical Officer of Medivation, Inc. where she served on the Executive Committee and led the development of Xtandi for the treatment of metastatic castration-resistant prostate cancer from IND-enabling studies through to NDA approval and post-approval clinical studies. Dr. Seely was responsible for building the clinical organization at Medivation, as well as the regulatory, quality, project management, medical affairs and biologics manufacturing functions. Dr. Seely currently serves on the board of directors of Blueprint Medicines Corporation, and she previously served as Vice-President of Clinical Development at Anesiva, Inc. (formerly Corgentech) and at Cytyc Health Corporation. Dr. Seely has served on the board of directors of Blueprint Medicines Corporation since April 2016. Dr. Seely received an M.D. from the University of Oklahoma College of Medicine and completed her residency in internal medicine at Yale-New Haven Hospital. After serving as Chief Resident in Internal Medicine at Yale University School of Medicine, she completed her basic science and clinical fellowship in endocrinology and metabolism at the University of California, San Diego.

Frank Karbe has served as our Principal Financial and Accounting Officer and as the interim Chief Financial Officer of Myovant Sciences, Inc. since September 2016. From September 2014 to July 2016, Mr. Karbe served as President of The Color Run, a global mass participation events platform. From January 2004 to June 2014, Mr. Karbe was the Executive Vice President and Chief Financial Officer of Exelixis, Inc., a publicly-traded biotechnology company. Prior to joining Exelixis in 2004, Mr. Karbe worked as an investment banker for Goldman Sachs & Co., where he served most recently as Vice President in the healthcare group focusing on corporate finance and mergers and acquisitions in the biotechnology industry. Prior to joining Goldman Sachs in 1997, Mr. Karbe held various positions in the finance department of The Royal Dutch/Shell Group in Europe. Mr. Karbe currently serves on the board of directors of Arbutus Biopharma Corporation and Kolltan Pharmaceuticals, Inc. Mr. Karbe received his Diplom-Kaufmann from the WHU-Otto Beisheim Graduate School of Management, Koblenz, Germany.

Marianne L. Romeo has served as our Head, Global Transactions & Risk Management since February 2016. Ms. Romeo has served as Head, Global Transactions & Risk Management of Roivant Sciences Ltd. since October 2014 and Axovant Sciences Ltd. since March 2015. Previously, Ms. Romeo had a 20 year career with Marsh Inc. in risk consulting and insurance brokerage, most recently serving as Managing Director and Head of Casualty from 2008 to 2014 and Senior Vice President and Healthcare Practice Leader from 2003 to 2008 for Bowring Marsh (Bermuda) Ltd., an international insurance placement broker and wholly owned subsidiary of Marsh Inc. During her time at Bowring Marsh, Ms. Romeo served in various functional roles, including excess casualty brokerage, risk management consulting, and business management. Ms. Romeo established the Healthcare Practice within Marsh's Bermuda operation in 2003 and continues to serve on the Board of the Bermuda Society for Healthcare Risk Management (BSHRM). Ms. Romeo has served on the board of directors of Axovant Sciences Ltd. since March 2015. Ms. Romeo received her B.Sc. in Manufacturing Engineering, *cum laude*, from Tufts University and her M.S. in Occupational Health and Environmental Science from the City University of New York, Hunter College.

Mark Altmeyer has served as a member of our board of directors since September 2016. Since March 2015, Mr. Altmeyer has served as the President and Chief Commercial Officer of Axovant Sciences, Inc., a wholly-owned subsidiary of Axovant Sciences Ltd. From February 2009 to December 2014, Mr. Altmeyer served as Chief Executive Officer and President of Otsuka America Pharmaceutical, Inc. Prior to his time at Otsuka, Mr. Altmeyer served in a number of executive leadership roles at Bristol-Myers Squibb, including Senior Vice President, Global Commercialization from 2006 to 2008 and Senior Vice President, Neuroscience Business Unit from 2002 to 2005 during the approval and launch of Abilify, a branded drug used to treat multiple psychiatric conditions, including schizophrenia, depression and bipolar disorder. Mr. Altmeyer received his B.A. from Middlebury College and his M.B.A. from Harvard Business School. We believe Mr. Altmeyer's extensive experience serving in executive leadership roles at pharmaceutical companies qualifies him to serve on our board of directors.

Wayne S. DeVeydt has served as a member of our board of directors since September 2016. From May 2007 to May 2016, Mr. DeVeydt served as Executive Vice President and Chief Financial Officer at Anthem, Inc., a health insurance company. From March 2005 to May 2007, he served as Anthem's Senior Vice President and Chief Accounting Officer and also served as Chief of Staff to the Chairman and Chief Executive Officer from 2006 to 2007. Prior to joining Anthem, Mr. DeVeydt served as an audit partner at PricewaterhouseCoopers LLP, focused on companies in the national managed care and insurance industries. Mr. DeVeydt currently serves on the board of directors of NiSource Inc. Mr. DeVeydt received his Bachelor of Science in Business Administration from the University of Missouri in St. Louis. We believe Mr. DeVeydt's significant experience in corporate governance, risk management and finance and accounting matters qualifies him to serve on our board of directors.

Keith Manchester, M.D. has served as a member of our board of directors since September 2016. He is also a member of the board of directors of Roivant Sciences Ltd., a position he has held since May 2014, and of Arbutus Biopharma, a position he has held since March 2015. Dr. Manchester currently serves as a Managing Director and Head of Life Sciences for QVT Financial LP, an investment firm, where he has been employed since 2005, and focuses on investments in both publicly-traded and privately-owned life sciences companies. Prior to joining QVT Financial, Dr. Manchester was Vice President of Business Development from 2002 to 2004 and Director of Business Development from 2000 to 2002 at Applied Molecular Evolution, Inc., a biotechnology company. From 1999 to 2000, Dr. Manchester was an associate at Vestar Capital Partners, a private equity firm. From 1997 to 1999, Dr. Manchester was an investment banker in the healthcare group at Goldman, Sachs & Co. Dr. Manchester received his A.B. degree from Harvard College and his M.D. from Harvard Medical School. We believe Dr. Manchester's medical background, significant knowledge of the life sciences industry and his experience as a life sciences investor qualify him to serve on our board of directors.

Vivek Ramaswamy has served as a member of our board of directors since September 2016. Since March 2015, Mr. Ramaswamy has served as the Principal Executive Officer of Axovant Sciences Ltd. and the Chief

Executive Officer of its wholly-owned subsidiary, Axovant Sciences, Inc. Mr. Ramaswamy also currently serves as President and Chief Executive Officer of Roivant Sciences, Inc., a drug development and commercialization company that is wholly-owned by Roivant Sciences Ltd., a position he has held since May 2014. From August 2007 to May 2014, Mr. Ramaswamy was a member of the investment team at QVT Financial LP. In addition, in 2007, Mr. Ramaswamy co-founded and served as the President of Campus Venture Network, a technology company that was acquired in 2009. Mr. Ramaswamy currently serves as member of the board of directors of Axovant Sciences Ltd. and Roivant Sciences Ltd., as well as chairman of the board of directors of Arbutus Biopharma Corporation. Mr. Ramaswamy received his A.B. degree, *summa cum laude*, in Biology from Harvard College and a J.D. from Yale Law School. We believe that Mr. Ramaswamy's experience as Chief Executive Officer of Roivant Sciences, Inc. and Axovant Sciences, Inc., and his experience as a life sciences investor and as a member of the board of directors.

Kathleen Sebelius has served as a member of our board of directors since September 2016. From 2009 to June 2014, Ms. Sebelius served as U.S. Secretary of Health and Human Services, or HHS. As Secretary of HHS, she presided over 11 operating divisions, including the Centers for Disease Control and Prevention, Food and Drug Administration and National Institutes of Health and oversaw the passage and implementation of the Affordable Care Act. From 2003 to 2009, Ms. Sebelius was Governor of Kansas. From 1995 until 2003, Ms. Sebelius held the position of Kansas Insurance Commissioner, and from 1987 to 1995, she served in the Kansas House of Representatives. Ms. Sebelius currently serves on the board of directors of Dermira, Inc., Humacyte, Inc., Grand Rounds, Inc. and Hampton Creek, Inc. Ms. Sebelius received her B.A. in political science from Trinity Washington University and her Master of Public Administration from the University of Kansas. We believe that Ms. Sebelius' extensive experience in executive leadership and public health qualify her to serve on our board of directors.

Family Relationships

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

Board of Directors

In accordance with our amended and restated bye-laws, which will become effective upon the closing of this offering, our board of directors will be divided into three classes, each of which will consist, as nearly as possible, of one-third of the total number of directors constituting our entire board and which will serve staggered three-year terms. At each general meeting of shareholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- Class I, which will consist of Mark Altmeyer and Keith Manchester, M.D., and their term will expire at our first general meeting of shareholders to be held after the completion of this offering;
- Class II, which will consist of Kathleen Sebelius and Lynn Seely, M.D., and their term will expire at our second general meeting of shareholders to be held after the completion of this offering; and
- Class III, which will consist of Wayne S. DeVeydt and Vivek Ramaswamy, and their term will expire at our third general meeting of shareholders to be held after the completion of this offering.

Our amended and restated bye-laws will provide that the authorized number of directors may be changed only by resolution approved by a majority of our board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Director Independence

Our board of directors has undertaken a review of the independence of the directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. As a result of this review, our board of directors has determined that Messrs. Altmeyer and DeVeydt and Ms. Sebelius representing three of the six members of our board of directors, are independent, as that term is defined under the applicable rules and regulations of the SEC and NYSE rules. Our board of directors has determined that (1) Dr. Seely, by virtue of her position as our Principal Executive Officer, (2) Dr. Manchester, by virtue of his affiliation with Roivant Sciences Ltd., and (3) Mr. Ramaswamy, by virtue of his affiliation with Roivant Sciences Ltd., are not independent under applicable SEC and NYSE rules.

After the closing of this offering, we will be a "controlled company" within the meaning of applicable NYSE rules because more than 50% of the voting power for the election of directors will be held by Roivant Sciences Ltd. Under NYSE rules, as a "controlled company," we will be exempt from the NYSE corporate governance requirements that our nominating and corporate governance committee and compensation committee consist solely of independent directors. We may rely on these exemptions from the corporate governance requirements until we are no longer a "controlled company" or until our board determines to no longer rely on these exemptions. It is currently contemplated that neither our compensation committee nor our nominating and corporate governance committee will consist entirely of independent directors. Accordingly, you may not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of the NYSE. We may continue to rely on these exemptions so long as we are allowed to as a "controlled company."

Committees of the Board of Directors

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

Audit Committee

Our audit committee will review our internal accounting procedures and consult with and review the services provided by our independent registered public accountants. Our audit committee consists of two directors, Mr. DeVeydt and Ms. Sebelius. Mr. DeVeydt is the chair of the audit committee, and our board of directors has determined that Mr. DeVeydt is an audit committee financial expert, as defined by SEC rules and regulations.

The controlled company exemption does not modify the independence requirements for an audit committee, and we intend to comply with the requirements of Rule 10A-3 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the applicable NYSE rules. Under Rule 10A-3 of the Exchange Act, we are permitted to phase in our compliance with the independent audit committee requirements set forth in Rule 10A-3 of the Exchange Act as follows: (1) one independent members at the time of listing, (2) a majority of independent members within 90 days of listing and (3) all independent members within one year of listing. We are relying on this phase in exception and expect that all three members of our audit committee will be determined by our board of directors to be independent within one year of our listing on the NYSE. Our board of directors has determined that such reliance will not materially and adversely affect the ability of our audit committee to act independently and to satisfy the other requirements set forth in Rule 10A-3 of the Exchange Act.

Our board of directors has determined that each of Mr. DeVeydt and Ms. Sebelius is an independent director under NYSE rules and each of Mr. DeVeydt and Ms. Sebelius is independent under Rule 10A-3 of the Exchange Act. We intend to continue to evaluate the requirements applicable to us and we intend to comply with future requirements to the extent that they become applicable to our audit committee.

The principal duties and responsibilities of our audit committee will include:

- recommending and retaining an independent registered public accounting firm to serve as independent auditor to audit our financial statements, overseeing the independent auditor's work and determining the independent auditor's compensation;
- approving in advance all audit services and non-audit services to be provided to us by our independent auditor;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls, auditing
 or compliance matters, as well as for the confidential, anonymous submission by our employees of concerns regarding questionable accounting or
 auditing matters;
- reviewing and discussing with management and our independent auditor the results of the annual audit and the independent auditor's review of our quarterly financial statements; and
- conferring with management and our independent auditor about the scope, adequacy and effectiveness of our internal accounting controls, the
 objectivity of our financial reporting and our accounting policies and practices.

Compensation Committee

Our compensation committee will review and determine the compensation of all our executive officers. Our compensation committee consists of three directors, Mr. DeVeydt, Dr. Manchester and Ms. Sebelius, each of whom is a non-employee member of our board of directors as defined in Rule 16b-3 under the Exchange Act. Ms. Sebelius is the chair of the compensation committee. As a controlled company, we intend to rely upon the exemption from the requirement that we have a compensation committee composed entirely of independent directors. The principal duties and responsibilities of our compensation committee will include:

- establishing and approving, and making recommendations to the board of directors regarding, performance goals and objectives relevant to the
 compensation of our chief executive officer, evaluating the performance of our chief executive officer in light of those goals and objectives and setting,
 or recommending to the full board of directors for approval, the chief executive officer's compensation, including incentive-based and equity-based
 compensation, based on that evaluation;
- · setting the compensation of our other executive officers, based in part on recommendations of the chief executive officer;
- · exercising administrative authority under our equity incentive plan and employee benefit plans;
- · establishing policies and making recommendations to our board of directors regarding director compensation;
- reviewing and discussing with management the compensation discussion and analysis that we may be required from time to time to include in SEC filings; and
- preparing a compensation committee report on executive compensation as may be required from time to time to be included in our annual proxy statements or annual reports on Form 10-K filed with the SEC.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of two directors, Dr. Manchester and Ms. Sebelius. Dr. Manchester is the chair of the nominating and corporate governance committee. As a controlled company, we intend to rely upon the exemption from the requirement that we have a nominating and corporate governance committee composed entirely of independent directors. The nominating and corporate governance committee's responsibilities will include:

assessing the need for new directors and identifying individuals qualified to become directors;

- recommending to the board of directors the persons to be nominated for election as directors and to each of the board's committees;
- assessing individual director performance, participation and qualifications;
- developing and recommending to the board corporate governance principles;
- monitoring the effectiveness of the board and the quality of the relationship between management and the board; and
- overseeing an annual evaluation of the board's performance.

Code of Business Conduct and Ethics for Employees, Executive Officers and Directors

Effective upon the closing of this offering, we will adopt a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, executive officers and directors. Following the closing of this offering, the Code of Conduct will be available on our website at www.myovant.com. The nominating and corporate governance committee of our board of directors will be responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers and directors. We expect that any amendments to the Code of Conduct, or any waivers of its requirements, will be disclosed on our website.

Compensation Committee Interlocks and Insider Participation

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

Director Compensation

We provide cash and equity-based compensation to our directors for the time and effort necessary to serve as a member of our board of directors. Each of Mr. DeVeydt and Ms. Sebelius is entitled to receive \$40,000 in annual director fees for his or her service on our board of directors. In September 2016, we granted Messrs. Altmeyer and DeVeydt and Ms. Sebelius options to purchase 33,846, 42,308 and 33,846 of our common shares, respectively, with an exercise price of \$5.11 per share. Each of these options vests over a period of three years. The option will vest as to one third of the shares on the first anniversary of the option grant date and the balance will vest in a series of eight equal quarterly installments thereafter. All common shares underlying these options will become fully vested upon a change in control, as defined in our 2016 Equity Incentive Plan.

We expect that our board of directors will adopt a director compensation policy for non-employee directors following the closing of this offering. Pursuant to this policy, we expect that any director who is also an employee of ours or our subsidiary will not receive any additional compensation for his or her service as a director.

2016 Director Compensation

During the fiscal year ended March 31, 2016, our sole director was Roivant Sciences Ltd., our majority shareholder.

EXECUTIVE COMPENSATION

2016 Summary Compensation Table

During the fiscal year ended March 31, 2016, Marianne A. Romeo, our Head, Global Transactions & Risk Management, was our only executive officer. Ms. Romeo is a co-employee of Roivant Sciences Ltd. and Axovant Sciences Ltd. Although we did not pay Ms. Romeo any compensation for her services as our executive officer during the fiscal year ended March 31, 2016, we have recorded \$7,400 in allocated compensation expense from Roivant Sciences Ltd. related to Ms. Romeo's services during such period.

Outstanding Equity Awards at March 31, 2016

As of March 31, 2016, Ms. Romeo did not hold any Myovant Sciences Ltd. equity awards.

Employment Arrangements

Lynn Seely, M.D.

In May 2016, our wholly-owned subsidiary, Myovant Sciences, Inc., entered into an employment agreement with Dr. Seely, pursuant to which she will serve as its President and Chief Executive Officer. The agreement provides for an annual base salary of \$300,000, which may be increased from time to time in the discretion of the board of directors of Myovant Sciences, Inc. Dr. Seely will be eligible to earn an annual discretionary cash bonus with a target of 50% of base salary based on the board of directors' assessment of her individual performance as well as company performance.

In June 2016, pursuant to the terms of her employment agreement, we granted Dr. Seely a restricted stock award of 1,128,222 common shares. Twenty-five percent of the shares will vest and be released from our right of repurchase on the first anniversary of Dr. Seely's commencement of employment, and the balance will vest in a series of 12 equal quarterly installments thereafter, in each case so long as Dr. Seely remains in continuous employment with Myovant Sciences, Inc. through the applicable vesting date. Dr. Seely is entitled to receive an equity award of 66,845 restricted stock units in Roivant Sciences Ltd., our majority shareholder. The restricted stock units will vest to the extent certain performance criteria are achieved and certain liquidity conditions are satisfied within eight years of the grant date. On the later of the first anniversary of Dr. Seely's commencement of employment and the completion of our initial public offering, and subject to the approval by our board of directors, Dr. Seely will receive an additional restricted stock award of 564,111 common shares. These restricted shares will vest if our stock price following an initial public offering, as follows: 1/3rd of the shares will vest if our stock price is four times the initial public offering price, and the final 1/3rd of the shares will vest if our stock price is four times the initial public offering price, and the final 1/3rd of the shares will vest if our stock price exceeds six times the initial public offering price, provided Dr. Seely remains employed on each vesting milestone. Finally, Dr. Seely will be eligible to receive additional discretionary annual equity incentive awards in amounts commensurate with her position as President and Chief Executive Officer, which will vest over a four-year vesting period. These grants will be based upon meeting performance metrics to be mutually agreed upon in writing within 60 days following her commencement of employment, and revised annually thereafter.

Dr. Seely will also participate in benefit plans and arrangements made available to similarly situated executives, will accrue four weeks of vacation per year and has entered into our standard form of non-disclosure and inventions assignment agreement.

If her employment is terminated by Myovant Sciences, Inc. without "cause" or by Dr. Seely for "good reason" (each as defined in the employment agreement), then, subject to the execution of an effective release, Dr. Seely will receive (a) a lump sum payment equal to the sum of her base salary and target bonus, (b) reimbursement of COBRA premiums for the first 12 months of COBRA coverage or a direct payment of equivalent value, if the COBRA reimbursement is not permitted pursuant to applicable law and (c) vesting of 50% of her then-unvested equity awards (100% if the termination occurs within 18 months following a change of



control). If any amounts would be subject to excise tax under Section 280G of the Internal Revenue Code, the amounts will either be paid in full (and subject to the tax), or cut back so that no excise tax applies, whichever would put Dr. Seely in a better after-tax position.

Frank Karbe

In September 2016, our wholly-owned subsidiary, Myovant Sciences, Inc., entered into an offer letter with Mr. Karbe, pursuant to which he will serve as its Interim Chief Financial Officer. The offer letter provides for an annual base salary of \$300,000. Mr. Karbe is eligible to earn a one-time discretionary performance bonus of \$150,000 if he is employed on the first anniversary of his start date. During the first six months of his employment, Mr. Karbe will be expected to devote 50% of his time to his duties. In September 2016, pursuant to the terms of his offer letter, we granted Mr. Karbe an option to purchase 225,644 of our common shares with an exercise price of \$5.11 per share. The option will vest as to 28,205 shares on the six-month anniversary of his start date, 28,205 shares will vest on the first anniversary of his start date and the balance will vest in a series of 12 equal quarterly installments thereafter.

2016 Equity Incentive Plan

In June 2016, our board of directors and our shareholders adopted our 2016 Equity Incentive Plan, or the 2016 Plan. In September 2016, our board of directors amended the 2016 Plan and our shareholders ratified such amendments. The 2016 Plan, as amended, will become effective upon the execution of the underwriting agreement related to this offering. The description of the 2016 Plan set forth below, reflects the 2016 Plan, as amended. Our 2016 Plan provides for the grant of incentive options within the meaning of Section 422 of the Internal Revenue Code, or the Code, to our employees and our parent and subsidiary corporations' employees, and for the grant of nonstatutory options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and other forms of stock compensation to our employees, including officers, consultants and directors. The 2016 Plan also provides for the grant of performance cash awards to our employees, consultants and directors.

Authorized Shares

The maximum number of common shares that may be issued under the 2016 Plan is 4,512,889 shares. The number of common shares reserved for issuance under the 2016 Plan will automatically increase on April 1 of each year, for a period of ten years, from April 1, 2017 continuing through April 1, 2026, by 4% of the total number of our common shares outstanding on March 31 of the preceding fiscal year, or a lesser number of shares as may be determined by our board of directors or the compensation committee. The maximum number of common shares that may be issued pursuant to the exercise of incentive options under the 2016 Plan is 22,564,449.

Shares issued under the 2016 Plan may be authorized but unissued or reacquired common shares. Shares subject to stock awards granted under the 2016 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, will not reduce the number of common shares available for issuance under the 2016 Plan. Additionally, common shares issued pursuant to stock awards under the 2016 Plan that we repurchase or that are forfeited, as well as shares reacquired by us as consideration for the exercise or purchase price of a stock award or to satisfy tax withholding obligations related to a stock award, will become available for future grant under the 2016 Plan.

Administration

Our board of directors, or a duly authorized committee thereof, will have the authority to administer the 2016 Plan. Our board of directors will delegate its authority to administer the 2016 Plan to our compensation committee under the terms of the compensation committee's charter. Our board of directors may also delegate to one or more of our officers the authority to (1) designate employees other than officers to receive specified stock

awards and (2) determine the number of our common shares to be subject to such stock awards. Subject to the terms of the 2016 Plan, the administrator has the authority to determine the terms of awards, including recipients, the exercise price or strike price of stock awards, if any, the number of common shares subject to each stock award, the fair market value of a common share, the vesting schedule applicable to the awards, together with any vesting acceleration, the form of consideration, if any, payable upon exercise or settlement of the stock award and the terms and conditions of the award agreements for use under the 2016 Plan.

The administrator has the power to modify outstanding awards under our 2016 Plan. Subject to the terms of the 2016 Plan, the administrator has the authority to reprice any outstanding option or stock appreciation right, cancel and re-grant any outstanding option or stock appreciation right in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

Section 162(m) Limits

At such time as necessary for compliance with Section 162(m) of the Code, no participant may be granted stock awards covering more than 1,128,222 common shares under the 2016 Plan during any fiscal year pursuant to options, stock appreciation rights and other stock awards whose value is determined by reference to an increase over an exercise price or strike price of at least 100% of the fair market value of our common shares on the date of grant. Additionally, no participant may be granted in a fiscal year a performance stock award covering more than 1,128,222 common shares or a performance cash award having a maximum value in excess of \$1.0 million under the 2016 Plan. These limitations enable us to grant awards that will be exempt from the \$1.0 million limitation on the income tax deductibility of compensation paid per covered executive officer imposed by Section 162(m) of the Code.

Performance Awards

The 2016 Plan permits the grant of performance-based stock and cash awards that may qualify as performance-based compensation that is not subject to the \$1.0 million limitation on the income tax deductibility of compensation paid per covered executive officer imposed by Section 162(m) of the Code. To enable us to grant performance-based awards that will qualify, our compensation committee can structure such awards so that the stock or cash will be issued or paid pursuant to such award only following the achievement of specified pre-established performance goals during a designated performance period.

Changes to Capital Structure

In the event there is a specified type of change in our capital structure, such as a split, reverse split or recapitalization, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under our 2016 plan, (2) the class and maximum number of shares by which the share reserve may increase automatically each year, (3) the class and maximum number of shares that may be issued upon the exercise of incentive stock options, (4) the class and maximum number of shares subject to stock awards that can be granted to any person in a calendar year (as established under the 2016 Plan pursuant to Section 162(m) of the Code), and (5) the class and number of shares and exercise price, strike price or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions

The 2016 Plan provides that in the event of a specified corporate transaction, including without limitation a consolidation, merger, or similar transaction involving our company, the sale of all or substantially all of the assets of our company, the direct or indirect acquisition by a person or persons acting as a group of ownership of shares representing a majority of the then outstanding share capital of our company, the administrator will determine how to treat each outstanding stock award. The administrator may:

- arrange for the assumption, continuation or substitution of a stock award by a successor corporation;
- arrange for the assignment of any reacquisition or repurchase rights held by us to a successor corporation;

- accelerate the vesting of the stock award and provide for its termination prior to the effective time of the corporate transaction;
- arrange for the lapse, in whole or in part, of any reacquisition or repurchase right held by us;
- cancel the stock award prior to the transaction in exchange for a cash payment, which may be reduced by the exercise price payable in connection with the stock award; or
- make a payment, in such form as determined by the administrator, equal to the excess, if any, of the value of the property that would have been received
 if such award was exercised immediately prior to the effective time of the corporate transaction over any exercise price payable.

The administrator is not obligated to treat all stock awards or portions of stock awards, even those that are of the same type, in the same manner. The administrator may take different actions with respect to the vested and unvested portions of a stock award.

Change in Control

The administrator may provide, in an individual award agreement or in any other written agreement between us and the participant, that the stock award will be subject to additional acceleration of vesting and exercisability in the event of a change in control. In the absence of such a provision, no such acceleration of the stock award will occur.

Plan Amendment or Termination

Our board has the authority to amend, suspend, or terminate the 2016 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. No incentive options may be granted after the tenth anniversary of the earlier of (1) the date the 2016 Plan was adopted by our board, or (2) the date the 2016 Plan was approved by our shareholders.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell our common shares on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information subject to compliance with the terms of our insider trading policy. Prior to 180 days after the date of this offering, subject to early termination, the sale of any shares under such plan would be prohibited by the lock-up agreement that the director or officer has entered into with the underwriters.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions since our inception on February 2, 2016 to which we have been a participant in which the amount involved exceeded or will exceed \$120,000, and in which any of our directors, executive officers or holders of more than 5% of our share capital, or any members of their immediate family, had or will have a direct or indirect material interest.

Relationship with Takeda Pharmaceuticals International AG

In April 2016, we entered in a series of agreements with Takeda Pharmaceuticals International AG, or Takeda, and its affiliate as discussed below.

License Agreement

In April 2016, we entered into a license agreement with Takeda. Pursuant to this license agreement, Takeda granted to us an exclusive, royalty-bearing license under certain patents and other intellectual property controlled by Takeda to develop and commercialize the compound TAK-385, which we now refer to as relugolix, and the compound TAK-448, which we now refer to as RVT-602, and products containing these compounds for all human diseases and condition. See the section titled "Business—License Agreement with Takeda Pharmaceuticals International AG" for a further description of the terms of this license agreement.

Manufacture and Supply Agreement

In June 2016, we and Takeda's affiliate, Takeda Pharmaceutical Company Limited, or Takeda Limited, entered into an agreement for the manufacture and supply of relugolix. Under this agreement, Takeda Limited will supply us, and we will obtain from Takeda Limited, all of our requirements for relugolix drug substance and drug product to be used under our development plans for all indications. If we request, Takeda Limited will assist us with a technical transfer of the manufacturing process for relugolix to us or our designee and we will pay the expenses related to such transfer. We expect the costs associated with the manufacture and supply of relugolix under this agreement to be approximately \$25.0 million.

Subscription Agreement

In April 2016, we entered into a subscription agreement with Takeda, pursuant to which we issued 5,077,001 common shares to Takeda. Takeda did not pay any cash consideration for the common shares.

Warrant

In April 2016, we issued a warrant to purchase an indeterminate number of capital shares to Takeda. This warrant entitles Takeda, to purchase, at any time following our issuance of any class of capital shares, that number of capital shares of such class that would allow Takeda, together with its affiliates, to maintain a 12% ownership in us, as determined after such exercise. The exercise price of this warrant is \$0.000017727 per share and contains an automatic net exercise provision. Upon the closing of this offering, pursuant to the terms of this warrant, we will automatically issue 1,772,724 common shares to Takeda, based upon the sale and issuance of 13,000,000 common shares to investors in this offering at an assumed initial public offering price of \$13.50 per common shares in full, we would issue an additional 265,911 common shares to Takeda. This warrant will terminate upon the earlier of (1) the day after the one year anniversary of its issuance, or (2) upon a change in control in Myovant, unless such change in control results in a privately-held entity in which the holders of 40% or more of the equity securities, calculated on a fully-diluted basis, of the surviving entity are held by persons and entities who were affiliates of Myovant prior to such change in control.

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Relationship with Roivant Sciences Ltd.

Option Agreement

In June 2016, we entered into an option agreement with Roivant Sciences Ltd. pursuant to which Roivant Sciences Ltd. granted to us an option to acquire the rights to products to which Roivant Sciences Ltd. or any non-public affiliate of Roivant Sciences Ltd. acquires the rights (other than a relugolix product or a competing product, as described in the section titled "Business—License Agreement with Takeda Pharmaceuticals International AG") for uterine fibroids or endometriosis, or for which the primary target indication is hormone-sensitive prostate cancer. Our option is exercisable at any time during the period commencing upon the completion of this offering and ending two years following the date of first commercial sale of a relugolix product in a major market country. If we elect to exercise our option for a product, we will be required to reimburse Roivant Sciences Ltd. for 110% of any payments made by Roivant Sciences Ltd. or its affiliate for such product, and will receive an assignment of the agreement through which Roivant Sciences Ltd. or its affiliate acquired the rights to such product.

Information Sharing and Cooperation Agreement

In July 2016, we entered into an information sharing and cooperation agreement, or the Cooperation Agreement, with Roivant Sciences Ltd. The Cooperation Agreement, among other things: (1) obligates us to deliver periodic financial statements and other financial information to Roivant Sciences Ltd. and to comply with other specified financial reporting requirements; and (2) requires us to supply certain material information to Roivant Sciences Ltd. to assist it in preparing any future SEC filings.

Subject to specified exceptions, the Cooperation Agreement will terminate upon the earlier of the mutual written consent of the parties or when Roivant Sciences Ltd. is no longer required by U.S. GAAP to consolidate our results of operations and financial position, account for its investment in us under the equity method of accounting or, by any rule of the SEC, include our separate financial statements in any filings it may make with the SEC.

Relationship with Roivant Sciences, Inc.

Services Agreement

In July 2016, we and our wholly-owned subsidiary, Myovant Sciences, Inc., entered into a services agreement with Roivant Sciences, Inc., a wholly-owned subsidiary of Roivant Sciences Ltd., or the Services Agreement effective as of April 29, 2016, pursuant to which Roivant Sciences, Inc. provides us with services in relation to the identification of potential product candidates, project management of clinical trials and other development, administrative and financial activities. Following the completion of this offering, we expect that our reliance on Roivant Sciences, Inc. will decrease over time as we, Myovant Sciences, Inc. and any other future subsidiary of ours continue to hire the necessary personnel to manage the development and potential commercialization of relugolix and RVT-602. The Services Agreement will continue in perpetuity until terminated by either party upon 60 days written notice.

Under the terms of the Services Agreement, we are obligated to pay or reimburse Roivant Sciences, Inc. for the costs it, or third parties acting on its behalf, incur(s) in providing services to us. In addition, we are obligated to pay to Roivant Sciences, Inc. a pre-determined mark-up, currently equal to 10%, on costs incurred by it in connection with any general and administrative and support services as well as research and development services.

Administrative and support services include, but are not limited to, payroll, general administrative, corporate and public relations, investor relations, financial marketing, activities in connection with raising capital, accounting and auditing, tax, health, safety, environmental and regulatory affairs, staffing and recruiting, benefits, information and technology services, purchasing and legal services. Research and development services include, but are not limited to, preparatory assistance in respect of the identification of product candidates,

performance and oversight of due diligence to evaluate potential product candidates, management and oversight of external consultants in connection with potential product candidate investment opportunities, participation in meetings with regulatory authorities related to product candidates, development of plans for potential clinical trials, selection of manufacturers of product candidates, management and oversight of clinical trials and product manufacturing, analysis of clinical trial data and management of regulatory filings and approval processes.

Under the Services Agreement, Roivant Sciences, Inc. has agreed to indemnify us and Myovant Sciences, Inc., and each our respective officers, employees and directors against all losses arising out of, due to or in connection with the provision of services (or the failure to provide services) under the Services Agreement, except to the extent such losses are the result of the gross negligence or willful misconduct of such indemnified parties. Such indemnification obligations will not exceed the payments made by us and by Myovant Sciences, Inc. under the Services Agreement for the specific service that allegedly caused or was related to the losses during the period in which such alleged losses were incurred.

Investor Rights Agreement

In April 2016, we entered into an investor rights agreement with Takeda and Roivant Sciences Ltd. After the closing of this offering, pursuant to the terms of this agreement, these shareholders will be entitled to rights with respect to the registration of their common shares under the Securities Act of 1933, as amended, including the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. For a description of these registration rights, see the section titled "Description of Share Capital—Registration Rights."

Employment Arrangements

Lynn Seely, M.D., our Principal Executive Officer, and Frank Karbe, our Principal Financial and Accounting Officer, have entered into employment arrangements with our wholly-owned subsidiary, Myovant Sciences, Inc. For additional information regarding the employment arrangements, see the section titled "Executive Compensation—Employment Arrangements." In addition, Marianne L. Romeo, our Head, Global Transactions & Risk Management, is also a co-employee of Roivant Sciences Ltd., our majority shareholder, and Axovant Sciences Ltd., our affiliate.

Other Transactions

We have and intend to continue to grant equity awards to members of our board of directors and our executive officers. For a description of these equity awards, see the sections titled "Management—Director Compensation" and "Executive Compensation—Employment Arrangements."

Indemnification Agreements

In connection with this offering, we will enter into indemnification agreements with each of our directors and executive officers. These indemnification agreements will provide the directors and executive officers with contractual rights to indemnification and expense advancement that are, in some cases, broader than the specific indemnification provisions contained under Bermuda law. See the section titled "Description of Share Capital—Indemnification of Directors and Officers" for additional information regarding indemnification under Bermuda law and our amended and restated bye-laws.

Related Person Transaction Policy

Prior to this offering, we have not had a formal policy regarding approval of transactions with related parties. We expect to adopt a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. The policy will become effective immediately upon the execution of the underwriting agreement for this offering. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of

similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds \$120,000. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including Roivant Sciences Ltd., and any of their respective immediate family members and any entity owned or controlled by such persons. Any transaction contemplated by the option agreement with Roivant Sciences Ltd., as described in the section titled "—Option Agreement" above, will also be subject to this policy.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant shareholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our Code of Conduct that we expect to adopt prior to the closing of this offering, our employees and directors will have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related person transactions, our audit committee, or other independent body of our board of directors and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our shareholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion.

PRINCIPAL SHAREHOLDERS

The following table sets forth the beneficial ownership of our common shares as of September 30, 2016 by:

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common shares;
- each of our executive officers;
- each of our directors; and
- all of our current executive officers and directors as a group.

The percentage ownership information before the offering is based upon 43,750,684 common shares outstanding as of September 30, 2016. The percentage ownership information after the offering assumes the (1) sale and issuance of 13,000,000 common shares in this offering and no exercise by the underwriters of their option to purchase additional common shares; and (2) the issuance of an additional 1,772,724 common shares to Takeda upon the closing of this offering pursuant to the automatic exercise of a warrant we issued to Takeda.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include common shares issuable pursuant to the exercise of options that are either immediately exercisable or exercisable on or before November 29, 2016, which is 60 days after September 30, 2016. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for persons or entities listed in the table is c/o Myovant Sciences Ltd. Clarendon House, 2 Church Street, Hamilton HM11, Bermuda.

	Shares Beneficially Owned Before this Offering		Shares Beneficially Owned After this Offering	
Name of Beneficial Owner	Shares	%	Shares	%
5% Shareholders				
Roivant Sciences Ltd.(1)	37,231,342	85.1%	37,231,342	63.6
Takeda Pharmaceuticals International AG(2)	5,391,120	12.3	7,163,844	12.2
Executive Officers and Directors				
Lynn Seely, M.D.(3)	1,128,222	2.6	1,128,222	1.9
Frank Karbe				_
Marianne L. Romeo.				
Mark Altmeyer				_
Wayne DeVeydt				
Keith Manchester, M.D.(4)				_
Vivek Ramaswamy(5)				
Kathleen Sebelius	—		—	
All current directors and executive officers as a group (8 persons)	1,128,222	2.6	1,128,222	1.9

(1) Consists of 37,231,342 common shares directly owned by Roivant Sciences Ltd. ("Roivant"). Under Roivant's internal governance arrangements, dispositive decisions over these shares require the approval of the majority of Roivant's board of directors, including (i) at least two "independent directors" (within the meaning of that term under Roivant's bye-laws), or (ii) if there is only one such independent director, that sole independent director. Vivek Ramaswamy, Ilan Oren, Keith Manchester, M.D., Andrew Lo, Ph.D. and Patrick Machado comprise the board of directors of Roivant. The approval of Dr. Lo and Mr. Machado, as an independent directors of Roivant (and, to the extent that each one is the only independent director of

Roivant then serving, the sole approval of Dr. Lo or Mr. Machado, as applicable), is needed to dispose of the common shares directly owned by Roivant and, accordingly, each of Dr. Lo and Mr. Machado may be deemed an indirect beneficial owner over the common shares directly owned by Roivant. Each of Dr. Lo and Mr. Machado disclaims beneficial ownership in the common shares except to the extent of his respective pecuniary interest therein. Additionally, any one of Roivant's three major shareholders (the "Major Shareholders"), voting unanimously with the other Major Shareholders, has the right to override certain decisions of the board of directors of Roivant, including with respect to dispositions of common shares directly owned by Roivant (the "Override Right"). The three Major Shareholders of Roivant are Dexxon Holdings Ltd. ("Dexxon"), QVT Fund V LP ("QVT Fund") and the Viking Funds. The Viking Funds are comprised of Viking Global Opportunities Illiquid Investments Sub-Master LP, Viking Global Equities LP, Viking Global Equities II LP, VGE III Portfolio Ltd. and Viking Long Fund Master Ltd. (the "Viking Funds"). With this Override Right, each of the Major Shareholders, along with certain affiliates of the Major Shareholders named below with voting and investment control over the Major Shareholders, may be deemed to share dispositive power and over the common shares directly owned by Roivant. The affiliates of the Major Shareholders that may be deemed indirect beneficial owners of the common shares indirectly beneficially owned by each of the Major Shareholders and directly owned by Roivant include the following: (i) Dan Oren, the sole director of Dexxon, insofar as voting and dispositive decisions of Dexxon are made by its sole director; (ii) QVT Financial LP, as the investment manager for QVT Fund, QVT Financial GP LLC, as the general partner of QVT Financial LP, and QVT Associates GP LLC, as the general partner of the QVT Fund; and (iii) Viking Global Performance LLC, as the general partner of Viking Global Equities LP and Viking Global Equities II LP and the investment manager for VGE III Portfolio Ltd., Viking Global Opportunities Portfolio GP LLC, as the general partner of Viking Global Opportunities Illiquid Investments Sub-Master LP, and Viking Long Fund GP LLC, as the investment manager for Viking Long Fund Master Ltd. (Viking Global Performance LLC, Viking Global Opportunities Portfolio GP LLC and Viking Long Fund GP LLC, collectively with the Viking Funds, the "Viking Shareholders"). Each of the Major Shareholders and each of their affiliates thereof named above disclaims beneficial ownership in the common shares owned by Roivant except to the extent of their pecuniary interest therein. The principal business address of Dr. Lo, Mr. Machado and Roivant is Clarendon House, 2 Church Street, Hamilton HM 11, Bermuda. The principal business address of Dexxon and Mr. Oren is 1 Dexcel Street, Or Akiva 30600000, Israel. The principal business address of QVT Financial, QVT Financial GP LLC and QVT Associates GP LLC is 1177 Avenue of the Americas, 9th Floor, New York, New York 10036. The registered office of the QVT Fund is located at 190 Elgin Avenue, George Town, Grand Cayman KY1-9005, Cayman Islands. The principal business address of each of the Viking Shareholders is 55 Railroad Avenue, Greenwich, Connecticut 06830.

- (2) Shares beneficially owned after this offering includes 1,772,724 common shares issuable upon the closing of this offering pursuant to the automatic exercise of a warrant held by Takeda Pharmaceuticals International AG ("Takeda"), based upon the sale and issuance of 13,000,000 common shares to investors in this offering at an assumed initial public offering price of \$13.50 per common share, which is the midpoint of the price range set forth on the cover page of this prospectus. See the section titled "Certain Relationships and Related Party Transactions—Relationship with Takeda Pharmaceuticals International AG—Warrant" for a description of the terms of this warrant. Takeda's percentage ownership before and after this offering is equal to 12.0% on a fully-diluted basis, after giving effect to stock options for 1,175,311 common shares outstanding as of September 30, 2016. The principal business address of Takeda is Thurgauerstrasse 130, 8152 Glattpark—Opfikon Zurich, Switzerland.
- (3) Represents 1,128,222 common shares subject to a repurchase right held by us. Twenty-five percent of the shares will vest and be released from our right of repurchase on the first anniversary of Dr. Seely's commencement of employment, and the balance will vest in a series of 12 quarterly installments, subject to Dr. Seely's continuous employment with Myovant Sciences, Inc. through each applicable vesting date. The principal business address of Dr. Seely is c/o Myovant Sciences, Inc., 320 West 37th Street, 5th Floor, New York, NewYork 10018.
- (4) Dr. Manchester is a director of Roivant Sciences Ltd., but does not have voting and dispositive power over the shares held of record by Roivant Sciences Ltd., as further described in footnote (1).
- (5) Mr. Ramaswamy is a director of Roivant Sciences Ltd., but does not have voting and dispositive power over the shares held of record by Roivant Sciences Ltd., as further described in footnote (1).

DESCRIPTION OF SHARE CAPITAL

The following description of our share capital and provisions of our memorandum of association and amended and restated bye-laws are summaries. You should also refer to the memorandum of association and the amended and restated bye-laws, which are filed as exhibits to the registration statement of which this prospectus is part.

General

We are an exempted company incorporated under the laws of Bermuda. We are registered with the Registrar of Companies in Bermuda under registration number 51163. We were incorporated on February 2, 2016 under the name Roivant Endocrinology Ltd. We changed our name to Myovant Sciences Ltd. in May 2016. Our registered office is located at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda, and we also have business operations at Park Place, 55 Par-La-Ville Road, 2nd Floor, Hamilton HM11, Bermuda.

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.

Prior to the closing of this offering, our shareholders will approve certain amendments to our bye-laws that will become effective upon the closing of this offering. The following description assumes that such amendments have become effective.

Since our incorporation, other than a subdivision of our authorized and issued share capital, there have been no material changes to our share capital, mergers, amalgamations or consolidations of us or any of our subsidiaries, no material changes in the mode of conducting our business, no material changes in the types of products produced or services rendered. There have been no bankruptcy, receivership or similar proceedings with respect to us or our subsidiaries.

There have been no public takeover offers by third parties for our shares nor any public takeover offers by us for the shares of another company that have occurred during the last or current financial years.

Initial settlement of our common shares will take place on the closing date of this offering through The Depository Trust Company, or DTC, in accordance with its customary settlement procedures for equity securities registered through DTC's book-entry transfer system. Each person beneficially owning common shares registered through DTC must rely on the procedures thereof and on institutions that have accounts therewith to exercise any rights of a holder of the common shares.

Share Capital

Immediately following the closing of this offering, our authorized share capital will consist of 564,111,242 common shares, \$0.000017727 par value per common share. As of June 30, 2016, we had 43,590,411 common shares issued and outstanding. All of our issued and outstanding common shares prior to the closing of this offering are fully paid. Pursuant to our amended and restated bye-laws, subject to the requirements of 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. There are no limitations on the right of non-Bermudians or non-residents of Bermuda to hold or vote our shares provided our common shares remain listed on an appointed stock exchange, which includes 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,

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

Under our amended and restated bye-laws, any U.S. person, other than any excluded person, as described below, whose controlled shares, as defined below, would constitute 9.5% or more of the total voting power of our issued share capital, would have their aggregate votes reduced by our board of directors to the extent necessary such that the controlled shares of such U.S. person will constitute less than 9.5% of the voting power of all issued and outstanding shares. These reductions will be made on an automatic basis pursuant to the procedures set forth in our amended and restated bye-laws, and are intended to reduce the risk of us becoming a CFC for U.S. federal income tax purposes as a result of more than 50% of the voting power or value of our issued and outstanding shares being owned, directly or indirectly by a United States person that possesses, directly or indirectly, 10% or more of the total voting power of our issued share capital. Under these provisions, certain shareholders may have their voting rights reduced to less than one vote per share, while other shareholders may have voting rights in excess of one vote per share. Any person, including any U.S. person, whose controlled shares constitute 9.5% or more of the total voting power of our issued share capital immediately prior to the closing of this offering, will be exempt from the foregoing voting restrictions. As a result, we expect that Roivant Sciences Ltd. directly, indirectly or constructively owned by any person, as determined pursuant to Sections 957 and 958 of the Code and the Treasury Regulations promulgated thereunder. Further, our board of directors may determine that shares shall carry different voting rights as it reasonably determines, based on the advice of counsel, to be appropriate to avoid the existence of a U.S. person whose controlled shares constitute 9.5% or more of the total voting power of our issued share capital.

In addition, under our amended and restated bye-laws, shares shall not carry voting rights to the extent that our board of directors reasonably determines, based on the advice of counsel, that it is necessary to do so to avoid adverse tax, legal or regulatory consequences to us, any of our subsidiaries or any direct or indirect holder of our common shares or its affiliates, provided that our board of directors will use reasonable efforts to afford equal treatment to similarly situated shareholders to the extent possible under the circumstances. Other than as set forth in our amended and restated bye-laws, shareholder voting rights may only be altered with the consent of our shareholders as set forth under "—Variation of Rights" below.

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

Preference Shares

Pursuant to Bermuda law and our amended and restated bye-laws, our board of directors may, by resolution, establish one or more series of preference shares having such number of shares, designations, dividend rates, relative voting rights, conversion or exchange rights, redemption rights, liquidation rights, 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.

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. We do not anticipate paying cash dividends in the foreseeable future.

Variation of Rights

If at any time we have more than one class of shares, the rights attaching to any class, unless otherwise provided for by the terms of issue of the relevant class, may be varied either: (1) with the consent in writing of the holders of 75% of the issued shares of that class; or (2) with the sanction of a resolution passed by a 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 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 be deemed to vary the rights attached to common shares or, subject to the terms of any other class or series of preference shares, to vary the rights attached to any other class or series of preference shares.

Transfer of Shares

Our board of directors may, in its absolute discretion and without assigning any reason, refuse to register the transfer of a share on the basis that it is not fully paid. Our board of directors may also refuse to recognize an instrument of transfer of a share unless it is accompanied by the relevant share certificate and such other evidence of the transferor's right to make the transfer as our board of directors shall reasonably require 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 certain tax, regulatory or legal consequences for us, any subsidiary of ours, holders of our common shares or their affiliates 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 byelaws (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.

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 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, 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 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 all issued and outstanding common shares.

Access to Books and Records and Dissemination of Information

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

Election and Removal of Directors

Our amended and restated bye-laws will provide that our board of directors shall consist of such number of directors as the board of directors may determine. Upon the closing of this offering, our board of directors will consist of six directors. Our board of directors will be divided into three classes that are, as nearly as possible, of equal size. Each class of directors will be elected for a three-year term of office, but the terms will be staggered so that the term of only one class of directors expires at each annual general meeting. The initial terms of the Class I, Class II and Class III directors will expire in 2017, 2018 and 2019, respectively. At each succeeding annual general meeting, successors to the class of directors whose term expires at the annual general meeting will be elected for a three-year term.

A shareholder holding any percentage of the common shares in issue may propose for election as a director someone who is not an existing director or is not proposed by our board of directors. Where a director is to be elected at an annual general meeting, notice of any such proposal for election must be given not less than 90 days nor more than 120 days before the anniversary of the last annual general meeting prior to the giving of the notice or, in the event the annual general meeting is called for a date that is not less than 30 days before or after such anniversary the notice must be given not later than ten days following the earlier of the date on which notice of the annual general meeting; provided, that our board of directors has determined that shareholders may nominate persons for election at such special general meeting, that notice must be given not later than seven days following the earlier of the date on which notice of the special general meeting, that notice must be given not later than seven days following the earlier of the date on which notice of the special general meeting, that notice must be given not later than seven days following the earlier of the date on which notice of the special general meeting, that notice must be given not later than seven days following the earlier of the date on which notice of the special general meeting was 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 a summary of the facts justifying the removal and must be served on the director not less than 14 days before the meeting. The director is entitled to attend the meeting and be heard on the motion for his removal.

Proceedings of Board of Directors

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

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

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

Indemnification of Directors and Officers

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

Our amended and restated bye-laws provide that we shall indemnify our officers and directors in respect of their actions and omissions, except in respect of their fraud or dishonesty, and that we shall advance funds to our officers and directors for expenses incurred in their defense upon receipt of an undertaking to repay the funds if any allegation of fraud or dishonesty is proved. Our amended and restated bye-laws provide that the shareholders waive all claims or rights of action that they might have, individually or in right of the company, against any of the company's directors or officers for any act or failure to act in the performance of such director's or officer's duties, except in respect of any fraud or dishonesty of such director or officer. Section 98A of the Companies Act permits us to purchase and maintain insurance for the benefit of any officer or director in respect of any loss or liability attaching to him in respect of any negligence, default, breach of duty or breach of trust, whether or not we may otherwise indemnify such officer or director. We have purchased and maintain a directors' 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. Bye-laws relating to election of directors, classes of directors, term of office of directors, removal of directors, business combinations and changes to the bye-laws shall not be rescinded, altered or amended without a resolution of our board of directors including the affirmative vote of $66 \frac{2}{3}$ % of the directors then in office and a resolution of our shareholders including the affirmative vote of $66 \frac{2}{3}$ % of all votes entitled to be cast on the resolution.

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 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, and the quorum for such meeting shall be two or more persons holding or representing more than 50% of the issued voting shares.

Under Bermuda law, in the event of an amalgamation or merger of a Bermuda company with another company or corporation, a shareholder of the Bermuda company who did not vote in favor of the amalgamation or merger and who is not satisfied that fair value has been offered for such shareholder's shares may, within one month of notice of the shareholders meeting, apply to the Supreme Court of Bermuda to appraise the fair value of those shares.

Business Combinations

Although the Companies Act does not contain specific provisions regarding "business combinations" between companies organized under the laws of Bermuda and "interested shareholders," we have included these provisions in our bye-laws. Specifically, our bye-laws contain provisions which prohibit us from engaging in a business combination with an interested shareholder for a period of three years after the date of the transaction in which the person became an interested shareholder, unless, in addition to any other approval that may be required by applicable law:

- prior to the date of the transaction that resulted in the shareholder becoming an interested shareholder, our board of directors approved either the business combination or the transaction that resulted in the shareholder becoming an interested shareholder;
- upon consummation of the transaction that resulted in the shareholder becoming an interested shareholder, the interested shareholder owned at least 85% of our issued and voting shares outstanding at the time the transaction commenced; or
- after the date of the transaction that resulted in the shareholder becoming an interested shareholder, the business combination is approved by our board
 of directors and authorized at an annual or special meeting of shareholders by the affirmative vote of at least 66²/3% 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 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 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 all of the common shares that are the subject of this offering to and between residents and non-residents of Bermuda for exchange control purposes, provided our shares remain listed on an appointed stock exchange, which includes 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.

Takeda Warrant

In April 2016, we issued a warrant to purchase an indeterminate number of our capital shares to Takeda. This warrant entitles Takeda to purchase, at any time, following our issuance of any class of capital shares, that number of capital shares of such class that would allow Takeda, together with its affiliates, to maintain 12% ownership of us, as determined after such exercise. See "Certain Relationships and Related Party Transactions—Relationship with Takeda Pharmaceuticals International AG—Warrant" for a further description of the terms of this warrant.

Registration Rights

In April 2016, we entered into an investor rights agreement with Takeda and Roivant Sciences Ltd. which provides these shareholders with certain registration rights. The registration of our common shares pursuant to the exercise of registration rights described below would enable these shareholders to sell these common shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses, other than underwriting discounts, selling commissions and transfer taxes, of the shares registered pursuant to the piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specific conditions, to limit the number of shares such holders may include. The piggyback and Form S-3 registration rights described below will expire upon the earlier of (1) five years after the effective date of the registration statement, of which this prospectus forms a part, (2) at such time as a shareholder can sell all of its shares under Rule 144 of the Securities Act during any three month period or (3) in the event of a change of control or liquidation of our company.

Piggyback Registration Rights

In connection with this offering, Takeda and Roivant Sciences Ltd., were entitled to, and have waived, their right to include their common shares in this offering. If we propose to register the offer and sale of any of our securities under the Securities Act either for our own account or for the account of other security holders, the holders of these common shares will be entitled to certain "piggyback" registration rights allowing them to include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act including a registration statement on Form S-3 as discussed below, other than with respect to a registration statement relating to the sale of securities to employees pursuant to an equity incentive plan, relating to an SEC Rule 145 transaction or where the registration statement would not include substantially the same information required to offer such securities, these shareholders are entitled to notice of the registration and have the right, subject to limitations that the underwriters may impose on the number of common shares included in the registration, to include their common shares in the registration.

Form S-3 Registration Rights

Takeda and Roivant Sciences Ltd. are entitled to certain Form S-3 registration rights. These shareholders may request that we register their common shares on Form S-3 if we are qualified to file a registration statement on Form S-3. Such request for registration on Form S-3 must cover securities the aggregate offering price of which, before payment of underwriting discounts, commissions and transfer taxes, is at least \$5 million.

Transfer Agent and Registrar

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

Listing

Our common shares have been authorized for listing on the NYSE under the trading symbol "MYOV."

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, no public market existed for our common shares. Future sales of our common shares in the public market after this offering, or the perception that these sales could occur, could adversely affect prevailing market prices for our common shares and could impair our future ability to raise equity capital.

Based on the number of common shares outstanding as of June 30, 2016, upon the closing of this offering and assuming no exercise by the underwriters of their option to purchase additional common shares, 58,523,408 common shares will be outstanding. All of the common shares sold in this offering will be freely tradable without restrictions or further registration under the Securities Act of 1933, as amended, or the Securities Act, except for any shares sold to our affiliates, as defined in Rule 144 under the Securities Act. The remaining 45,523,408 common shares held by existing shareholders, including the 160,273 common shares issued to Takeda in August and September 2016 and the 1,772,724 common shares to be issued to Takeda upon the closing of this offering pursuant to the automatic exercise of the warrant we issued to Takeda, are restricted securities, as that term is defined in Rule 144 under the Securities Act. Restricted securities may be sold in the public market only if registered or if their resale qualifies for exemption from registration described below under Rule 144 promulgated under the Securities Act.

As a result of contractual restrictions described below and the provisions of Rules 144 and 701, the common shares sold in this offering and the restricted securities will be available for sale in the public market as follows:

- all the common shares sold in this offering will be eligible for immediate sale upon the closing of this offering; and
- 45,523,408 common shares will be eligible for sale in the public market upon expiration of lock-up agreements 180 days after the date of this prospectus, subject in certain circumstances to the volume, manner of sale and other limitations under Rule 144 and Rule 701.

Rule 144

In general, persons who have beneficially owned our common shares for at least six months, and any affiliate of the company who owns our common shares, are entitled to sell their securities without registration with the SEC under an exemption from registration provided by Rule 144 under the Securities Act.

Non-Affiliates

Any person who is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale may sell an unlimited number of common shares under Rule 144 if:

- the common shares have been held for at least six months, including the holding period of any prior owner other than one of our affiliates;
- we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale; and
- we are current in our Exchange Act reporting at the time of sale.

Any person who is not deemed to have been an affiliate of ours at the time of, or at any time during the three months preceding, a sale and has held the common shares for at least one year, including the holding period of any prior owner other than one of our affiliates, will be entitled to sell an unlimited number of common shares without regard to the length of time we have been subject to Exchange Act periodic reporting or whether we are current in our Exchange Act reporting.

Affiliates

Persons seeking to sell restricted securities who are our affiliates at the time of, or any time during the three months preceding, a sale, would be subject to the restrictions described above. They are also subject to additional

restrictions, by which such person would be required to comply with the manner of sale and notice provisions of Rule 144 and would be entitled to sell within any three-month period only that number of securities that does not exceed the greater of either of the following:

- 1% of the number of our common shares then outstanding, which will equal approximately 585,234 shares immediately after the closing of this offering based on the number of shares outstanding as of June 30, 2016; or
- the average weekly trading volume of our common shares on the NYSE during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Additionally, persons who are our affiliates at the time of, or any time during the three months preceding, a sale may sell unrestricted securities under the requirements of Rule 144 described above, without regard to the six-month holding period of Rule 144, which does not apply to sales of unrestricted securities.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Our employees, executive officers or directors who purchase shares under a written compensatory plan or contract will be entitled to rely on the resale provisions of Rule 701, but any holders of Rule 701 shares will be required to wait until 90 days after the date of this prospectus before selling their shares. However, all our Rule 701 shares are subject to lock-up agreements as described below and in the section titled "Underwriting" and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Form S-8 Registration Statements

As soon as practicable after the closing of this offering, we intend to file with the SEC one or more registration statements on Form S-8 under the Securities Act to register the our common shares that are issuable pursuant to our 2016 Plan. These registration statements will become effective immediately upon filing. Shares covered by these registration statements will then be eligible for sale in the public markets, subject to vesting restrictions, any applicable lock-up agreements described below and Rule 144 limitations applicable to affiliates.

Lock-Up Agreements

We and the holders of all of our common shares outstanding on the date of this prospectus, including each of our executive officers, directors and option holders have entered into lock-up agreements with the underwriters or otherwise agreed, subject to certain exceptions, that we and they will not, directly or indirectly, offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale, or otherwise dispose of or hedge any of our common shares, any options or warrants to purchase our common shares, or any securities convertible into, or exchangeable for or that represent the right to receive our common shares, without the prior written consent of Citigroup Global Markets Inc. for a period of 180 days from the date of this prospectus.

BERMUDA COMPANY CONSIDERATIONS

Our corporate affairs are governed by our memorandum of association and bye-laws and by the corporate law of Bermuda. The provisions of the Companies Act, which applies to us, differ in certain material respects from laws generally applicable to U.S. companies incorporated in the State of Delaware and their stockholders. The following is a summary of significant differences between the Companies Act (including modifications adopted pursuant to our bye-laws) and Bermuda common law applicable to us and our shareholders and the provisions of the Delaware General Corporation Law applicable to U.S. companies organized under the laws of Delaware and their stockholders.

Shareholder Meetings

• May be called by the board of directors and must be called upon the request of shareholders holding not less than 10% of the paid-up capital of the company carrying the right to vote at general meetings.

Bermuda

- May be held in or outside Bermuda.
- Notice:
- Shareholders must be given at least five days' advance notice of a general meeting, but the unintentional failure to give notice to any person does not invalidate the proceedings at a meeting.
- Notice of general meetings must specify the place, the day and hour of the meeting and in the case of special general meetings, the general nature of the business to be considered.
- Our bye-laws provide that at least 14 days' notice of an annual general meeting and 10 days' notice of a special general meeting must be given to each shareholder entitled to vote at such meeting.

Shareholders' Voting Rights

- Shareholders may act by written consent to elect directors. Shareholders may not act by written consent to remove a director or auditor.
- Generally, except as otherwise provided in the bye-laws, or the Companies Act, any action or resolution requiring approval of the shareholders may be passed by a simple majority of votes cast. Any person authorized to vote may authorize another person or persons to act for him or her by proxy.
- The voting rights of shareholders are regulated by a company's bye-laws and, in certain circumstances, by the Companies Act. The bye-laws may specify the number to constitute a quorum and if the bye-laws permit, a general meeting of the shareholders of a company may be held with only one individual present if the requirement for a quorum is satisfied.

• May be held at such time or place as designated in the certificate of incorporation or the bylaws, or if not so designated, as determined by the board of directors.

Delaware

- May be held in or outside of Delaware.
- Notice:
 - Written notice shall be given not less than ten nor more than 60 days before the meeting.
 - Whenever stockholders are required to take any action at a meeting, a written notice of the meeting shall be given which shall state the place, if any, date and hour of the meeting, and the means of remote communication, if any.
- With limited exceptions, stockholders may act by written consent to elect directors unless prohibited by the certificate of incorporation.
- Any person authorized to vote may authorize another person or persons to act for him or her by proxy.
- For stock corporations, the certificate of incorporation or bylaws may specify the number to constitute a quorum, but in no event shall a quorum consist of less than one-third of shares entitled to vote at a meeting. In the absence of such specifications, a majority of shares entitled to vote shall constitute a quorum.

Bermuda

Subject to the rules of the NYSE, our bye-laws provide that 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 all issued and outstanding common shares.

- Our bye-laws provide that, in the event that any U.S. person holds, directly, indirectly or constructively, 9.5% or more of the total voting power of our issued share capital, excluding any U.S. person that holds, directly, indirectly or constructively, 9.5% or more of the total voting power of issued share capital immediately prior to the closing of this offering, the aggregate votes conferred by the common shares held by such person (or by any person through which such U.S. person indirectly or constructively holds shares) will be reduced by our board of directors to the extent necessary such that the common shares held, directly, indirectly or constructively, by such U.S. person will constitute less than 9.5% of the voting power of all issued and outstanding shares. Our byelaws further provide that, our board of directors may determine that shares shall carry different or no voting rights as it reasonably determines, based on the advice of counsel, to be appropriate to (1) avoid the existence of any U.S. person who holds 9.5% or more of the total voting power of our issued share capital or (2) avoid adverse tax, legal or regulatory consequences to us, any subsidiary of ours or any holder of our common shares or its affiliates.
- Our bye-laws provide that when a quorum is once present in general meeting it is not broken by the subsequent withdrawal of any shareholders.
- The bye-laws may provide for cumulative voting, although our bye-laws do not.
- The amalgamation or merger of a Bermuda company with another company or corporation (other than certain affiliated companies) requires the amalgamation or merger agreement to be approved by the company's board of directors and by its shareholders. Unless the company's bye-laws provide otherwise, the approval of 75% of the shareholders voting at such meeting is required to approve the amalgamation or merger agreement, and the quorum for such meeting must be two or more persons holding or representing more than one-third of the issued shares of the company.

Delaware

- When a quorum is once present to organize a meeting, it is not broken by the subsequent withdrawal of any stockholders.
- The certificate of incorporation may provide for cumulative voting.
- Any two or more corporations existing under the laws of the state may merge into a single corporation pursuant to a board resolution and upon the majority vote by stockholders of each constituent corporation at an annual or special meeting.

Bermuda

- Every company may at any meeting of its board of directors sell, lease or exchange all or substantially all of its property and assets as its board of directors deems expedient and in the best interests of the company to do so when authorized by a resolution adopted by the holders of a majority of issued and outstanding shares of a company entitled to vote.
- Any company that is the wholly owned subsidiary of a holding company, or one or more companies which are wholly owned subsidiaries of the same holding company, may amalgamate or merge without the vote or consent of shareholders provided that the approval of the board of directors is obtained and that a director or officer of each such company signs a statutory solvency declaration in respect of the relevant company.
- Any mortgage, charge or pledge of a company's property and assets may be authorized without the consent of shareholders subject to any restrictions under the bye-laws.

Directors

- The board of directors must consist of at least one director.
- The number of directors is fixed by the bye-laws, and any changes to such number must be approved by the board of directors and/or the shareholders in accordance with the company's bye-laws.
- Removal:
- Under our bye-laws, any or all directors may be removed only with cause by the holders of a majority of the shares entitled to vote at a special meeting convened and held in accordance with the bye-laws for the purpose of such removal.

- Every corporation may at any meeting of the board sell, lease or exchange all or substantially all of its property and assets as its board deems expedient and for the best interests of the corporation when so authorized by a resolution adopted by the holders of a majority of the outstanding stock of a corporation entitled to vote.
- Any corporation owning at least 90% of the outstanding shares of each class of another corporation may merge the other corporation into itself and assume all of its obligations without the vote or consent of stockholders; however, in case the parent corporation is not the surviving corporation, the proposed merger shall be approved by a majority of the outstanding stock of the parent corporation entitled to vote at a duly called stockholder meeting.
- Any mortgage or pledge of a corporation's property and assets may be authorized without the vote or consent of stockholders, except to the extent that the certificate of incorporation otherwise provides.
- The board of directors must consist of at least one member.
- Number of board members shall be fixed by the bylaws, unless the certificate of incorporation fixes the number of directors, in which case a change in the number shall be made only by amendment of the certificate of incorporation.
- Removal:
 - Any or all of the directors may be removed, with or without cause, by the holders of a majority of the shares entitled to vote unless the certificate of incorporation otherwise provides.
 - In the case of a classified board, stockholders may effect removal of any or all directors only for cause.

Duties of Directors

Bermuda

- The Companies Act authorizes the directors of a company, subject to its byelaws, to exercise all powers of the company except those that are required by the Companies Act or the company's bye-laws to be exercised by the shareholders of the company. Our bye-laws provide that our business is to be managed and conducted by our Board of Directors. At common law, members of a board of directors owe a fiduciary duty to the company to act in good faith in their dealings with or on behalf of the company and exercise their powers and fulfill the duties of their office honestly. This duty includes the following essential elements:
- a duty to act in good faith in the best interests of the company;
- a duty not to make a personal profit from opportunities that arise from the office of director;
- a duty to avoid conflicts of interest; and
- a duty to exercise powers for the purpose for which such powers were intended.
- The Companies Act imposes a duty on directors and officers of a Bermuda company:
- to act honestly and in good faith with a view to the best interests of the company; and
- to exercise the care, diligence and skill that a reasonably prudent person would exercise in comparable circumstances.
- The Companies Act also imposes various duties on directors and officers of a company with respect to certain matters of management and administration of the company. Under Bermuda law, directors and officers generally owe fiduciary duties to the company itself, not to the company's individual shareholders, creditors or any class thereof. Our shareholders may not have a direct cause of action against our directors.

- Under Delaware law, the business and affairs of a corporation are managed by or under the direction of its board of directors. In exercising their powers, directors are charged with a fiduciary duty of care to protect the interests of the corporation and a fiduciary duty of loyalty to act in the best interests of its stockholders. The duty of care requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of, and disclose to stockholders, all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director act in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. This duty prohibits self-dealing by a director and mandates that the best interest of the corporation and its stockholders take precedence over any interest possessed by a director, officer or controlling shareholder and not shared by the stockholders generally.
- In general, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Should such evidence be presented concerning a transaction by a director, a director must prove the procedural fairness of the transaction, and that the transaction was of fair value to the corporation.

Takeovers

Bermuda

- An acquiring party is generally able to acquire compulsorily the common shares of minority holders of a company in the following ways:
- By a procedure under the Companies Act known as a "scheme of arrangement." A scheme of arrangement could be effected by obtaining the agreement of the company and of holders of common shares, representing in the aggregate a majority in number and at least 75% in value of the common shareholders present and voting at a court ordered meeting held to consider the scheme of arrangement. The scheme of arrangement must then be sanctioned by the Bermuda Supreme Court. If a scheme of arrangement receives all necessary agreements and sanctions, upon the filing of the court order with the Registrar of Companies in Bermuda, all holders of common shares could be compelled to sell their shares under the terms of the scheme of arrangement.
- By acquiring pursuant to a tender offer 90% of the shares or class of shares not already owned by, or by a nominee for, the acquiring party (the offeror), or any of its subsidiaries. If an offeror has, within four months after the making of an offer for all the shares or class of shares not owned by, or by a nominee for, the offeror, or any of its subsidiaries, obtained the approval of the holders of 90% or more of all the shares to which the offer relates, the offeror may, at any time within two months beginning with the date on which the approval was obtained, by notice compulsorily acquire the shares of any nontendering shareholder on the same terms as the original offer unless the Supreme Court of Bermuda (on application made within a one-month period from the date of the offeror's notice of its intention to acquire such shares) orders otherwise.
- Where the acquiring party or parties hold not less than 95% of the shares or a class of shares of the company, by acquiring, pursuant to a notice given to the remaining shareholders or class of shareholders, the shares of such remaining shareholders or class of shareholders. When this notice is given, the acquiring party is entitled and bound to acquire the shares of the remaining shareholders on the terms set out in the notice, unless a remaining shareholder, within one month of receiving such notice, applies to the Supreme Court of Bermuda for an appraisal of the value of their shares. This provision only applies where the acquiring party offers the same terms to all holders of shares whose shares are being acquired.

- Delaware law provides that a parent corporation, by resolution of its board of directors and without any stockholder vote, may merge with any subsidiary of which it owns at least 90% of each class of its capital stock. Upon any such merger, and in the event the parent corporate does not own all of the stock of the subsidiary, dissenting stockholders of the subsidiary are entitled to certain appraisal rights.
- Delaware law also provides, subject to certain exceptions, that if a person acquires 15% of voting stock of a company, the person is an "interested stockholder" and may not engage in "business combinations" with the company for a period of three years from the time the person acquired 15% or more of voting stock.

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Delaware

Bermuda

Dissenter's Rights of Appraisal

• A dissenting shareholder (that did not vote in favor of the amalgamation or merger) of a Bermuda exempted company is entitled to be paid the fair value of his or her shares in an amalgamation or merger.

Dissolution

• Under Bermuda law, a solvent company may be wound up by way of a shareholders' voluntary liquidation. Prior to the company entering liquidation, a majority of the directors shall each make a statutory declaration, which states that the directors have made a full enquiry into the affairs of the company and have formed the opinion that the company will be able to pay its debts within a period of 12 months of the commencement of the winding up and must file the statutory declaration with the Registrar of Companies in Bermuda. The general meeting will be convened primarily for the purposes of passing a resolution that the company be wound up voluntarily and appointing a liquidator. The winding up of the company is deemed to commence at the time of the passing of the resolution.

Shareholders' Derivative Actions

 Class actions and derivative actions are generally not available to shareholders under Bermuda law. Bermuda courts, however, would ordinarily be expected to permit a shareholder to commence an action in the name of a company to remedy a wrong to the company where the act complained of is alleged to be beyond the corporate power of the company or illegal, or would result in the violation of the company's memorandum of association or bye-laws.
 Furthermore, consideration would be given by a Bermuda court to acts that are alleged to constitute a fraud against the minority shareholders or, for instance, where an act requires the approval of a greater percentage of the company's shareholders than that which actually approved it.

- With limited exceptions, appraisal rights shall be available for the shares of any class or series of stock of a corporation in a merger or consolidation.
- The certificate of incorporation may provide that appraisal rights are available for shares as a result of an amendment to the certificate of incorporation, any merger or consolidation or the sale of all or substantially all of the assets.
- Under Delaware law, a corporation may voluntarily dissolve (1) if a majority of the board of directors adopts a resolution to that effect and the holders of a majority of the issued and outstanding shares entitled to vote thereon vote for such dissolution; or (2) if all stockholders entitled to vote thereon consent in writing to such dissolution.

• In any derivative suit instituted by a stockholder of a corporation, it shall be averred in the complaint that the plaintiff was a stockholder of the corporation at the time of the transaction of which he complains or that such stockholder's stock thereafter devolved upon such stockholder by operation of law.

MATERIAL BERMUDA AND U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a discussion of the material Bermuda and U.S. federal income tax considerations that may be relevant to an investment decision by a potential investor with respect to our common shares.

Bermuda Tax Considerations

At the present time, there is no Bermuda withholding tax, capital gains tax, capital transfer tax, estate duty or inheritance tax payable by our shareholders in respect of our common shares. We have obtained an assurance from the Minister of Finance of Bermuda under the Exempted Undertakings Tax Protection Act 1966 that, in the event that any legislation is enacted in Bermuda imposing any tax computed on 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 our common shares, except insofar as such tax applies to persons ordinarily resident in Bermuda.

U.S. Federal Income Tax Considerations

The following are the material U.S. federal income tax consequences to U.S. Holders (as defined below) of owning and disposing of common shares acquired in this offering. This discussion does not address any aspects of U.S. taxation other than U.S. federal income taxation, does not address any U.S. state, local or non-U.S. tax considerations, and does not purport to be a comprehensive description of all tax considerations that may be relevant to a particular person's decision to acquire common shares. This discussion applies only to U.S. Holders that hold their common shares as capital assets for U.S. federal income tax purposes. In addition, it does not describe all of the tax consequences that may be relevant in light of a U.S. Holder's particular circumstances including alternative minimum, gift, and estate tax consequences, and does not address the tax consequences applicable to U.S. Holders subject to special rules, such as:

- a holder of common shares who actually or constructively owns or is deemed to own 10% or more of the total combined voting power of all classes of our shares entitled to vote;
- a U.S. Holder who is also resident or ordinarily resident in Bermuda for Bermuda tax purposes or who is otherwise subject to Bermuda income tax or capital gains tax with respect to our common shares;
- a bank or other financial institution;
- an insurance company;
- a dealer or trader in securities who uses a mark-to-market method of tax accounting;
- a person holding common shares as part of a hedging transaction, straddle, wash sale, conversion transaction or integrated transaction or a person entering into a constructive sale with respect to common shares;
- a U.S. Holder whose functional currency for U.S. federal income tax purposes is not the U.S. dollar;
- an entity classified as a partnership or other pass-through entity for U.S. federal income tax purposes, including persons that will hold our common shares through such an entity;
- a tax-exempt entity, including an "individual retirement account" or "Roth IRA" or retirement plan;
- a U.S. expatriate;
- a real estate investment trust;
- a regulated investment company;
- · a person who acquired our common shares pursuant to the exercise of an employee stock option or otherwise as compensation; or
- a person holding our common shares in connection with a trade or business conducted outside of the United States.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds common shares, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding common shares and partners in such partnerships should consult their tax advisers as to the particular U.S. federal income tax consequences of owning and disposing of common shares.

This discussion is based on the Code, administrative pronouncements, judicial decisions and final, temporary and proposed U.S. Treasury regulations all as of the date hereof, any of which is subject to change, possibly with retroactive effect, and to differing interpretations, all of which could affect the tax considerations described below. There can be no assurances that the Internal Revenue Service, or IRS, will not take a different position concerning the tax consequences of the acquisition, ownership and disposition of the common shares or that such a position would not be sustained.

A "U.S. Holder" is a beneficial owner of common shares that for U.S. federal income tax purposes is:

- an individual citizen or individual resident of the United States;
- a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States or any political subdivision thereof; or
- a trust, if a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the ability to
 control all of the substantial decisions of such trust, or if such trust has a valid election in effect to be treated as a United States person; or
- an estate the income of which is subject to U.S. federal income taxation regardless of its source.

U.S. Holders should consult their tax advisers concerning the U.S. federal, state, local and foreign tax consequences of owning and disposing of common shares in their particular circumstances.

Subject to the discussion below under "Passive Foreign Investment Company Rules," this discussion assumes that we are a foreign corporation that is not, and will not become, a passive foreign investment company, or PFIC, as described below.

Taxation of Distributions

Although we do not currently plan to pay dividends, any future distributions paid on common shares (including the amount of any foreign taxes withheld therefrom) will be treated as taxable dividends to a U.S. Holder to the extent of such U.S. Holder's pro rata share of our current and/or accumulated earnings and profits (as determined under U.S. federal income tax principles). To the extent that a distribution paid to a U.S. Holder with respect to our common shares exceeds such U.S. Holder's pro rata share of our current and accumulated earnings and profits, it will be treated as a non-taxable return of capital to the extent of the U.S. Holder's basis in the common shares (determined on a share-by-share basis), will reduce (but not below zero) such basis, and thereafter generally will be treated as a capital gain. See "—Sale or Other Taxable Disposition of Common Shares" below. We may not maintain calculations of our earnings and profits under U.S. federal income tax principles. Accordingly, distributions, if any, generally will be reported to U.S. Holders as dividends.

Dividends received by a non-corporate U.S. Holder are eligible to be taxed at reduced rates, if we are a "qualified foreign corporation" and certain other applicable requirements, including holding period requirements, are met. The reduced rate applicable to dividends paid to non-corporate U.S. Holders is not available for dividends paid by a PFIC (described below) or in certain other situations, including if we are not a qualified foreign corporation. A non-United States corporation (other than a corporation that is classified as a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation (a) if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of this provision and which includes an exchange of information provision, or (b) with respect to any dividend it pays on common shares which are readily tradable on an established securities market in the United States. The common

shares are expected to be listed on the NYSE, which is an established securities market in the United States, and we expect the common shares to be readily tradable on the NYSE. However, there can be no assurance that the common shares will be considered readily tradable on an established securities market in the United States in later years. Subject to the discussion under "Passive Foreign Investment Company Rules," below, such dividends will generally be "qualified dividend income" (which is taxed at a reduced rate) in the hands of non-corporate U.S. Holders, including individuals, provided that the holding period requirement and certain other requirements are met. Dividends received by a corporate U.S. Holder will not be eligible for the dividends-received deduction generally available to U.S. corporate shareholders under the Code for dividends received from certain U.S. and non-U.S. corporations.

For foreign tax credit limitation purposes, distributions paid on the common shares that are treated as dividends will be treated as income from sources outside the United States and will generally constitute passive category income.

Sale or Other Taxable Disposition of Common Shares

For U.S. federal income tax purposes, gain or loss recognized on the sale or other taxable disposition of common shares generally will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the shares for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder's adjusted tax basis in the common shares disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. Long-term capital gains recognized by non-corporate U.S. Holders are taxable at reduced rates. There are limitations on the deductibility of capital losses. Any such capital gain or loss will generally be U.S.-source gain or loss for foreign tax credit limitation purposes.

If the consideration received for the common shares is paid in foreign currency, the amount realized will be the U.S. dollar value of the payment received translated at the spot rate of exchange on the date of disposition. A U.S. Holder may realize additional gain or loss upon the subsequent sale or disposition of such currency, which will generally be treated as U.S. source ordinary income or loss. If the common shares are treated as traded on an established securities market and the relevant holder is either a cash basis taxpayer or an accrual basis taxpayer who has made a special election (which must be applied consistently from year to year and cannot be changed without the consent of the IRS), such holder will determine the U.S. dollar value of the amount realized in a foreign currency by translating the amount received at the spot rate of exchange on the settlement date of the disposition. If the common shares are not treated as traded on an established securities market, or the relevant U.S. Holder is an accrual basis taxpayer that is not eligible to or does not elect to determine the amount realized using the spot rate on the settlement date, such U.S. Holder will recognize foreign currency gain or loss to the extent of any difference between the U.S. dollar amount realized on the date of disposition (as determined above) and the U.S. dollar value of the currency received at the spot rate on the settlement date. Any such foreign currency gain or loss will generally be U.S. source ordinary income or loss.

Passive Foreign Investment Company Rules

In general, a corporation organized outside the United States will be a PFIC in any taxable year in which either (1) at least 75% of its gross income is "passive income" or (2) on average at least 50% of the value of its assets is attributable to assets that produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, dividends, interest, royalties, rents, and gains from commodities transactions and from the sale or exchange of property that gives rise to passive income. Assets that produce or are held for the production of passive include cash, even if held as working capital or raised in a public offering, marketable securities and other assets that may produce passive income. The average value of a corporation's assets for this purpose, in the case of a corporation whose shares are publicly traded for the taxable year, generally is the average of their fair market value at the end of each quarter. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

We believe that we were not a CFC prior to this offering in the current taxable year which will end on March 31, 2017. Based on this belief, we do not believe we were a PFIC in the taxable year that ended March 31, 2016 and based on the nature of our business, the projected composition of our income and the projected composition and estimated fair market values of our assets, we do not expect to be a PFIC in the taxable year commencing April 1, 2016. However, there can be no assurances in this regard, or that the IRS will agree with our conclusion, because we expect to hold following this offering a substantial amount of cash, and the calculation of the value of our assets may be based in part on the value of our shares, which may fluctuate considerably after this offering. In the event that we receive passive income in the future that would cause us to be a PFIC, we would expect to evaluate and may implement alternative structures and arrangements including structures and arrangements intended to mitigate the possibility that we will be classified as a PFIC. The failure or inability to implement such structures or arrangements may have an adverse impact on the determination of whether we are classified as a PFIC. In addition, there can be no assurances regarding our PFIC status in one or more subsequent years to the extent that our activities change, and our United States counsel expresses no opinion with respect to our predictions regarding our PFIC status in the future.

If we are a PFIC in any taxable year during which a U.S. Holder owns our shares, such U.S. Holder could be liable for additional taxes and interest charges upon (1) a distribution paid during a taxable year that is greater than 125% of the average annual distributions paid in the three preceding taxable years, or, if shorter, the U.S. Holder's holding period for the shares, and (2) any gain recognized on a sale, exchange or other taxable disposition, including a pledge, of the shares, whether or not we continue to be a PFIC. In these circumstances, the tax will be determined by allocating such distribution or gain ratably over the U.S. Holder's holding period for the shares. The amount allocated to the current taxable year (i.e., the year in which the distribution occurs or the gain is recognized) and any year prior to the first taxable year in which we are a PFIC will be taxed as ordinary income earned in the current taxable year. The amount allocated to other taxable years will be taxed at the highest marginal rates in effect for individuals or corporations, as applicable, to ordinary income for each such taxable year, and an interest charge, generally applicable to underpayments of tax, will be added to the tax. If we are a PFIC for any year during which a U.S. Holder holds the shares, we must generally continue to be treated as a PFIC by that holder for all succeeding years during which the U.S. Holder holds the shares it holds at their fair market value on the last day of the last taxable year in which we qualified as a PFIC, and any gain from such deemed sale election was made will not be treated as shares in a PFIC unless we subsequently become a PFIC.

If we are a PFIC for any taxable year during which a U.S. Holder holds the shares and one of our non-United States subsidiaries is also a PFIC (i.e., a lower-tier PFIC), such U.S. Holder generally would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC and would be subject to the rules described above on certain distributions by the lower-tier PFIC and a disposition of shares of the lower-tier PFIC even though such U.S. Holder would not receive the proceeds of those distributions or dispositions. Each U.S. Holder is advised to consult its tax advisors regarding the application of the PFIC rules to any of our subsidiaries.

The tax consequences that would apply if we were a PFIC would be different from those described above if a timely and valid "mark-to-market" election is made by a U.S. Holder for the shares held by such U.S. Holder. An electing U.S. Holder generally would take into account as ordinary income each year, the excess of the fair market value of the shares held at the end of the taxable year over the adjusted tax basis of such shares. The U.S. Holder would also take into account, as an ordinary loss each year, the excess of the adjusted tax basis of such shares over their fair market value at the end of the taxable year, but only to the extent of the excess of amounts previously included in income over ordinary losses deducted as a result of the mark-to-market election. The U.S. Holder's tax basis in the shares would be adjusted to reflect any income or loss recognized as a result of the

mark-to-market election. Any gain from a sale, exchange or other taxable disposition of the shares in any taxable year in which we are a PFIC would be treated as ordinary income and any loss from such sale, exchange or other taxable disposition would be treated first as ordinary loss (to the extent of any net mark-to-market gains previously included in income) and thereafter as capital loss. If, after having been a PFIC for a taxable year, we cease to be classified as a PFIC, the U.S. Holder would not be required to take into account any latent gain or loss in the manner described above and any gain or loss recognized on the sale or exchange of the shares would be classified as a capital gain or loss.

A mark-to-market election is available to a U.S. Holder only for "marketable stock." Generally, stock will be considered marketable stock if it is "regularly traded" on a "qualified exchange" within the meaning of applicable U.S. Treasury regulations. A class of stock is regularly traded during any calendar year during which such class of stock is traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. The shares will be marketable stock as long as they remain listed on a qualified exchange, such as the NYSE, and are regularly traded. A mark-to-market election will not apply to the shares for any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC. Such election will not apply to any subsidiary that we own. Accordingly, a U.S. Holder may continue to be subject to the PFIC rules with respect to any lower-tier PFICs notwithstanding the U.S. Holder's mark-to-market election for our shares.

The tax consequences that would apply if we were a PFIC would also be different from those described above if a U.S. Holder were able to make a valid "qualified electing fund," or QEF, election. As we do not expect to provide U.S. Holders with the information required in order to permit a QEF election, prospective investors should assume that a QEF election will not be available.

Each U.S. Holder who is a shareholder of a PFIC must file an annual report containing certain information.

Medicare Tax

In general, a United states person that is an individual or estate, or a trust that does not fall into a special class of trusts that is exempt from such tax, is subject to a 3.8% tax on the lesser of (1) the United States person's "net investment income" for the relevant taxable year and (2) the excess of the United States person's modified adjusted gross income for the taxable year over a certain threshold (which in the case of individuals will be between \$125,000 and \$250,000, depending on the individual's circumstances). A U.S. holder's net investment income will include its gross dividend income and its net gains from the disposition of our common shares, unless such dividends or net gains are derived in the ordinary course of the conduct of a trade or business (other than a trade or business that consists of certain passive or trading activities). If you are a United States person that is an individual, estate or trust, you are encouraged to consult your tax advisors regarding the applicability of the Medicare tax to your income and gains in respect of your investment in our common shares.

Information Reporting and Backup Withholding

U.S. Holders may be required to file certain U.S. information reporting returns with the IRS with respect to an investment in our common shares, including, among others, IRS Form 8938 (Statement of Specified Foreign Financial Assets). Substantial penalties may be imposed upon a U.S. Holder that fails to comply with the required information reporting.

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (1) the U.S. Holder is a corporation or other exempt recipient or (2) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the U.S. Holder's U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the IRS.

Each U.S. Holder is urged to consult with its tax advisor concerning the United States federal income tax consequences of purchasing, holding, and disposing of our common shares if we are or become classified as a PFIC, including the procedure for, and the possibility and consequences of, making a purging or mark-to-market election. We cannot provide any assurances that the IRS will agree with our annual determinations of our PFIC status.

UNDERWRITING

Citigroup Global Markets Inc., Cowen and Company, LLC, Evercore Group L.L.C. and Barclays Capital Inc. are acting as book-running managers of this offering and as representatives of the underwriters named below. Subject to the terms and conditions stated in the underwriting agreement dated the date of this prospectus, each of the underwriters named below has severally agreed to purchase, and we have agreed to sell to that underwriter, the number of common shares indicated below.

Underwriter	Common Shares
Citigroup Global Markets Inc.	Shares
Cowen and Company, LLC	
Evercore Group L.L.C.	
Barclays Capital Inc.	
JMP Securities LLC	
Robert W. Baird & Co. Incorporated	
Total	13,000,000

The underwriting agreement provides that the obligations of the underwriters to purchase the common shares included in this offering are subject to approval of legal matters by counsel and to other conditions. The underwriters are obligated to purchase all of the common shares (other than those covered by the underwriters' option to purchase additional common shares described below) if they purchase any of the common shares.

Common shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover page of this prospectus. Any common shares sold by the underwriters to securities dealers may be sold at a discount from the initial public offering price not to exceed \$ per common share. If all the common shares are not sold at the initial offering price, the underwriters may change the initial offering price and the other selling terms. The representatives have advised us that the underwriters do not intend to make sales to discretionary accounts.

If the underwriters sell more common shares than the total number set forth in the table above, we have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 1,950,000 additional common shares at the initial public offering price less the underwriting discount. The underwriters may exercise the option solely for the purpose of covering over-allotments, if any, in connection with this offering. To the extent the option is exercised, each underwriter must purchase a number of additional common shares approximately proportionate to that underwriter's initial purchase commitment set forth in the table above. Any common shares issued or sold under the option will be issued and sold on the same terms and conditions as the other common shares that are the subject of this offering.

We, our executive officers, our board of directors and all of our other shareholders and optionholders have agreed that, subject to specified limited exceptions, for a period of 180 days from the date of this prospectus, we and they will not, without the prior written consent of Citigroup Global Markets Inc., offer, sell, contract to sell, pledge or otherwise dispose of any common shares or any securities convertible into, or exercisable or exchangeable for, our common shares. Citigroup Global Markets Inc. in its sole discretion may release any of the securities subject to these lock-up agreements at any time, which, in the case of our management board members and supervisory board members, shall be with notice.

Prior to this offering, there has been no public market for our common shares. Consequently, the initial public offering price for our common shares will be determined by negotiations between us and the representatives. Among the factors considered in determining the initial public offering price will be our results of operations, our current financial condition, our future prospects, our markets, the economic conditions in and future prospects for the industry in which we compete, our management board, and currently prevailing general

conditions in the equity securities markets, including current market valuations of publicly traded companies considered comparable to our Company. We cannot assure you, however, that the price at which our common shares will sell in the public market after this offering will not be lower than the initial public offering price or that an active trading market in our common shares will develop and continue after this offering.

Our common shares have been authorized for listing on the NYSE under the symbol "MYOV."

The following table shows the per share and total underwriting discounts and commissions that we are to pay to the underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional common shares.

	Paid by	Paid by Myovant	
	No Exercise	Full Exercise	
Per common share	\$	\$	
Total	\$	\$	

We estimate that our portion of the total expenses of this offering, exclusive of underwriting discounts and commissions payable by us, will be approximately \$2.5 million. We have also agreed to reimburse the underwriters for expenses in an amount of up to \$25,000 relating to the clearance of this offering with the Financial Industry Regulatory Authority, Inc.

In connection with this offering, the underwriters may purchase and sell our common shares in the open market. Purchases and sales in the open market may include short sales, purchases to cover short positions, which may include purchases pursuant to the underwriters' option to purchase additional common shares, and other transactions that would stabilize, maintain or otherwise affect the price of our common shares.

- Short sales involve secondary market sales by the underwriters of a greater number of common shares than they are required to purchase in this offering.
 - "Covered" short sales are sales of common shares in an amount up to the number of common shares represented by the underwriters' option to purchase additional common shares.
 - "Naked" short sales are sales of common shares in an amount in excess of the number of common shares represented by the underwriters' option to purchase additional common shares.
- Covering transactions involve purchases of common shares either pursuant to the underwriters' option to purchase additional common shares or in the
 open market in order to cover short positions.
 - To close a naked short position, the underwriters must purchase common shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common shares in the open market after pricing that could adversely affect investors who purchase in this offering.
 - To close a covered short position, the underwriters must purchase common shares in the open market or must exercise their option to purchase
 additional common shares. In determining the source of common shares to close the covered short position, the underwriters will consider, among
 other things, the price of common shares available for purchase in the open market as compared to the price at which they may purchase common
 shares through the underwriters' option to purchase additional common shares.
- Stabilizing transactions involve bids to purchase common shares so long as the stabilizing bids do not exceed a specified maximum, to stabilize the price of the common shares.

Purchases to cover short positions and stabilizing purchases, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our common shares. They may also cause the price of the common shares to be higher than the price that would otherwise exist in the open market in the absence of these transactions. The underwriters may conduct these

transactions on the NYSE, in the over-the-counter market or otherwise. The underwriters are not required to engage in any of these transactions, and they may discontinue them at any time.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act or the Exchange Act, and to contribute to payments the underwriters may be required to make because of any of those liabilities.

A prospectus in electronic format may be made available on websites maintained by one or more of the underwriters or their respective affiliates. The representatives may agree with us to allocate a number of common shares to underwriters for sale to their online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' or their respective affiliates' websites and any information contained in any other website maintained by any of the underwriters or their respective affiliates is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors in this offering.

Other Relationships

The underwriters are full-service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, principal investment, hedging, financing and brokerage activities. The underwriters and their respective affiliates may, from time to time, engage in transactions with and perform services for us in the ordinary course of their business for which they may receive customary fees and reimbursement of expenses. In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (which may include bank loans and/or credit default swaps) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments or financial instruments that they acquire, long and/or short positions in such securities and instruments.

Notice to Prospective Investors in the European Economic Area

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State), an offer to the public of any common shares which are the subject of the offering contemplated by this prospectus supplement and the accompanying prospectus may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any common shares may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- to any legal entity which is a qualified investor, as defined in the Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal
 persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior
 consent of the underwriters or the underwriters nominated by us for any such offer: or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of common shares shall require us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer common shares to the public" in relation to the common shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the common shares to be offered so as to enable an investor to decide to purchase or subscribe to the common shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

Notice to Prospective Investors in United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated (each such person being referred to as a "relevant person").

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

Notice to Prospective Investors in Bermuda

Securities may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act 2003 of Bermuda which regulates the sale of securities in Bermuda and it is not intended for any offer or sale of common shares to the public to take place in Bermuda.

Notice to Prospective Investors in Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the Company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
- a person associated with the Company under Section 708(12) of the Corporations Act; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the securities issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

Notice to Prospective Investors in Hong Kong

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to professional investors, as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong ("SFO") and any rules made under that Ordinance; or in other circumstances which do not result in the document being a prospectus, as defined in the Companies Ordinance (Cap. 32) of Hong Kong ("CO") or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors, as defined in the SFO and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

Notice to Prospective Investors in Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the initial purchaser will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for reoffering or resale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been and will not be lodged or registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the common shares may not be circulated or distributed, nor may the common shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the common shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is
 an accredited investor, securities (as defined in Section



239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the common shares pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Notice to Prospective Investors in Switzerland

The common shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a of the CO or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing relating to the common shares or this offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to this offering, the Company or the common shares has been or will be filed with or approved by any Swiss regulatory authority.

Notice to Prospective Investors in Canada

The common shares may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the common shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the Underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

LEGAL MATTERS

The validity of the common shares and certain other matters of Bermuda law will be passed upon for us by Conyers Dill & Pearman Limited, our special Bermuda counsel. Certain other legal matters will be passed upon for us by Cooley LLP, Palo Alto, California, and for the underwriters by Latham & Watkins LLP, New York, New York.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements at March 31, 2016 and for the period from February 2, 2016 (date of inception) to March 31, 2016, as set forth in their report (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 1 to the financial statements). We've included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the common shares being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to our company and the common shares offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the internet at the SEC's website at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

Upon the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above. We also maintain a website at www.myovant.com, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this prospectus.

EXCHANGE CONTROLS

The permission of the Bermuda Monetary Authority is required, pursuant to the provisions of the Exchange Control Act 1972 and related regulations, for all issuances and transfers of shares (which includes our common shares) of Bermuda companies to or from a non-resident of Bermuda for exchange control purposes, other than in cases where the Bermuda Monetary Authority has granted a general permission. The Bermuda Monetary Authority, in its notice to the public dated June 1, 2005, has granted a general permission for the issue and subsequent transfer of any securities of a Bermuda company from or to a non-resident of Bermuda for exchange control purposes for so long as any "Equity Securities" of the company (which would include our common shares) are listed on an "Appointed Stock Exchange" (which would include the NYSE). Certain issues and transfers of common shares involving persons deemed resident in Bermuda for exchange control purposes require the specific consent of the Bermuda Monetary Authority. We have sought and have obtained a specific permission from the Bermuda Monetary Authority for the issue and transfer of our common shares up to the amount of our authorized capital from time to time, and options, warrants, depository receipts, rights, loan notes, debt instruments and our other securities to persons resident and non-resident for exchange control purposes with the need for prior approval of such issue or transfer.

ENFORCEMENT OF CIVIL LIABILITIES UNDER UNITED STATES FEDERAL SECURITIES LAWS

We are a Bermuda exempted company. As a result, the rights of holders of our common shares will be governed by Bermuda law and our memorandum of association and bye-laws. The rights of shareholders under Bermuda law may differ from the rights of shareholders of companies incorporated in other jurisdictions. It may be difficult for investors to enforce in the United States judgments obtained in U.S. courts against us based on the civil liability provisions of the U.S. securities laws. Our registered office address is Clarendon House, 2 Church Street, Hamilton HM11, Bermuda, and we also have business operations at Park Place, 55 Par-La-Ville Road, 2nd Floor, Hamilton HM11, Bermuda.

We have been advised by our special Bermuda counsel that there is no treaty in force between the United States and Bermuda providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. As a result, whether a U.S. judgment would be enforceable in Bermuda against us or our directors and officers depends on whether the U.S. court that entered the judgment is recognized by a Bermuda court as having jurisdiction over us or our directors and officers, as determined by reference to Bermuda conflict of law rules. The courts of Bermuda would recognize as a valid judgment, a final and conclusive judgment in personam obtained in a U.S. court pursuant to which a sum of money is payable (other than a sum of money payable in respect of multiple damages, taxes or other charges of a like nature or in respect of a fine or other penalty). The courts of Bermuda would give a judgment based on such a U.S. judgment as long as (1) the U.S. court had proper jurisdiction over the parties subject to the judgment; (2) the U.S. court did not contravene the rules of natural justice of Bermuda; (3) the U.S. judgment was not obtained by fraud; (4) the enforcement of the U.S. judgment would not be contrary to the public policy of Bermuda; (5) no new admissible evidence relevant to the action is submitted prior to the rendering of the judgment by the courts of Bermuda; (6) there is due compliance with the correct procedures under the laws of Bermuda; and (7) the U.S. judgment is not inconsistent with any judgment of the courts of Bermuda in respect of the same matter.

In addition, and irrespective of jurisdictional issues, the Bermuda courts will not enforce a U.S. federal securities law that is either penal or contrary to Bermuda public policy. We have been advised that an action brought pursuant to a public or penal law, the purpose of which is the enforcement of a sanction, power or right at the instance of the state in its sovereign capacity, is unlikely to be entertained by a Bermuda court. Certain remedies available under the laws of U.S. jurisdictions, including certain remedies under U.S. federal securities laws, would not be available under Bermuda law or enforceable in a Bermuda court, as they are likely to be contrary to Bermuda public policy. Further, it may not be possible to pursue direct claims in Bermuda against us or our directors and officers for alleged violations of U.S. federal securities laws are unlikely to have extraterritorial effect and do not have force of law in Bermuda. A Bermuda court may, however, impose civil liability on us or our directors and officers if the facts alleged and proved in the Bermuda proceedings constitute or give rise to a cause of action under the applicable governing law, not being a foreign public, penal or revenue law.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholder of Myovant Sciences Ltd.:

We have audited the accompanying balance sheet of Myovant Sciences Ltd. as of March 31, 2016, and the related statements of operations and comprehensive loss, shareholder's deficit and cash flows for the period from February 2, 2016 (date of inception) to March 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Myovant Sciences Ltd. at March 31, 2016, and the results of its operations and its cash flows for the period from February 2, 2016 (date of inception) to March 31, 2016, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has insufficient capital to fund its operations which raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

Metro Park, New Jersey July 8, 2016, except for Note 11, as to which the date is October 19, 2016

MYOVANT SCIENCES LTD. CONSOLIDATED BALANCE SHEETS

	As of March 31, 2016	As of June 30, 2016 (unaudited)	
Assets	· · · · ·		
Deferred initial public offering costs	\$ —	\$ 523,681	
Total assets	\$ —	\$ 523,681	
Liabilities and Shareholders' Deficit			
Current liabilities:			
Accrued expenses and accounts payable	\$ 222,650	\$ 990,343	
Due to Roivant Sciences Ltd. and Roivant Science, Inc.	_	1,153,378	
Income tax payable	—	3,054	
Total current liabilities	\$ 222,650	\$ 2,146,775	
Warrant liability	_	6,975,000	
Total liabilities	\$ 222,650	\$ 9,121,775	
Commitments and contingencies (Note 9)			
Shareholders' deficit:			
Common shares, par value \$0.000017727 per share, 564,111,242 shares authorized, 37,231,342, 43,590,411 and 58,523,408 issued and outstanding at March 31, 2016, June 30, 2016 and June 30,			
2016 pro forma, respectively	660	773	
Common shares subscribed	(660)	(660)	
Additional paid-capital	1,434,138	12,029,070	
Accumulated deficit	(1,656,788)	(20,627,277)	
Total shareholders' deficit	\$ (222,650)	\$ (8,598,094)	
Total liabilities and shareholders' deficit	\$	\$ 523,681	

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

MYOVANT SCIENCES LTD.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Fel (Da	Period from bruary 2, 2016 te of Inception) March 31, 2016	Three Months Ended June 30, 2016 (unaudited)
Operating expenses:			
Research and development	\$	_	\$ 14,573,014
General and administrative		1,656,788	2,561,878
Total operating expenses		1,656,788	17,134,892
Other (expense) income:			
Changes in the fair value of the warrant liability			(1,832,543)
Loss before provision for income tax		(1,656,788)	(18,967,435)
Income tax expense			3,054
Net loss and comprehensive loss	\$	(1,656,788)	\$(18,970,489)
Net loss per common share—basic and diluted	\$	(0.04)	\$ (0.47)
Weighted average common shares outstanding—basic and diluted		37,231,342	40,771,548
Pro forma net loss per common share—basic and diluted (unaudited)			\$ (0.45)
Pro forma weighted average common shares outstanding—basic and diluted (unaudited)			42,544,277

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

MYOVANT SCIENCES LTD.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' DEFICIT FOR THE PERIOD FROM FEBRUARY 2, 2016 (DATE OF INCEPTION) TO MARCH 31, 2016 AND FOR THE THREE MONTHS ENDED JUNE 30, 2016 (UNAUDITED)

	Common S	stock	Common Stock	Additional	Accumulated	Total Shareholder's
	Shares	Amount	Subscribed	Paid-in Capital	Deficit	Deficit
Balance at February 2, 2016	37,231,342	\$ 660	\$ (660)	\$ _	\$ —	\$ _
Capital contribution		_	—	1,434,138		1,434,138
Net loss		—	—		(1,656,788)	(1,656,788)
Balance at March 31, 2016	37,231,342	\$ 660	\$ (660)	\$ 1,434,138	\$ (1,656,788)	\$ (222,650)
Shares issued to Takeda under the Takeda license						
agreement	5,077,001	90	—	7,739,910		7,740,000
Share-based compensation expense	1,128,222	20	—	18,278		18,298
Shares issued for the warrant liability, under the						
Takeda license agreement	153,846	3	—	234,540		234,543
Capital contribution - share based compensation		_	—	2,602,204		2,602,204
Net loss		—	—		(18,970,489)	(18,970,489)
Balance at June 30, 2016 (unaudited)	43,590,411	\$ 773	\$ (660)	\$ 12,029,070	\$ (20,627,277)	\$ (8,598,094)

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

MYOVANT SCIENCES LTD. CONSOLIDATED STATEMENTS OF CASH FLOWS

	Period from February 2, 2016 (Date of Inception) to March 31, 2016	Three Months Ended June 30, 2016 (unaudited)
Cash flows from operating activities:		
Net loss	\$ (1,656,788)	\$(18,970,489)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	1,434,138	2,620,502
Purchase of in-process research and development expenses	_	13,117,000
Changes in the fair value of the warrant liability	_	1,832,543
Changes in operating assets and liabilities:		
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc.	_	1,153,378
Income tax payable	_	3,054
Accrued expenses and accounts payable	222,650	244,012
Net cash used in operating activities		_
Cash flows from investing activities:		
Net cash used in investing activities		_
Cash flows from financing activities:		
Net cash provided by financing activities		—
Net change in cash		
Cash—beginning of period	_	
Cash—end of period	\$ —	\$ —
Noncash financing activities:		
Deferred initial public offering costs, unpaid	\$ —	\$ 523,681
Purchase of in-process research and development	\$ —	\$ 13,117,000

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

MYOVANT SCIENCES LTD.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited as of June 30, 2016 and for the three months ended June 30, 2016)

Note 1—Description of Business and Liquidity

[A] Description of Business:

Myovant Sciences Ltd. and its subsidiaries (the "Company") is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for women's health diseases and other endocrine-related disorders. The Company is developing its lead product candidate, relugolix, for the treatment of heavy menstrual bleeding associated with uterine fibroids, endometriosis-associated pain and advanced prostate cancer, and its second product candidate, RVT-602, for the treatment of female infertility as part of assisted reproduction. The Company was founded on February 2, 2016 as a Bermuda Exempted Limited Company and a wholly-owned subsidiary of Roivant Sciences Ltd. ("RSL"), under the name Roivant Endocrinology Ltd. The Company changed its name to Myovant Sciences Ltd. ("MSL") in May 2016. In April 2016, Roivant Endocrinology Inc. ("REI"), a wholly-owned subsidiary of the Company was formed and based in the United States of America and subsequently changed its name to Myovant Sciences, Inc. ("MSI"). The Company's fiscal year ends on March 31.

Since its inception, the Company has devoted substantially all of its efforts to organizing the Company, acquiring its drug development programs and preparing for and advancing its product candidates into clinical development. The Company has determined that it has one operating and reporting segment. The Company has two product candidates, relugolix and RVT-602, under development which were licensed from Takeda Pharmaceuticals International AG ("Takeda") on April 29, 2016 (See Note 3).

[B] Unaudited Interim Consolidated Financial Information:

The accompanying interim consolidated balance sheet as of June 30, 2016 and the consolidated statements of operations, cash flows and shareholder's deficit for the three months ended June 30, 2016 are unaudited. The unaudited interim consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles and on the same basis as the audited consolidated financial statements. In the opinion of management, the unaudited interim consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of our financial position at June 30, 2016 and the consolidated results of operations and cash flows for the three months ended June 30, 2016. The results for the three months ended June 30, 2016 are not necessarily indicative of the results to be expected for the year ending March 31, 2017 or for any future period.

[C] Unaudited Pro Forma Information:

The unaudited pro forma net loss per share is computed using the weighted average number of common shares outstanding after giving effect to the issuance of 1,772,724 additional common shares to Takeda upon the closing of the Company's initial public offering, as if such exercise had occurred at the beginning of the period presented, pursuant to the automatic exercise of a warrant held by Takeda.

[D] Liquidity:

The Company has not been capitalized with sufficient funding to conduct its operations. Certain other costs of conducting the Company's operations were paid by RSL or RSL's wholly-owned subsidiary, Roivant Sciences, Inc. ("RSI"), and will be reimbursed by the Company upon receipt of additional external funding pursuant to a services agreement with RSI and MSI. The Company has not generated any revenues and does not anticipate generating any revenues in the foreseeable future. Since the Company has no available cash or credit facilities, the Company is dependent upon RSL and its affiliates to provide services and funding to support the operations of the Company until, at least, such time as external financing is completed.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. The Company anticipates incurring additional losses until such time, if ever, that it can obtain marketing approval to sell, and then generate significant sales, of its product candidates that are currently in development. Substantial additional financing will be needed by the Company to fund its operations and to develop and commercialize its product candidates. These factors raise substantial doubt about the Company's ability to continue as a going concern.

The Company will seek to obtain additional capital through the sale of debt or equity financings or other arrangements to fund operations; however, there can be no assurance that the Company will be able to raise needed capital under acceptable terms, if at all. The sale of additional equity may dilute existing shareholders and newly issued shares may contain senior rights and preferences compared to currently outstanding common shares. Issued debt securities may contain covenants and limit the Company's ability to pay dividends or make other distributions to shareholders. If the Company is unable to obtain such additional financing, operations would need to be scaled back or discontinued. The Company is currently exploring external financing alternatives which will be needed by the Company to fund its operations.

The Company's future operations are highly dependent on a combination of factors, including (i) the timely and successful completion of additional financing discussed above; (ii) the success of its research and development program; (iii) the development of competitive therapies by other biotechnology and pharmaceutical companies, (iv) the Company's ability to manage growth of the organization; (v) the Company's ability to protect its proprietary technology; and, ultimately; (vi) regulatory approval and market acceptance of the Company's product candidates.

Note 2—Summary of Significant Accounting Policies

[A] Basis of Presentation:

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

In April 2012, the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") was enacted. Section 107(b) of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company has irrevocably elected not to avail itself of this extended transition period, and, as a result, the Company will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

[B] Use of Estimates:

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company regularly evaluates estimates and assumptions related to assets, liabilities, costs, expenses and research and development costs. The Company bases its estimates and assumptions on historical experience and on various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

[C] Risks and Uncertainties:

The Company is subject to risks common to companies in the pharmaceutical industry including, but not limited to, uncertainties related to commercialization of products, regulatory approvals, dependence on key products, third-party service providers such as contract research organizations and protection of intellectual property rights.

[D] Deferred Offering Costs:

Deferred offering costs, which consisted of direct costs related to the Company's initial public offering of its common stock, are being capitalized in other assets until the consummation of the initial public offering. These offering costs will be reclassified to additional paid-in capital upon the closing of the Company's initial public offering.

[E] Research and Development Expense:

Research and development 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. Payments for a product license prior to regulatory approval of the product and payments for milestones achieved prior to regulatory approval of the product are expensed in the period incurred as research and development. Milestone payments made in connection with regulatory approvals are capitalized and amortized to cost of revenue over the remaining useful life of the asset. Research and development expenses primarily consist of the intellectual property and research and development materials acquired, certain costs charged by RSI under its services agreement with the Company and expenses from third parties who conduct research and development activities on behalf of the Company. The Company expenses in-process research and development projects acquired as asset acquisitions which have not reached technological feasibility and which have no alternative future use. Clinical study costs are accrued over the service periods specified in the contracts and adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred.

[F] Warrant Liability:

The Company records the warrant liability at its estimated fair value as a liability in the consolidated balance sheet. The Company remeasures the estimated fair value of the warrant liability each reporting period and records the changes in the fair value in the statement of operations as other (expense) income (See Note 8).

[G] Company Valuation:

To estimate certain expenses and record certain transactions, it is necessary for the Company to estimate the fair value of its common shares. Given the absence of a public trading market, and in accordance with the American Institute of Certified Public Accountants' Practice Guide, "Valuation of Privately-Held-Company Equity Securities Issued as Compensation", the Company exercised reasonable judgment and considered numerous objective and subjective factors to determine its best estimate of the fair value of its common shares (See Note 3).

[H] 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.

[I] Share-Based Compensation:

Share-based awards to employees and directors are valued at fair value on the date of the grant and that fair value is recognized as share based compensation expense over the requisite service period. The Company values its stock options using the Black-Scholes option pricing model. Certain assumptions need to be made with respect to utilizing the Black-Scholes option pricing model, including the expected life of the award, volatility of the underlying shares, the risk-free interest rate, the fair value of the Company's common shares and anticipated forfeiture of the share-based awards. Since the Company has limited option exercise history, it has generally elected to estimate the expected life of an award based upon the Securities and Exchange Commission-approved "simplified method" noted under the provisions of Staff Accounting Bulletin No. 107 with the continued use of this method extended under the provisions of Staff Accounting Bulletin No. 107 with the continued use of this method extended under the provisions of Staff Accounting Bulletin No. 107 with the continued use of the saverage historical price volatility for industry peers. Estimates of pre-vesting award forfeitures are based on the Company's expectations of future employee turnover. The Company will adjust its estimate of forfeitures over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures will be recognized through a cumulative catch-up adjustment in the period of change and will also impact the amount of compensation expense to be recognized in future periods.

The Company accounts for share-based payments to non-employees issued in exchange for services based upon the fair value of the equity instruments issued. Compensation expense for stock options issued to non-employees is calculated using the Black-Scholes option pricing model and is recorded over the service performance period. Options subject to vesting are required to be periodically remeasured over their service performance period, which is generally the same as the vesting period.

[J] Net Loss per Common Share:

Basic net loss per common share is computed by dividing net loss applicable to common shareholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing the net loss applicable to common shareholders by the diluted weighted-average number of common shares outstanding during the period calculated in accordance with the treasury stock method. For the period from February 2, 2016 (date of inception) to March 31, 2016, there were no instruments outstanding that would be anti-dilutive. For the three months ended June 30, 2016, 1,128,222 restricted stock awards were not included in the calculation of diluted weighted-average common shares outstanding because they were anti-dilutive.

[K] Recently Issued Accounting Pronouncements:

In August 2014, the FASB issued ASU No. 2014-15, "*Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*" (ASU No. 2014-15). ASU No. 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Specifically, ASU No. 2014-15 provides a definition of the term substantial doubt and requires an assessment for a period of one year after the date that the financial statements are issued. It also requires certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans and requires an express statement and other disclosures when substantial doubt is not alleviated. The new

standard will be effective for reporting periods ending after December 15, 2016, with early adoption permitted. Management does not expect the adoption of ASU No. 2014-15 will significantly impact its consolidated financial statements and disclosures.

In November 2015, the FASB issued ASU No. 2015-17, "*Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*" (ASU No. 2015-17). This amendment will simplify the presentation of deferred tax assets and liabilities on the balance sheet and require all deferred tax assets and liabilities to be treated as non-current. ASU No. 2015-17 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016, with early adoption permitted. The Company has adopted ASU No. 2015-17. The adoption of ASU No. 2015-17 did not have a significant impact on the Company's consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, "*Leases (Topic 842)*" (ASU No. 2016-02), which is a comprehensive new lease standard that amends various aspects of existing accounting guidance for leases. The core principle of ASU No. 2016-02 will require lesses to present the assets and liabilities that arise from leases on their balance sheets. ASU No. 2016-02 is effective for annual periods beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company is currently evaluating the new standard and its impact on the Company's consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, "*Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*" (ASU No. 2016-09). This ASU makes several modifications to Topic 718 related to the accounting for forfeitures, employer tax withholding on share-based compensation, and the financial statement presentation of excess tax benefits or deficiencies. ASU No. 2016-09 also clarifies the statement of cash flows presentation for certain components of share-based awards. The standard is effective for interim and annual reporting periods beginning after December 15, 2016, with early adoption permitted. The Company expects to adopt this guidance when effective and is currently evaluating the effect that the updated standard will have on its consolidated financial statements and related disclosures.

Note 3—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 RVT-602, in exchange for the following:

- The Company issued and delivered 5,077,001 common shares at closing.
- The Company will pay Takeda a fixed, high single-digit royalty on net sales of relugolix and RVT-602 products in the Company's territory, subject to certain agreed reductions. Takeda will pay the Company a royalty at the same rate as the Company's on net sales of relugolix products for prostate cancer in Japan and certain other Asian countries, subject to certain agreed reductions. Royalties are required to be paid, on a product-by-product and country-by-country basis, until the latest 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 this license agreement, there are no payments upon the achievement of clinical development or marketing approval milestones.
- The Company issued a warrant to Takeda to purchase an indeterminate number of capital shares. The warrant entitles Takeda, together with its affiliates, to maintain a 12% ownership interest in the Company, as determined after such exercise, through the later of (i) the one-year anniversary of the issuance of the warrant (April 2017) or (ii) the final closing of an initial public offering as per the agreement, unless earlier terminated upon a change in control.

For the consideration above, the Company also received a small quantity of relugolix and RVT-602, and certain historical research and development records. The Company did not hire, or receive, any Takeda workforce or employees working on relugolix and RVT-602, or any research, clinical or manufacturing equipment. The Company did not assume any contracts, licenses or agreements between Takeda and any third party with respect to relugolix and RVT-602. The Company will need to independently develop all clinical processes and procedures for its clinical trials through the use of internal and external resources once appropriate and acceptable resources have been identified and obtained. If the 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 cap, or complete by itself the conduct of any clinical trials of relugolix for prostate cancer that are ongoing as of the effective date of such termination, at its cost and expense.

As the intellectual property and inventory acquired had no alternative future use, the Company recorded \$13,117,000 as research and development expense at the closing date of the acquisition of the rights, April 29, 2016, which consisted of \$7,740,000 for the estimated fair value of the 5,077,001 common shares issued and \$5,377,000 for the estimated fair value of warrant liability. Significant judgment and estimates were used to estimate the fair value of common shares and warrant liability, as they are not publicly traded and are considered Level 3 measurement within the fair value hierarchy.

The estimation of the fair value of the common shares considered factors including the following: the estimated present value of the Company's future cash flows; industry information such as market size and growth; market capitalization of comparable companies and the estimated value of transactions such companies have engaged in; and macroeconomic conditions. No events have come to the attention of the Company's management between the date of the most recent valuation and the balance sheet date which would have a material impact on the valuation of the Company.

The estimation of the fair value of the warrant liability was determined based on a Monte Carlo simulation model which requires various highly subjective unobservable inputs (See Note 8).

Note 4—Related Party Transactions

[A] Services Agreement:

In July 2016, the Company entered into a formal services agreement with RSI (the "Services Agreement") effective April 29, 2016, under which RSI agreed to provide certain administrative and research and development services to the Company during the formative period of the Company. Under the Services Agreement, the Company will pay or reimburse RSI for any expenses it, or third parties acting on its behalf, incurs for the Company. For any general and administrative and research and development activities performed by RSI employees, RSI will charge back the employee compensation expense plus a predetermined mark-up. RSI also provided such services prior to the formalization of the Services Agreement, and such costs have been recognized by the Company in the period in which the services were rendered. Employee compensation expense, inclusive of base salary and fringe benefits, is determined based upon the relative percentage of time utilized on Company matters. All other costs will be billed back at cost.

During the period from February 2, 2016 (date of inception) to March 31, 2016 and the three months ended June 30, 2016, RSL and RSI provided certain administrative services on behalf of the Company during the formative period of the Company. Total compensation expense, inclusive of base salary, fringe benefits and share-based compensation, is proportionately allocated to the Company based upon the relative percentage of time utilized on the Company's matters. A significant component of total compensation expense allocated back to the Company relates to the RSL common share awards and RSL options issued by RSL to RSL and RSI employees.

For the period from February 2, 2016 (date of inception) to March 31, 2016 the amount of salary and fringe benefits and share-based compensation allocated to the Company was \$1,390,798. For the three months ended June, 30, 2016 the share-based compensation allocated to the Company was \$2,602,204. For the three months ended June 30, 2016, salary and fringe benefits were included in the \$1,031,559 that was billed to the Company under the Services Agreement.

[B] Option Agreement:

In June 2016, the Company entered into an option agreement with RSL pursuant to which RSL granted to the Company an option to acquire the rights to products to which RSL or any nonpublic affiliate of RSL acquires the rights (other than a relugolix product or a competing product) for uterine fibroids or endometriosis, or for which the primary target indication is advanced prostate cancer. The Company's option is exercisable at any time during the period commencing upon the completion of its initial public offering and ending two years following the date of first commercial sale of a relugolix product in a major market country. If the Company elects to exercise its option for a product, it will be required to reimburse RSL for 110% of any payments made by RSL or its affiliate for such product, and will receive an assignment of the agreement through which RSL or its affiliate acquired the rights to such product.

[C] Information Sharing and Cooperation Agreement:

In July 2016, the Company entered into an information sharing and cooperation agreement, or the Cooperation Agreement, with RSL. The Cooperation Agreement, among other things: (1) obligates the Company to deliver periodic financial statements and other financial information to RSL and to comply with other specified financial reporting requirements; and (2) requires the Company to supply certain material information to RSL to assist it in preparing any future SEC filings. Subject to specified exceptions, the Cooperation Agreement will terminate upon the earlier of the mutual written consent of the parties or when RSL is no longer required by U.S. GAAP to consolidate the Company's results of operations and financial position, account for its investment in the Company under the equity method of accounting or, by any rule of the SEC, include the Company's separate financial statements in any filings it may make with the SEC.

[D] Manufacture and Supply Agreement:

In June 2016, the Company and Takeda's affiliate, Takeda Pharmaceutical Company Limited ("Takeda Limited") entered into an agreement for the manufacture and supply of relugolix. Under this agreement, Takeda Limited will supply the Company, and the Company will obtain from Takeda Limited, all of its requirements for relugolix drug substance and drug product to be used under its development plans for all indications. If the Company requests, Takeda Limited will assist it with a technical transfer of the manufacturing process for relugolix to it or its designee and the Company will pay the expenses related to such transfer.

Note 5—Shareholder's Deficit

[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 June 30, 2016, the Company had 564,111,242 shares authorized with a par value of \$0.000017727 per share.

[B] Restricted Stock Award:

In June 2016, the Company granted a restricted stock award for 1,128,222 common shares to the Company's Principal Executive Officer under the 2016 Equity Incentive Plan.

[C] Warrant Liability:

In June 2016, the Company issued 153,846 common shares to Takeda upon the automatic exercise of the warrant, which was initiated by the grant of a restricted stock award for 1,128,222 common shares.

Note 6—Income Taxes

The Company's provision for income taxes is based on income taxes in the United States for federal, state and local income taxes. The Company is not subject to taxation under the laws of Bermuda since it is was organized as a Bermuda Exempted Limited Company, for which there is no current tax regime. The Company's effective tax rate for the period from February 2, 2016 (date of inception) to March 31, 2016 and for the three months ended June 30, 2016 was 0.0% and (0.02)%, respectively. As of March 31, 2016 and June 30, 2016, there were no significant uncertain tax positions.

Note 7—Share-Based Compensation

[A] Stock Options and Restricted Stock Awards Granted:

In June 2016, the Company adopted its 2016 Equity Incentive Plan (the "2016 Plan"), under which 4,230,834 common shares are reserved for grant. The Company's employees, directors and consultants are eligible to receive non-qualified and incentive stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other stock awards under the plan. Generally, 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 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. As of June 30, 2016, no stock options had been granted by the Company.

In June 2016, the Company granted a restricted stock award for 1,128,222 common shares to the Company's Principal Executive Officer under the 2016 Plan.

For the period from February 2, 2016 (date of inception) to March 31, 2016, there was no share-based compensation expense. For the three months ended June 30, 2016, share-based compensation expense was \$18,298. At June 30, 2016, total unrecognized compensation expense related to non-vested restricted stock award was \$1,701,702 and is expected to be recognized over the remaining weighted-average service period of 3.92 years.

[B] Share-Based Compensation Allocated to the Company:

In relation to the RSL common share awards and options issued by RSL to RSL and RSI employees, the Company recorded share-based compensation expense of \$987,066 and \$2,602,204, respectively, for the period from February 2, 2016 (date of inception) to March 31, 2016 and the three months ended June 30, 2016.

Share-based compensation expense is allocated to the Company by RSL based upon the relative percentage of time utilized by RSL and RSI employees on Company matters.

The RSL common share awards are valued at fair value on the date of grant and that fair value is recognized over the requisite service period. Significant judgment and estimates were used to estimate the fair value of these awards, as they are not publicly traded. RSL common share awards are subject to specified vesting schedules and requirements (a mix of time-based, performance-based and corporate event-based, including targets for RSL's post-IPO market capitalization and future financing events). The Company estimated the fair value of each RSL option on the date of grant using the Black-Scholes closed-form option-pricing model.

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

Note 8—Fair Value Measurements

The Company applies a fair value framework in order to measure and disclose its financial assets and liabilities. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The fair value hierarchy requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. There are three levels of inputs that may be used to measure fair value:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Fair values are determined by utilizing quoted prices for similar assets and liabilities in active markets or other market observable inputs such as interest rates and yield curves.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. The Company's Level 3 assets and liabilities consist of the warrant liability associated with the license agreement with Takeda. The fair value of the warrant liability was determined based on a Monte Carlo simulation model which requires various highly subjective unobservable inputs. The significant unobservable inputs used in the fair value measurement are the probability of a future financing event; the expected date or dates of a future financing event; the potential size of a future financing event; the enterprise value of the Company; and the expected volatility in the Company's valuation.

Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

Financial assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability.

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The following table sets forth the Company's assets and liabilities that are measured at fair value on a recurring basis at March 31, 2016 and June 30, 2016, by level, within the fair value hierarchy:

	As of March 31, 2016							As of June 30, 2016								
	Pri A Ma for Io	ioted ces in ctive irkets lentical s (Level 1)	Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs (Level 3)		Balance as of March 31, 2016		Quoted Prices in Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs (Level 3)		Balance as of June 30, 2016	
Assets:		<u>,</u>		<u>, </u>							`					
Total assets at fair value	\$		\$		\$	—	\$	—	\$		\$		\$	_	\$	—
Liabilities:			. <u> </u>													
Warrant liability	\$	—	\$		\$	_	\$	—	\$	—	\$	_	\$ 6,97	'5,000	\$ 6,9	75,000
Total liabilities at fair value	\$		\$		\$		\$		\$		\$		\$ 6,97	'5,000	\$ 6,9	75,000

There were no transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy that occurred during the three months ended June 30, 2016.

Level 3 Disclosures

The Company measures the warrant liability at fair value based on significant inputs not observable in the market, which causes it to be classified as a Level 3 measurement within the fair value hierarchy. The valuation of the warrant liability uses assumptions and estimates the Company believes would be made by a market participant in making the same valuation. The Company assesses these assumptions and estimates on an ongoing basis as additional data impacting the assumptions and estimates are obtained. Changes in the fair value of the warrant liability related to updated assumptions and estimates are recognized as other expenses in the accompanying condensed consolidated statements of operations.

The warrant liability may change significantly as additional data is obtained, impacting the Company's assumptions regarding probabilities of successful financing events used to estimate the fair value of the liability. In evaluating this information, considerable judgment is required to interpret the data used to develop the assumptions and estimates. The estimates of fair value may not be indicative of the amounts that could be realized in a financing event. Accordingly, the use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts, and such changes could materially impact the Company's results of operations in future periods.

The fair value of our warrant liability as of June 30, 2016 was calculated using the following significant unobservable inputs:

Input	Range or Point Estimate Used
Projected time frame to an equity financing	Oct. 2016 – Oct. 2017
Probability of a successful equity financing	60.0%
Annualized equity volatility	72.0% - 81.9%
Risk-free interest rate	0.29% - 0.45%

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The changes in fair value of the Company's Level 3 warrant liability during the three months ended June 30, 2016 were as follows:

Balance at March 31, 2016	\$ —
Fair value of the warrant liability issued	5,377,000
Changes in the fair value of the warrant liability, included in net loss	1,832,543
Settlements	(234,543)
Balance at June 30, 2016	\$6,975,000

For the three months ended June 30, 2016, changes in the carrying value of the warrant liability resulted from changes in the fair value of the warrant liability primarily due to changes in the estimated probabilities of future financing events, change in the enterprise value of the Company, automatic exercise of the warrant, and the passage of time.

Note 9—Commitments and Contingencies

The Company entered into certain commitments under the Takeda license agreement (See Note 3), and a services agreement with RSI (See Note 10). As of March 31, 2016 and June 30, 2016, the Company did not have any ongoing material financial commitments. The Company expects to enter into other commitments as the business further develops.

Note 10—Subsequent Events

In July 2016, the Company entered into a formal services agreement with RSI (the "Services Agreement") effective April 29, 2016, under which RSI agreed to provide certain administrative and research and development services to the Company during the formative period of the Company. Under the Services Agreement, the Company will pay or reimburse RSI for any expenses it, or third parties acting on its behalf, incurs for the Company. For any general and administrative and research and development activities performed by RSI employees, RSI will charge back the employee compensation expense plus a predetermined markup. RSI also provided such services prior to the formalization of the Services Agreement, and such costs have been recognized by the Company in the period in which the services were rendered (See Note 4). Employee compensation expense, inclusive of base salary and fringe benefits, is determined based upon the relative percentage of time utilized on Company matters. All other costs will be billed back at cost.

In August 2016, (1) the Company granted options to purchase 602,743 common shares to certain employees and consultants of the Company, with an exercise price of \$2.38 under the 2016 plan and (2) the Company issued 82,194 common shares to Takeda upon the automatic exercise of the warrant, which was initiated by the grant of options to purchase 602,743 common shares.

In September 2016, (1) the Company granted options to purchase 572,568 common shares to certain employees and directors of the Company, with a weighted-average exercise price of \$4.00 under the 2016 plan and (2) the Company issued 78,079 common shares to Takeda upon the automatic exercise of the warrant, which was initiated by the grant of options to purchase 572,568 common shares.

Note 11—Reverse Common Stock Split

On October 18, 2016, the Company's board of directors approved a 1-for-1.7727 reverse stock split of the Company's outstanding common shares. The reverse split became effective on October 18, 2016. The accompanying consolidated financial statements and notes to the consolidated financial statements give retroactive effect to the reverse stock split for all periods presented.

13,000,000 Shares



Common Shares

PRELIMINARY PROSPECTUS

, 2016

Citigroup Cowen and Company Evercore ISI Barclays JMP Securities Baird

PART II INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the sale of the common shares being registered. All amounts shown are estimates except for the SEC registration fee, the Financial Industry Regulatory Authority, or FINRA, filing fee and the NYSE initial listing fee.

	Amount to be Paid
SEC registration fee	\$ 23,369
FINRA filing fee	34,138
NYSE initial listing fee	97,840
Printing and engraving expenses	275,000
Legal fees and expenses	1,600,000
Accounting fees and expenses	350,000
Transfer agent and registrar fees and expenses	25,000
Miscellaneous fees and expenses	94,653
Total	\$ 2,500,000

Item 14. 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.

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

In connection with this offering, we expect to enter into indemnification agreements with each of our directors and executive officers. These indemnification agreements will provide the directors and executive officers with contractual rights to indemnification and expense advancement that are, in some cases, broader than the specific indemnification provisions contained under Bermuda law.

In addition, the underwriting agreement filed as Exhibit 1.1 to this Registration Statement provides for indemnification by the underwriters of us and our officers and directors for certain liabilities arising under the Securities Act, or otherwise.

Item 15. Recent Sales of Unregistered Securities.

Issuances of Share Capital

1. In February 2016, we issued 5,641,112 common shares to Roivant Sciences Ltd. our majority shareholder for \$100, or \$0.000017727 per common share.

2. In April 2016, we issued an additional 31,590,230 common shares to Roivant Sciences Ltd. for no consideration.

3. In April 2016, we issued 5,077,001 common shares to Takeda Pharmaceuticals International AG in connection with the execution of that certain license agreement by and between us and Takeda Pharmaceuticals International AG.

4. In April 2016, we issued a warrant for an indeterminate number of capital shares to Takeda Pharmaceuticals International AG.

5. In June 2016, we issued 1,128,222 common shares to Lynn Seely, M.D., our Principal Executive Officer, pursuant to a restricted stock grant.

6. In June 2016, we issued 153,846 common shares to Takeda Pharmaceuticals International AG upon the automatic exercise of the warrant set forth in paragraph (4) above.

7. In August 2016, we granted stock options to purchase an aggregate of 602,743 common shares, with an exercise price of \$2.38 per share, to our employees and consultants under our 2016 Equity Incentive Plan.

8. In August 2016, we issued 82,194 common shares to Takeda Pharmaceuticals International AG upon the automatic exercise of the warrant set forth in paragraph (4) above.

9. In September 2016, we granted stock options to purchase an aggregate of 572,568 common shares, with a weighted-average exercise price of \$4.00 per share, to our employees and directors under our 2016 Equity Incentive Plan.

10. In September 2016, we issued 78,079 common shares to Takeda Pharmaceuticals International AG upon the automatic exercise of the warrant set forth in paragraph (4) above.

The offers, sales and issuances of the securities set forth in paragraphs (1), (2), (3), (4), (6), (8) and (10) above were deemed to be exempt from registration under Section 4(a)(2) of the Securities Act.

The offers, sales and issuances of the securities set forth in paragraphs (5), (7) and (9) above were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 thereunder as offers and sale of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in compliance with Rule 701.

The offers, sales and issuances of the securities set forth above give effect to the 100,000-for-1 stock split effected on April 27, 2016 and the 1-for-1.7727 reverse stock split to be effected prior to the effective date of this Registration Statement.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

The exhibits to the registration statement are listed in the Exhibit Index attached hereto and are incorporated by reference herein.

(b) Financial Statement Schedules.

See Index to Consolidated Financial Statements on Page F-1. All schedules have been omitted because they are not required or are not applicable.

Item 17. Undertakings.

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant has duly caused this Amendment No. 3 to Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in New York, New York, on the 20th day of October, 2016.

MYOVANT SCIENCES LTD.

By: /s/ Lynn Seely, M.D. Lynn Seely, M.D. Principal Executive Officer

Pursuant to the requirements of the Securities Act, this Amendment No. 3 to Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Lynn Seely, M.D.	Principal Executive Officer and	October 20, 2016
Lynn Seely, M.D.	Director	
/s/ Frank Karbe	Principal Financial and Accounting	October 20, 2016
Frank Karbe	Officer	
*	Director	October 20, 2016
Mark Altmeyer		
*	Director	October 20, 2016
Wayne DeVeydt		
*	Director	October 20, 2016
Keith Manchester, M.D.		
*	Director	October 20, 2016
Vivek Ramaswamy		
*	Director	October 20, 2016
Kathleen Sebelius		
*By: /s/ Lynn Seely, M.D.		
Lynn Seely, M.D.		
Attorney-in-fact		

EXHIBIT INDEX

Exhibit <u>Number</u>	Description of Exhibit
1.1†	Form of Underwriting Agreement.
3.1†	Certificate of Incorporation.
3.2†	Memorandum of Association.
3.3†	Amended and Restated Bye-laws, as currently in effect.
3.4†	Form of Second Amended and Restated Bye-laws, to be effective immediately prior to the closing of this offering.
5.1	Opinion of Conyers Dill & Pearman Limited as to legality.
10.1*	License Agreement, dated April 29, 2016, by and between the Registrant and Takeda Pharmaceuticals International AG, as amended.
10.2*	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.
10.3†	Investor Rights Agreement, dated April 29, 2016, by and between the Registrant, Roivant Sciences Ltd. and Takeda Pharmaceuticals International AG.
10.4*†	Warrant, dated April 29, 2016, issued to Takeda Pharmaceuticals International AG.
10.5+	2016 Equity Incentive Plan, as amended.
10.6+†	Forms of Option Grant Notice and Option Agreement under 2016 Equity Incentive Plan, as amended.
10.7+†	Form of Early Exercise Stock Purchase Agreement under 2016 Equity Incentive Plan, as amended.
10.8+†	Form of Indemnification Agreement with directors and executive officers.
10.9†	Services Agreement, dated as of July 6, 2016, by and among Roivant Sciences, Inc., Myovant Sciences, Inc. and the Registrant.
10.10*†	Option Agreement, dated June 1, 2016, by and between Roivant Sciences Ltd. and the Registrant.
10.11†	Information Sharing and Cooperation Agreement, dated as of July 6, 2016, by and between Roivant Sciences Ltd. and the Registrant.
10.12+*†	Employment Agreement, dated as of May 31, 2016, by and between Lynn Seely, M.D. and Myovant Sciences, Inc.
10.13+†	Offer Letter, dated September 20, 2016, by and between Frank Karbe and Myovant Sciences, Inc.
21.1†	Subsidiaries of the Registrant.
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm.
23.2	Consent of Conyers Dill & Pearman Limited (included in Exhibit 5.1).
24.1†	Powers of Attorney (included on the signature page to this registration statement).
+ Indicator	-

+

Indicates management contract or compensatory plan. Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and have been separately filed with the * Securities and Exchange Commission.

Previously filed. t

Matter No.:354656 Doc Ref: 11590202

+1441-278-7904 edward.rance@conyersdill.com

Myovant Sciences Ltd. Clarendon House 2 Church Street Hamilton HM 11 Bermuda

Dear Sirs,

Re: Myovant Sciences Ltd. (the "Company")

We have acted as special Bermuda legal counsel to the Company in connection with a registration statement on form S-1 as amended (Registration No. 333-213891) initially filed with the U.S. Securities and Exchange Commission (the "Commission") on 30 September, 2016 (the "Registration Statement", which term does not include any other document or agreement whether or not specifically referred to therein or attached as an exhibit or schedule thereto) relating to the registration under the U.S. Securities Act of 1933, as amended, (the "Securities Act") of an aggregate of 13,000,000 common shares, par value US\$0.000017727 each, of which 13,000,000 are being offered by the Company, together with an additional 1,950,000 common shares, par value US\$0.000017727 each, subject to an over-allotment option granted to the underwriters by the Company (all such common shares, collectively, the "Shares").

For the purposes of giving this opinion, we have examined a copy of the Registration Statement. We have also reviewed the memorandum of association and the bye-laws of the Company, each certified by the Secretary of the Company on 14 October, 2016, minutes of a meeting of its board of directors held on 26 September, 2016, and unanimous written resolutions of its board of directors dated 18 October, 2016, each as certified by the Secretary of the Company on 18 October, 2016; written resolutions of its members dated 30 September, 2016, as certified by the Secretary of the Company on 14 October, 2016, and written resolutions of its members dated 18 October, 2016, as certified by the Secretary of the Company on 14 October, 2016, and written resolutions of its members dated 18 October, 2016, as certified by the Secretary of the Company on 18 October, 2016 (collectively, 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 and/or filed 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 accuracy and completeness of all factual representations made in the Registration Statement and other documents reviewed by us, (d) 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, (e) 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, and (f) that upon issue of any Shares to be sold by the Company the Company will receive consideration for the full issue price thereof which shall be equal to at least the par value thereof.

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 the purposes of the filing of the Registration Statement and the offering of the Shares by the Company and is not to be relied upon 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 in good standing (meaning solely that it has not failed to make any filing with any Bermuda government authority or to pay any Bermuda government fees 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).

2. When issued and paid for as contemplated by the Registration Statement, the Shares will be validly issued, fully paid and non-assessable (which term means when used herein that no further sums are required to be paid by the holders thereof in connection with the issue of such Shares).

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement and to the references to our firm under the caption "Legal Matters" in the prospectus forming a part of the Registration Statement. In giving this consent, we do not hereby admit that we are experts within the meaning of Section 11 of the Securities Act or that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the Rules and Regulations of the Commission promulgated thereunder.

Yours faithfully, Conyers Dill & Pearman Limited

/s/ Conyers Dill & Pearman Limited

Edward Rance

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LICENSE AGREEMENT

by and between

TAKEDA PHARMACEUTICALS INTERNATIONAL AG

and

ROIVANT ENDOCRINOLOGY LTD.

Dated as of April 29, 2016

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LICENSE AGREEMENT

This License Agreement (this "<u>Agreement</u>") is made effective as of April 29, 2016 (the "<u>Effective Date</u>") 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 ("<u>Takeda</u>") 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 ("<u>Licensee</u>"). Licensee and Takeda are sometimes referred to herein individually as a "<u>Party</u>" and collectively as the "<u>Parties</u>."

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 "<u>Accounting Standards</u>" means GAAP in the case of Licensee and IFRS in the case of Takeda.

- **1.2** "<u>Adverse Event</u>" or "<u>AE</u>" 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.

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- 1.4 "<u>Applicable Law</u>" 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. "<u>Applicable Law</u>" 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** "<u>Assigned Regulatory Materials</u>" has the meaning set forth in Section 4.3.1 (Licensed Product INDs).
- **1.6** "<u>Bankruptcy Laws</u>" has the meaning set forth in Section 13.14 (Rights in Bankruptcy).
- **1.7** "[<u>***</u>].
- **1.8** "<u>Breaching Party</u>" 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** "<u>Calendar Quarter</u>" 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** "<u>Calendar Year</u>" 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** "<u>Cash-on-Hand</u>" has the meaning set forth in Section 11.4.2 (Cash-on-Hand).
- **1.13** "<u>Change of Control</u>" 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.

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- **1.14** "<u>Claim</u>" has the meaning set forth in Section 15.1 (Indemnification by Licensee).
- **1.15** "<u>Clinical Trial</u>" 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, or any post-approval clinical trial in humans.
- **1.16** "<u>CMC</u>" means chemistry, manufacturing, and controls.
- **1.17** "<u>Combination Product</u>" 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** "<u>Commercial Viability Termination</u>" has the meaning set forth in Section 13.5.1 (Commercial Viability Termination).
- **1.20** "<u>Commercialization</u>" 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 "<u>Commercialization Diligence Obligations</u>" has the meaning set forth in Section 7.2 (Commercialization Diligence Obligations).
- **1.22** "<u>Commercialization Plan</u>" 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** "<u>Competing Product</u>" 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.

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- **1.25** "<u>Complementary Product</u>" 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** "<u>Contact Person</u>" 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** "<u>Control</u>" 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** "<u>Cover</u>" or "<u>Covered</u>" or "<u>Covering</u>" 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** "<u>Cure Period</u>" has the meaning set forth in Section 13.3.1 (Cure Periods).
- **1.32** "<u>Development</u>" 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, "<u>Develop</u>" means to engage in Development activities.

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- **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** "<u>Diligent Efforts</u>" 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** "<u>Endometriosis</u>" 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** "<u>FFDCA</u>" 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** "<u>First Commercial Sale</u>" 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.

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- **1.46** "<u>FTE</u>" 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** "<u>FTE Rate</u>" 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** "<u>Generic Competition Percentage</u>" 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** "<u>Generic Licensed Product</u>" 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** "<u>Good Clinical Practices</u>" or "<u>GCP</u>" 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 "<u>Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance</u>" (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** "<u>Good Laboratory Practices</u>" or "<u>GLP</u>" 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

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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** "<u>Governmental Authority</u>" 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** "<u>ICH</u>" means International Conference on Harmonization.
- **1.57** "<u>IFRS</u>" means the International Financial Reporting Standards as promulgated by the International Standards Accounting Board, as consistently applied.
- **1.58** "<u>IND</u>" 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** "<u>Indemnifying Party</u>" has the meaning set forth in Section 15.3.1 (Notice).
- **1.61** "<u>Indemnitee</u>" has the meaning set forth in Section 15.3.1 (Notice).
- **1.62** "<u>Indication</u>" 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** "<u>Information</u>" 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

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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** "<u>Initial Clinical Supply</u>" 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** "<u>Intellectual Property Rights</u>" 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** "<u>Inventions</u>" 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 ("<u>CCSI</u>"), and company core data sheet ("<u>CCDS</u>").
- 1.76 "Licensed Compound" means a TAK-385 Licensed Compound or a TAK-448 Licensed Compound.

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- 1.77 "Licensed Product" means any TAK-385 Licensed Product or TAK-448 Licensed Product.
- **1.78** "<u>Licensed Product IND</u>" 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 <u>Schedule 1.78(a)</u> (TAK-385 Licensed Product INDs) and <u>Schedule 1.78(b)</u> (TAK-448 Licensed Product INDs).
- **1.79** "<u>Licensed Product Infringement</u>" 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** "<u>Licensee Know-How</u>" 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** "<u>Licensee Obligations</u>" has the meaning set forth in Section 16.8 ([***]).
- **1.85** "<u>Licensee Patent Rights</u>" 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** "<u>Licensee Regulatory Materials</u>" 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).

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- **1.92** "<u>MAA</u>" 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** "<u>Major Market Country</u>" means each of [***].
- **1.94** "<u>Manufacture</u>" or "<u>Manufacturing</u>" 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, "<u>Manufacture</u>" or "<u>Manufacturing</u>" means any and all activities involved in Manufacturing.
- **1.95** "<u>Manufacturing and Supply Agreement</u>" means the Takeda Clinical Manufacturing and Supply Agreement or the Commercial Manufacturing and Supply Agreement (if any), as applicable.
- **1.96** "<u>Manufacturing Arbitration Draft</u>" 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** "<u>NDA</u>" 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 "<u>NDA</u>" herein will refer to a JNDA or MAA as applicable.
- **1.99** "<u>Net Sales</u>" 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:

[***];
[***];
[***];
[***];
[***];
[***]; or
[***].

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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 "<u>Net Sales</u>" 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 "<u>Net Sales</u>" 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 "<u>Net Sales</u>" 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 "<u>Net Sales</u>" definition).

- 1.100 "<u>Neutral Expert</u>" has the meaning set forth in Section 8.2.1 (Notice; Experts).
- 1.101 "<u>Non-Breaching Party</u>" has the meaning set forth in Section 13.3.1 (Cure Periods).
- **1.102** "<u>Notifying Party</u>" has the meaning set forth in Section 6.2.4(b) (Meetings).
- **1.103** "[<u>***</u>]" means [***].

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- **1.104** "[***]" means the Co-Development Agreement dated June 30, 2015 between Takeda and [***].
- **1.105** "<u>On-Going Clinical Trials</u>" 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** "<u>PCT</u>" 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** "<u>Person</u>" 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 "<u>Pharmacovigilance Agreement</u>" has the meaning set forth in Section 6.3.1 (Pharmacovigilance Agreement).
- **1.113** "<u>Phase III Clinical Trial</u>" 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 "<u>PMDA</u>" means the Japanese Pharmaceuticals and Medical Devices Agency and any successor entity.
- 1.115 "<u>Product Trademarks</u>" has the meaning set forth in Section 10.9 (Trademarks).

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- **1.116** "<u>Prosecution</u>" or "<u>Prosecute</u>" 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** "<u>Recall</u>" 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 "<u>Receiving Party</u>" has the meaning set forth in Section 12.1 (Nondisclosure and Non-Use).
- **1.120** "<u>Regulatory Approval</u>" 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** "<u>Regulatory Authority</u>" 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** "<u>Regulatory Exclusivity</u>" 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** "<u>Regulatory Materials</u>" 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 "<u>Reimbursed Expenses</u>" has the meaning set forth in Section 13.9.2(b)(i) (Clinical Trial Completion).
- 1.125 "<u>ROFN Notice Period</u>" has the meaning set forth in Section 3.7 (Right of First Negotiation).
- **1.126** "<u>ROFN Period</u>" has the meaning set forth in Section 3.7 (Right of First Negotiation).
- 1.127 "<u>Royalties</u>" has the meaning set forth in Section 9.2.1 (Royalty Rates).
- 1.128 "<u>Royalty Report</u>" has the meaning set forth in Section 9.3 (Manner of Payment; Royalty Reports).

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- **1.129** "<u>Royalty Term</u>" 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** "<u>RSL</u>" means Roivant Sciences Ltd., a Bermuda exempt limited company.
- **1.131** "<u>RSL Collaboration Agreement</u>" 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, i
- **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).

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- **1.138** "<u>TAK-385 Development Plan</u>" 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 <u>Schedule 5.3</u> (TAK-385 Development Plan), as may be amended in accordance with Section 5.3 (Development Plans).
- **1.139** "<u>TAK-385 Licensed Compound</u>" means: (a) the chemical compound coded by Takeda as TAK-385 and the structure of which is set forth on <u>Schedule 1.138</u> (TAK-385 Licensed Compound); (b) any compound other than TAK-385 that is Covered by any Takeda Patent Right set forth on <u>Schedule 1.151</u> (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** "<u>TAK-448 Licensed Compound</u>" means: (a) the oligopeptide coded by Takeda as TAK-448 and the structure of which is set forth on <u>Schedule</u> <u>1.141</u> (TAK-448 Licensed Compound); (c) any oligopeptide other than TAK-448 that is Covered by any Takeda Patent Right set forth on <u>Schedule</u> <u>1.151</u> (Takeda Patent Rights) that also Covers TAK-448; and (d) any [***] of any compound described in clause (a).
- **1.142** "<u>TAK-448 Licensed Product</u>" 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 "<u>Takeda Know-How</u>" 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** "<u>Takeda Manufacturing Know-How</u>" 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).

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- **1.151** "<u>Takeda Patent Rights</u>" means (a) those Patent Rights set forth on <u>Schedule 1.151 part (a)</u> (TAK-385 Patent Rights), (b) those Patent Rights set forth on <u>Schedule 1.151 part (b)</u> (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** "<u>Takeda Regulatory Materials</u>" 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** "<u>Takeda Territory</u>" 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** "<u>Term</u>" has the meaning set forth in Section 13.1 (Term).
- **1.158** "<u>Terminated Compound</u>" 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** "<u>Terminated Product</u>" has the meaning set forth in Section 13.9.1 (All Termination Events).
- **1.161** "<u>Territory</u>" means the Licensee Territory and the Takeda Territory. When used to refer to a Party's Territory, "<u>Territory</u>" 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** "<u>Third Party Distributor</u>" 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** "<u>Trademark</u>" 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.

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- **1.166** "<u>Transaction Agreements</u>" 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** "<u>Transition Plan</u>" 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** "<u>Uterine Fibroids</u>" means the condition in which a non-cancerous tumor originates from the uterus.
- **1.171** "<u>Valid Claim</u>" 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 <u>Establishment; Responsibilities</u>. 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 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);

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- (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);
- 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

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(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.

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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 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 <u>Expenses</u>. 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 ("<u>Withdrawal Notice</u>"). 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

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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 "<u>Contact Person</u>"), 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 <u>Non-Exclusive License Grant</u>. Subject to the terms and conditions of this Agreement, Takeda hereby grants to Licensee a nonexclusive, 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

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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 <u>Non-Exclusive License Grant</u>. Subject to the terms and conditions of this Agreement, Licensee hereby grants to Takeda a nonexclusive, 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 <u>Right to Sublicense</u>. 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 "<u>Sublicensee</u>") 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.

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- 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 <u>Performance by Licensee Sublicensees</u>. 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 "<u>Subcontractor</u>"); *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

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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.

- Takeda Retained Rights. Any rights of Takeda not expressly granted to Licensee under the provisions of this Agreement will be 3.5.1 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 nonexclusive 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

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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 "<u>ROFN Notice Period</u>") 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 "<u>ROFN Period</u>"). 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 <u>Transition Services</u>. Takeda will perform certain services to facilitate the technology transfer described in Section 4.2 (Technology Transfer) in accordance with the Transition Plan (the "<u>Transition Services</u>"). 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

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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 <u>Takeda Materials Disclaimer</u>. 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 "<u>IND</u> <u>Transfer Date</u>".
- 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 "<u>Assigned</u> <u>Regulatory Materials</u>"). 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.

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- 4.3.4 <u>Clinical Trial Data</u>. 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 <u>Initial Development Activities</u>. 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 <u>Takeda Development</u>. 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.

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- 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.
- Development Plans. During the Term, Licensee will conduct all Development activities in connection with the TAK-385 Licensed Compound or 5.3 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 <u>General Reporting</u>.

(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

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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 <u>Exclusivity Covenants</u>.
 - (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 <u>Excluded Affiliate Divestitures</u>. 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 <u>Licensee Right of First Option</u>. 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

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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 <u>Options</u>. 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 <u>Divestiture or Termination</u>. 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 until it is 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 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.

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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 <u>Takeda Ownership</u>. 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 <u>Takeda Responsibilities</u>. Subject to Applicable Law and this Section 6.2 (Regulatory Cooperation), Takeda will, at is sole expense, oversee, monitor, and manage all

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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 <u>Common Technical Documents</u>. 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 <u>Cooperation, Meetings and Sharing Final Materials</u>.

- (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) <u>Meetings</u>. Each Party (the "<u>Notifying Party</u>") 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;

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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 <u>Pharmacovigilance Agreement</u>. 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 "<u>Pharmacovigilance Agreement</u>"). 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 <u>Safety Data Exchange</u>. 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

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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 <u>Clinical Trial Holds</u>. 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 take such actions as reasonably cooperate in all such efforts. All expenses incurred in connection with any 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 Licensee of amounts paid for such TAK-385 Licensed Product in the 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.

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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 <u>Of Licensee</u>. 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 <u>Of Takeda</u>. 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 "<u>Takeda Diligence Obligations</u>").

7.3 Commercialization Plans.

- Licensee Commercialization Plans. Licensee will perform all Commercialization activities in accordance with the terms and 7.3.1 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 <u>Takeda Commercialization Plans</u>. 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

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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 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 Bealth Field render Commercialization Plan. Following the [***] anniversary of the First Commercial Sale of the first TAK-385 Licensed Product in the Men's Health Field 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 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 Commercialization 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 (Commerc

7.4 Commercialization Reporting.

- 7.4.1 <u>Licensee Obligations</u>. 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 <u>Takeda Obligations</u>. 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 <u>Clinical Supply</u>. 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

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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 "<u>Initial Clinical Supply</u>") 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 "<u>Takeda</u> <u>Clinical Manufacturing and Supply Agreement</u>"), 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 <u>Commercial Supply</u>. 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 "<u>Commercial Manufacturing and Supply Agreement</u>"). 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 <u>Licensee CMO Engagement</u>. 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.

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- **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 <u>Arbitration Drafts</u>. 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 "<u>Manufacturing Arbitration Draft</u>") 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 <u>Arbitration Proceedings</u>. 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
 - 8.2.4 <u>Expenses</u>. [***].
- 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,

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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 <u>Schedule 9.1(a)</u> (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 <u>Schedule 9.1(b</u>) (Takeda Warrant) to purchase Licensee's capital stock (the "<u>Warrant</u>").

9.2 Royalties.

- 9.2.1 <u>Royalty Rates</u>. 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, "<u>Royalties</u>").
 - (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 ("<u>Takeda</u> <u>Royalties</u>"). 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 <u>Royalty Term</u>. 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 <u>Royalty Reductions</u>.
 - (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

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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 "<u>Royalty Report</u>") 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 "<u>Net Sales</u>", (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

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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 <u>Payment of Tax</u>. 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 <u>Tax Residence Certificate</u>. 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 <u>Assessment</u>. 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 <u>Assignment</u>. 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.

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- **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 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 accountant's report. The requesting Party will bear the full cost of 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 "<u>carve out</u>" financial statements related to the 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.

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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 "<u>Sole Inventions</u>"). 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 "<u>Joint Inventions</u>").

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).

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- 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).
- **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

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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.

Prosecution in the Takeda Territory. Except as otherwise provided in this Section 10.4.2 (Prosecution in the Takeda Territory), as 10.4.2 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 <u>Covenants in Support of Assignment</u>.

(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

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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 <u>Pending PCT Application</u>. The Parties acknowledge as of the Effective Date patent application number [***] has been filed under the PCT (the "<u>Pending PCT Application</u>"). 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 <u>Cooperation in Prosecution</u>. 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

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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 <u>Takeda Territory</u>. 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 <u>Cooperation</u>. 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 <u>Notification</u>. 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.

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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.

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- (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 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 royalties from a license agreement with a Stollows: (a) [***], then [***], then [***] of any such monetary damages.

10.7 Infringement of Third Party Rights.

- 10.7.1 <u>Notice</u>. 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 "<u>Third Party IP Claim</u>").
- 10.7.2 <u>Defense in the Licensee Territory</u>.
 - (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.

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- (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 <u>Takeda Territory</u>. 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 <u>Third Party Patent Rights</u>. 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.

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- 10.8.2 <u>Parties' Patent Rights</u>. 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 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 "<u>Product Trademarks</u>"); *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 Product in the Takeda Territory, and in the case of Licensee, with respect to the Commercialization of TAK-385 Licensed Product Trademarks") to Commercialize TAK-385 Licensed Product in the Takeda Product Trademarks") to Commercialize TAK-385 Licensee and Takeda will enter into a separate trademark license agreement containing commercially reasonable and customary terms pursuant to which Licensee or Takeda, as

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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 <u>Organization</u>. 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 <u>Binding Agreement</u>. 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 <u>Authorization</u>. 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 <u>No Further Approval</u>. 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 <u>No Inconsistent Obligations</u>. 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 <u>Transparency Reporting</u>. 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."

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11.2 Additional Representations and Warranties of Takeda.

Takeda represents and warrants as of the Effective Date to Licensee that:

- 11.2.1 <u>Sufficient Rights</u>. 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 <u>Ownership of Takeda Patent Rights</u>. Takeda is the sole and exclusive owner of the entire right, title, and interest in the Takeda Patent Rights set forth on <u>Schedule 1.151</u> (Takeda Patent Rights) free of any encumbrance, lien, or claim of ownership by any Third Party.
- 11.2.3 <u>Completeness of Patent Schedule</u>. <u>Schedule 1.151</u> (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 <u>Infringement</u>. 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 <u>No Government Funding</u>. The Inventions claimed or disclosed by the Takeda Patent Rights set forth on <u>Schedule 1.151</u> (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,

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(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 <u>No Debarment</u>. 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 <u>No Claims</u>. 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 <u>Safety Data</u>. 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 <u>Regulatory Materials</u>. 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 <u>No Conflicting Rights</u>. 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 <u>No Debarment</u>. 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

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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 <u>Invention Assignment</u>. 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 <u>Foreign Corruption Compliance</u>. 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 <u>No Debarment</u>. 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 <u>Cash-on-Hand</u>. Licensee or RSL has at least [***] in immediately available funds as of the Effective Date (the "<u>Cash-on-Hand</u>"). The bank statements of RSL attached hereto as <u>Schedule 11.4.2</u> (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 <u>No Debarment</u>. 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.

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- 11.5.2 <u>Specific Notifications Regarding Licensed Products</u>. 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 <u>Foreign Corruption Compliance</u>. 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 <u>Non-Solicit</u>. 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 "<u>AS IS</u>" 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.

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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 "<u>Receiving Party</u>") receiving Confidential Information of the other Party (the "<u>Disclosing Party</u>") 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 <u>Permitted Disclosure</u>. 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

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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 "<u>need-to-know</u>" 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

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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 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 <u>Publication Plan</u>. 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 <u>Publication Guidelines</u>. 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

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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 "<u>Term</u>"). 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's receipt of the first Regulatory Approval for a Licensed Product for the Terminated Field in the Licensee's receipt of the first Regulatory Approval for a Licensed Product for the Terminated Field in the Licensee's receipt of the first Regulatory Approval for a Licensed Product for the Terminated Field in the Licensee's receipt of the first Regulatory Approval for a Licensed Product for the Terminated Field in the Licensee's receipt of the first Regulatory Approval for a Licensed Product for the Terminated Field in the Licensee's receipt of the first Regulatory Approval for a Licensed Product for the Terminated Field in the Licensee's receipt of the first Regulatory Approval for a Licensed Product for the Terminated Field in the Licensee's receipt of the first Regulatory Approval for a Licensed Product for the Terminated Field in the Licensee's receipt of the first Regulatory Approval for a Licensee's receipt field in the Licensee's receipt field in the Licensee's receipt field in the Licensee's receipt field field in the Licensee's receipt field field field field field field field field

13.3 Termination for Material Breach.

13.3.1 <u>Cure Periods</u>. Either Party (the "<u>Non-Breaching Party</u>") 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 "<u>Breaching Party</u>") 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 other breach (as applicable, the "<u>Cure Period</u>"). 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.

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13.3.2 <u>Tolling of Cure Period</u>. 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 <u>Termination by Licensee</u>. 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 thenavailable data, to preclude continued Development or Commercialization of a Licensed Product (such termination, a "<u>Safety</u> <u>Termination</u>"). 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 <u>Termination by Consensus</u>. 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 <u>Commercial Viability Termination</u>. 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 "<u>Commercial Viability Termination</u>").
- 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

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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 <u>All Termination Events</u>. 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 "<u>Terminated Compounds</u>" and "<u>Terminated Products</u>", respectively), or the Men's Health Field or the Women's Health Field for the TAK-385 Licensed Compound (the "<u>Terminated Field</u>"):
 - (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

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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 <u>Certain Termination Events</u>. 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 Terminated Products in the Terminated Field in the Terminated Territory.
 - (b) Clinical Trials.(i) Clin

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 [***] (such amount, the "<u>Reimbursed Expenses</u>"); 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).

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- (ii) <u>Clinical Trial Wind-Down</u>. 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) <u>Clinical Trial Information and Documents</u>. 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 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) 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.

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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.

(d)

- (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 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 Rights 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.

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- Selected Third Party Agreements. In the event Licensee has assumed responsibility for Manufacturing any Terminated (h) 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 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 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 13.3 (Termination for Material Breach), or by Takeda pursuant to Section 13.5 (Termination for Commercial Viability) 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 <u>Licenses to Licensee</u>. 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 <u>Licenses to Takeda</u>. 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 <u>Expiration of Term in Entirety</u>. 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

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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 13.19 (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").

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- 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, or 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 should be stayed by reason of the 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

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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 "<u>Takeda Indemnitee</u>") from and against any and all claims, suits, actions, demands or other proceedings brought by any Third Party (each, a "<u>Claim</u>") and all liabilities, expenses, damages, or losses, including reasonable legal expense and attorneys' fees (collectively, "<u>Losses</u>"), 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 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, 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.
- 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 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 in this Agreement.

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15.3 Indemnification Procedures.

- 15.3.1 <u>Notice</u>. Promptly after a Takeda Indemnitee or a Licensee Indemnitee (each, an "<u>Indemnitee</u>") 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 "<u>Indemnifying Party</u>"). 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 <u>Defense</u>. 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 Indemnifee, (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 <u>Cooperation</u>. 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 <u>Settlement</u>. 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

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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

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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.

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- **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

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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]

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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:			

[Signature Page to License Agreement]

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		
	[C:t		

[Signature Page to License Agreement]

Part (a) – TAK-385 Patent Rights

[***]

<u>Schedule 1.78(a)</u>

TAK-385 Licensed Product INDs

IND Nos. [***]

<u>Schedule 1.78(b)</u>

TAK-448 Licensed Product INDs

IND [***]

Schedule 1.138

[***]

Schedule 1.141

[***]

Schedule 5.3

[***]

Schedule 9.1(a)

Subscription Agreement

EXECUTION VERSION

Dated this April 29, 2016

BETWEEN:

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,

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	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 <u>Exhibit A</u> (the " Investor Rights Agreement ") and that certain Right of First Refusal and Co-Sale Agreement in the form attached hereto as <u>Exhibit B</u> (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
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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 <u>Schedule 1</u> in the register of members of the Company.

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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 <u>Section 3.2</u>, 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

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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 <u>Section 4.3</u> 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.

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- 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,

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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

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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 <u>Sections 4.1</u> and <u>4.2</u> 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.

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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.

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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.

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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:

[Signature Page to REL Subscription Agreement]

AGREED by the Parties through their authorised signatories on the date first written above:

For, and on behalf of

TAKEDA PHARMACEUTICALS INTERNATIONAL AG

[Signature Page to REL Subscription Agreement]

[***] = Portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission. C	Confidential treatment
requested under 17 C.F.R. Sections 200.80(b)(4) and 230.406.	

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

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 <u>Schedule A</u> hereto and the Key Holders set forth on <u>Schedule B</u> 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 <u>Schedule A</u> hereto and each Person to whom the rights of such parties are assigned pursuant to <u>Subsection 6.8</u>, each Person who hereafter becomes a signatory to this Agreement pursuant to <u>Subsection 6.15</u> 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 <u>Schedule B</u> hereto, each Person to whom the rights of a Key Holder are assigned pursuant to <u>Subsection 3.1</u>, each Person who hereafter becomes a signatory to this Agreement pursuant to <u>Subsection 6.8</u> or <u>6.16</u> 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.

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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) <u>Grant</u>. Subject to the terms of <u>Section 3</u> 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) <u>Notice</u>. 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 Transfere and the intended date of the Proposed Key Holder Transfer. To exercise its Right of First Refusal under this <u>Section 2</u>, 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 <u>Subsection 2.1(a)</u> and this <u>Subsection 2.1(b)</u>.

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(c) <u>Grant of Secondary Refusal Right to the Investors</u>. Subject to the terms of <u>Section 3</u> 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 <u>Subsection 2.1(c)</u>. 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) <u>Undersubscription of Transfer Securities</u>. 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 <u>Subsection 2.1(c)</u> (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 <u>Subsection 2.1(d)</u>, 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 <u>Subsection 2.1(d)</u> 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) <u>Consideration; Closing</u>. 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) <u>Shares Includable</u>. 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 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) <u>Purchase and Sale Agreement</u>. The Participating Investors and the selling Key Holder agree that the terms and conditions of any Proposed Key Holder Transfer in accordance with <u>Subsection 2.2</u> 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 <u>Subsection 2.2</u>.

(d) <u>Allocation of Consideration</u>. Subject to <u>Subsection 2.2(d)(ii)</u>, 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 <u>Subsection 2.2(b)</u>, <u>provided</u> 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.

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(e) <u>Purchase by Selling Key Holder; Deliveries</u>. Notwithstanding <u>Subsection 2.2(c)</u> 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 <u>Subsection 2.2(d)(i)</u>. 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 Proposed Transfere 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 <u>Subsection 2.2(e)</u>.

(f) <u>Additional Compliance</u>. 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 <u>Section 2</u>. 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 <u>Subsection 2.2</u>.

2.3 Effect of Failure to Comply.

(a) <u>Transfer Void; Equitable Relief</u>. 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) <u>Violation of First Refusal Right</u>. 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,

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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) <u>Violation of Co-Sale Right</u>. 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 <u>Subsection 2.2</u>, 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 <u>Subsection 2.2</u>. The sale will be made on the same terms, including, without limitation, as provided in <u>Subsection 2.2(d)(i)</u> and the first sentence of <u>Subsection 2.2(d)(i)</u>, 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 <u>Subsection 2.2</u>. 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 <u>Subsection 2.2</u>.

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 <u>Section 2</u>.

3.2 <u>Exempted Offerings</u>. Notwithstanding the foregoing or anything to the contrary herein, the provisions of <u>Section 2.1</u> shall not apply to the sale of any Transfer

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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 <u>Section 2.2</u> 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 <u>Prohibited Transferees</u>. 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. <u>Legend</u>. 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 <u>Subsection 3.1</u> 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 <u>Section 4</u> 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. <u>"Market Stand-off" Agreement</u>. 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

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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 <u>Section 5</u> 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; <u>provided</u> that such Affiliate shall agree to be bound by the provisions of this <u>Section 5</u> with respect to future transfers; <u>provided further</u> that this <u>Section 5</u> 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 <u>Section 5</u> 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 <u>Section 5</u> 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 per

6. Miscellaneous.

6.1 <u>Term</u>. 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 <u>Ownership</u>. 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 <u>WAIVER OF JURY TRIAL</u>. 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

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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 <u>Notices</u>. 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 <u>Schedule A</u> and <u>Schedule B</u>, 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 <u>Entire Agreement</u>. 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 <u>Delays or Omissions</u>. 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 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 <u>Amendment; Waiver and Termination</u>. This Agreement may be amended, modified or terminated (other than pursuant to <u>Section 6.1</u> 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

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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 <u>Severability</u>. 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.

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6.10 <u>Governing Law and Jurisdiction</u>. 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 <u>Titles and Subtitles</u>. 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 <u>Counterparts</u>. 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 <u>Aggregation of Securities</u>. 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 <u>Specific Performance</u>. 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 <u>Additional Investors</u>. 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 <u>Additional Key Holders</u>. 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]

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COMPANY:

ROIVANT ENDOCRINOLOGY LTD.

By:

Name:

Title:

Address:

Clarendon House 2 Church Street Hamilton HM 11 Bermuda

[Signature page to REL Right of First Refusal and Co-Sale Agreement]

INVESTORS:

TAKEDA PHARMACEUTICALS INTERNATIONAL AG

By: ______Name:

Title:

[Signature page to REL Right of First Refusal and Co-Sale Agreement]

INVESTORS:

Title:

[Signature page to REL Right of First Refusal and Co-Sale Agreement]

KEY HOLDERS:

TAKEDA PHARMACEUTICALS INTERNATIONAL AG

[Signature page to REL Right of First Refusal and Co-Sale Agreement]

KEY HOLDERS:

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

<u>Key Holders</u>

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

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 New York (the "**Delaware Courts**"); (l) the validity and binding effect under the 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 subdivision 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

<u>Schedule 9.1(b)</u>

Takeda Warrant

Financial Statements

[***]

AMENDMENT TO LICENSE AGREEMENT

This Amendment to the License Agreement (this "<u>Amendment</u>"), effective as of August 30, 2016 (the "<u>Amendment Effective Date</u>"), modifies and amends the License Agreement, with the effective date of April 29, 2016 (the "<u>License Agreement</u>"), by and between Roivant Endocrinology Ltd. (n/k/a Myovant Sciences Ltd., Clarendon House, 2 Church Street, Hamilton, Bermuda ("<u>Myovant</u>") and Takeda Pharmaceuticals International AG, Thurgauerstrasse 130, 8152, Glattpark-Opfikon Zurich, Switzerland ("<u>Takeda</u>").

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.)

TAKEDA PHARMACEUTICALS INTERNATIONAL AG

By: /s/ Marianne L. Romeo

Name:	Marianne L. Romeo
Title:	Head, Global Transactions & Risk Management

By: /s/ Marcello Agosti

 Name:
 Marcello Agosti

 Title:
 Head of Global Commercial

Part (a) – TAK-385 Patent Rights

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Part (b) – TAK-448 Patent Rights

[***]

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:

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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: [***].

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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.

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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.

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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 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

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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

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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

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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

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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.

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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, 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.

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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.

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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;

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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.

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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.

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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

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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

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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.

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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 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 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

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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]

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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]

A-1

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

[***]

CONFIDENTIAL

EXHIBIT B

Formulations of Drug Product

[Appears on following page]

B-1

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TAK-385 Tablet Formulations
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[***]

B-1

EXHIBIT C

Initial Rolling Forecast

Myovant Forecast of Desired Quantities of Drug Substance and Formulation of Drug Product

[***]

C-1

[***]

C-2

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. <u>Description of Services</u>:
- 2. Project Start Date:
- 3. Estimated Completion Date:
- 4. <u>Description of Services</u>:
- 5. <u>Company Purchase Order No.</u>:
- 6. <u>Fees</u>. 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. <u>Expenses</u>. 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. <u>Payment Terms and Schedule</u>. 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.

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MYOVANT SCIENCES LTD.	TAKEDA PHARMACEUTICAL COMPANY LIMITED
Signature:	Signature:
Name:	Name:
Title:	Title:
Date:	Date:

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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.

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(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.

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This Amendment is accepted and agreed by the Parties through their duly authorized representatives below as of the Amendment Date.

TAKEDA PHARMACEUTICALS COMPANY LIMITED

By:

/s/ Shigeo Yanai

Name: Shigeo Yanai

MYOVANT SCIENCES LTD.

By: /s/ Marianne L. Romer

Name: Marianne L. Romer

Title: Head, Global Transactions & Risk Management

Title: Japan Head of Formulation Development, Pharmaceutical Sciences

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MYOVANT SCIENCES LTD.

2016 EQUITY INCENTIVE PLAN, AS AMENDED AND RESTATED

Adopted by the Board of Directors: September 26, 2016 Approved by the Shareholders: September 29, 2016

EFFECTIVE DATE: _____, 2016

1. GENERAL.

(a) Eligible Award Recipients. Employees, Directors and Consultants are eligible to receive Awards.

(b) Available Awards. The Plan provides for the grant of the following types of Awards: (i) Incentive Stock Options, (ii) Nonstatutory Stock Options, (iii) Stock Appreciation Rights, (iv) Restricted Stock Awards, (v) Restricted Stock Unit Awards, (vi) Performance Stock Awards, (vii) Performance Cash Awards, and (viii) Other Stock Awards.

(c) **Purpose.** The Plan, through the granting of Awards, is intended to help the Company secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate and provide a means by which the eligible recipients may benefit from increases in value of the Common Stock.

2. ADMINISTRATION.

(a) Administration by Board. The Board will administer the Plan. The Board may delegate administration of the Plan to a Committee or Committees, as provided in Section 2(c).

(b) Powers of Board. The Board will have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To determine (A) who will be granted Awards; (B) when and how each Award will be granted; (C) what type of Award will be granted; (D) the provisions of each Award (which need not be identical), including when a person will be permitted to exercise or otherwise receive cash or Common Stock under the Award; (E) the number of shares of Common Stock subject to, or the cash value of, an Award; and (F) the Fair Market Value applicable to an Award.

(ii) To construe and interpret the Plan and Awards granted under it, and to establish, amend and revoke rules and regulations for administration of the Plan and Awards. The Board, in the exercise of these powers, may correct any defect, omission or inconsistency in the Plan or in any Award Agreement or in the written terms of a Performance Cash Award, in a manner and to the extent it will deem necessary or expedient to make the Plan or Award fully effective.

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(iii) To settle all controversies regarding the Plan and Awards granted under it.

(iv) To accelerate, in whole or in part, the time at which an Award may be exercised or vest (or at which cash or shares of Common Stock may be issued).

(v) To suspend or terminate the Plan at any time. Except as otherwise provided in the Plan or an Award Agreement, suspension or termination of the Plan will not impair a Participant's rights under his or her then-outstanding Award without his or her written consent except as provided in subsection (viii) below.

(vi) To amend the Plan in any respect the Board deems necessary or advisable, including, without limitation, by adopting amendments relating to Incentive Stock Options and certain nonqualified deferred compensation under Section 409A of the Code and/or to make the Plan or Awards granted under the Plan compliant with the requirements for Incentive Stock Options or exempt from or compliant with the requirements for nonqualified deferred compensation under Section 409A of the Code, subject to the limitations, if any, of applicable law. However, if required by applicable law or listing requirements, and except as provided in Section 9(a) relating to Capitalization Adjustments, the Company will seek shareholder approval of any amendment of the Plan that (A) materially increases the number of shares of Common Stock available for issuance under the Plan, (B) materially expands the class of individuals eligible to receive Awards under the Plan, (C) materially increases the benefits accruing to Participants under the Plan, or (F) materially expands the types of Awards available for issuance under the Plan, or (F) materially expands the types of Awards available for issuance under the Plan. Except as otherwise provided in the Plan or an Award Agreement, no amendment of the Plan will materially impair a Participant's rights under an outstanding Award unless (1) the Company requests the consent of the affected Participant, and (2) such Participant consents in writing.

(vii) To submit any amendment to the Plan for shareholder approval, including, but not limited to, amendments to the Plan intended to satisfy the requirements of (A) Section 162(m) of the Code regarding the exclusion of performance-based compensation from the limit on corporate deductibility of compensation paid to Covered Employees, (B) Section 422 of the Code regarding Incentive Stock Options, or (C) Rule 16b-3.

(viii) To approve forms of Award Agreements for use under the Plan and to amend the terms of any one or more Awards, including, but not limited to, amendments to provide terms more favorable to the Participant than previously provided in the Award Agreement, subject to any specified limits in the Plan that are not subject to Board discretion; *provided however*, that a Participant's rights under any Award will not be impaired by any such amendment unless (A) the Company requests the consent of the affected Participant, and (B) such Participant consents in writing. Notwithstanding the foregoing, (1) a Participant's rights will not be deemed to have been impaired by any such amendment if the Board, in its sole discretion, determines that the amendment, taken as a whole, does not materially impair the Participant's rights, and (2) subject to the limitations of applicable law, if any, the Board may amend the terms of any one or more Awards without the affected Participant's consent (A) to maintain the qualified status of the Award as an Incentive Stock Option under Section 422 of the Code; (B) to change the terms of an Incentive Stock Option, if such change results in impairment

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of the Stock Award solely because it impairs the qualified status of the Stock Award as an Incentive Stock Option under Section 422 of the Code; (C) to clarify the manner of exemption from, or to bring the Award into compliance with, Section 409A of the Code; or (D) to comply with other applicable laws or listing requirements.

(ix) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan or Awards.

(x) To adopt such procedures and sub-plans as are necessary or appropriate to permit participation in the Plan by Employees, Directors or Consultants who are foreign nationals or employed outside the United States (provided that Board approval will not be necessary for immaterial modifications to the Plan or any Award Agreement that are required for compliance with the laws of the relevant foreign jurisdiction).

(xi) To effect, with the consent of any adversely affected Participant, (A) the reduction of the exercise, purchase or strike price of any outstanding Award; (B) the cancellation of any outstanding Stock Award and the grant in substitution therefor of a new (1) Option or SAR, (2) Restricted Stock Award, (3) Restricted Stock Unit Award, (4) Other Stock Award, (5) cash and/or (6) other valuable consideration determined by the Board, in its sole discretion, with any such substituted award (x) covering the same or a different number of shares of Common Stock as the cancelled Stock Award and (y) granted under the Plan or another equity or compensatory plan of the Company; or (C) any other action that is treated as a repricing under generally accepted accounting principles.

(c) Delegation to Committee.

(i) General. The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board will thereafter be to the Committee or subcommittee, as applicable). Any delegation of administrative powers will be reflected in resolutions, not inconsistent with the provisions of the Plan, adopted from time to time by the Board or Committee (as applicable). The Board may retain the authority to concurrently administer the Plan with the Committee and may, at any time, revest in the Board some or all of the powers previously delegated.

(ii) Section 162(m) and Rule 16b-3 Compliance. The Committee may consist solely of two or more Outside Directors, in accordance with Section 162(m) of the Code, or solely of two or more Non-Employee Directors, in accordance with Rule 16b-3.

(d) Delegation to an Officer. The Board may delegate to one (1) or more Officers the authority to do one or both of the following: (i) designate Employees who are not Officers to be recipients of Options and SARs (and, to the extent permitted by applicable law, other Stock Awards) and, to the extent permitted by applicable law, the terms of such Stock Awards, and (ii)

determine the number of shares of Common Stock to be subject to such Stock Awards granted to such Employees; provided, however, that the Board resolutions regarding such delegation will specify the total number of shares of Common Stock that may be subject to the Stock Awards granted by such Officer and that such Officer may not grant a Stock Award to himself or herself. Any such Stock Awards will be granted on the form of Stock Award Agreement most recently approved for use by the Committee or the Board, unless otherwise provided in the resolutions approving the delegation authority. The Board may not delegate authority to an Officer who is acting solely in the capacity of an Officer (and not also as a Director) to determine the Fair Market Value pursuant to Section 13(x)(iii) below.

(e) Effect of Board's Decision. All determinations, interpretations and constructions made by the Board in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

3. SHARES SUBJECT TO THE PLAN.

(a) Share Reserve.

(i) Subject to Section 9(a) relating to Capitalization Adjustments and the following sentence regarding the annual increase, the aggregate number of shares of Common Stock that may be issued pursuant to Stock Awards from and after the Effective Date will not exceed 4,512,889 shares (the "*Share Reserve*"). In addition, the Share Reserve will automatically increase on April 1st of each year, for the period commencing on (and including) April 1, 2017 and ending on (and including) April 1, 2026, in an amount equal to four percent (4%) of the total number of shares of Capital Stock outstanding on March 31st of the preceding fiscal year. Notwithstanding the foregoing, the Board may act prior to March 31st of a given year to provide that there will be no April 1st increase in the Share Reserve for such year or that the increase in the Share Reserve for such year will be a lesser number of shares of Common Stock than would otherwise occur pursuant to the preceding sentence.

(ii) For clarity, the Share Reserve in this Section 3(a) is a limitation on the number of shares of Common Stock that may be issued pursuant to the Plan. Accordingly, this Section 3.(a) does not limit the granting of Stock Awards except as provided in Section 7(a).

(iii) Shares may be issued in connection with a merger or acquisition as permitted by NASDAQ Listing Rule 5635(c) or, if applicable, NYSE Listed Company Manual Section 303A.08, AMEX Company Guide Section 711 or other applicable rule, and such issuance will not reduce the number of shares available for issuance under the Plan.

(b) Reversion of Shares to the Share Reserve. If a Stock Award or any portion thereof (i) expires or otherwise terminates without all of the shares covered by such Stock Award having been issued or (ii) is settled in cash (i.e., the Participant receives cash rather than stock), such expiration, termination or settlement will not reduce (or otherwise offset) the number of shares of Common Stock that may be available for issuance under the Plan. If any shares of Common Stock issued pursuant to a Stock Award are forfeited back to or repurchased by the Company because of the failure to meet a contingency or condition required to vest such shares in the Participant, then the shares that are forfeited or repurchased will revert to and again

become available for issuance under the Plan. Any shares reacquired by the Company in satisfaction of tax withholding obligations with respect to a Stock Award or as consideration for the exercise or purchase price of a Stock Award will again become available for issuance under the Plan.

(c) Incentive Stock Option Limit. Subject to the provisions of Section 9(a) relating to Capitalization Adjustments, the aggregate maximum number of shares of Common Stock that may be issued pursuant to the exercise of Incentive Stock Options will be 22,564,449 shares of Common Stock.

(d) Section 162(m) Limitations. Subject to the provisions of Section 9.(a) relating to Capitalization Adjustments, at such time as the Company may be subject to the applicable provisions of Section 162(m) of the Code, the following limitations shall apply.

(i) A maximum of 1,128,222 shares of Common Stock subject to Options, SARs and Other Stock Awards whose value is determined by reference to an increase over an exercise or strike price of at least 100% of the Fair Market Value on the date the Stock Award is granted may be granted to any one Participant during any one fiscal year of the Company. Notwithstanding the foregoing, if any additional Options, SARs or Other Stock Awards whose value is determined by reference to an increase over an exercise or strike price of at least 100% of the Fair Market Value on the date the Stock Award whose value is determined by reference to an increase over an exercise or strike price of at least 100% of the Fair Market Value on the date the Stock Award are granted to any Participant during any one fiscal year, compensation attributable to the exercise of such additional Stock Awards will not satisfy the requirements to be considered "qualified performance-based compensation" under Section 162(m) of the Code unless such additional Stock Award is approved by the Company's shareholders.

(ii) A maximum of 1,128,222 shares of Common Stock subject to Performance Stock Awards may be granted to any one Participant during any one fiscal year of the Company (whether the grant, vesting or exercise is contingent upon the attainment during the Performance Period of the Performance Goals).

(iii) A maximum of value of \$1,000,000 may be granted as a Performance Cash Award to any one Participant during any one fiscal year of the Company.

(e) Source of Shares. The stock issuable under the Plan will be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market or otherwise.

4. ELIGIBILITY.

(a) Eligibility for Specific Stock Awards. Incentive Stock Options may be granted only to employees of the Company or a "parent corporation" or "subsidiary corporation" thereof (as such terms are defined in Sections 424(e) and 424(f) of the Code). Stock Awards other than Incentive Stock Options may be granted to Employees, Directors and Consultants; *provided, however*, that Stock Awards may not be granted to Employees, Directors and Consultants; *provided, however*, that Stock Awards may not be granted to Employees, Directors and Consultants who are providing Continuous Service only to any "parent" of the Company, as such term is defined in Rule 405, unless (i) the stock underlying such Stock Awards is treated as "service recipient stock" under Section 409A of the Code (for example, because the Stock Awards are granted pursuant to a corporate transaction such as a spin off transaction), or (ii) the Company, in consultation with its legal counsel, has determined that such Stock Awards comply with the distribution requirements of Section 409A of the Code.

(b) Ten Percent Shareholders. A Ten Percent Shareholder will not be granted an Incentive Stock Option unless the exercise price of such Option is at least one hundred ten percent (110%) of the Fair Market Value on the date of grant and the Option is not exercisable after the expiration of five (5) years from the date of grant.

5. PROVISIONS RELATING TO OPTIONS AND STOCK APPRECIATION RIGHTS.

Each Option or SAR will be in such form and will contain such terms and conditions as the Board deems appropriate. All Options will be separately designated Incentive Stock Options or Nonstatutory Stock Options at the time of grant, and, if certificates are issued, a separate certificate or certificates will be issued for shares of Common Stock purchased on exercise of each type of Option. If an Option is not specifically designated as an Incentive Stock Option but some portion or all of the Option fails to qualify as an Incentive Stock Option under the applicable rules, then the Option (or portion thereof) will be a Nonstatutory Stock Option. The provisions of separate Options or SARs need not be identical; *provided, however*, that each Stock Award Agreement will conform to (through incorporation of provisions hereof by reference in the applicable Stock Award Agreement or otherwise) the substance of each of the following provisions:

(a) **Term.** Subject to the provisions of Section 4(b) regarding Ten Percent Shareholders, no Option or SAR will be exercisable after the expiration of ten (10) years from the date of its grant or such shorter period specified in the Stock Award Agreement.

(b) Exercise Price. Subject to the provisions of Section 4(b) regarding Ten Percent Shareholders, the exercise or strike price of each Option or SAR will be not less than one hundred percent (100%) of the Fair Market Value of the Common Stock subject to the Option or SAR on the date the Stock Award is granted. Notwithstanding the foregoing, an Option or SAR

may be granted with an exercise or strike price lower than one hundred percent (100%) of the Fair Market Value of the Common Stock subject to the Stock Award if such Stock Award is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a Transaction and in a manner consistent with the provisions of Section 409A of the Code and, if applicable, Section 424(a) of the Code. Each SAR will be denominated in shares of Common Stock equivalents.

(c) Purchase Price for Options. The purchase price of Common Stock acquired pursuant to the exercise of an Option may be paid, to the extent permitted by applicable law and as determined by the Board in its sole discretion, by any combination of the methods of payment set forth below. The Board will have the authority to grant Options that do not permit all of the following methods of payment (or otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to use a particular method of payment. The permitted methods of payment are as follows:

(i) by cash, check, bank draft or money order payable to the Company;

(ii) pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of the stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds;

(iii) by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock;

(iv) if an Option is a Nonstatutory Stock Option, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; provided, however, that the Company will accept a cash or other payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole shares to be issued. Shares of Common Stock will no longer be subject to an Option and will not be exercisable thereafter to the extent that (A) shares issuable upon exercise are used to pay the exercise price pursuant to the "net exercise," (B) shares are delivered to the Participant as a result of such exercise, and (C) shares are withheld to satisfy tax withholding obligations; or

(v) in any other form of legal consideration that may be acceptable to the Board and specified in the applicable Stock Award Agreement.

(d) Exercise and Payment of a SAR. To exercise any outstanding SAR, the Participant must provide written notice of exercise to the Company in compliance with the provisions of the Stock Appreciation Right Agreement evidencing such SAR. The appreciation distribution payable on the exercise of a SAR will be not greater than an amount equal to the excess of (A) the aggregate Fair Market Value (on the date of the exercise of the SAR) of a number of shares of Common Stock equal to the number of Common Stock equivalents in which the Participant is vested under such SAR, and with respect to which the Participant is exercising the SAR on such date, over (B) the aggregate strike price of the number of Common Stock

equivalents with respect to which the Participant is exercising the SAR on such date. The appreciation distribution may be paid in Common Stock, in cash, in any combination of the two or in any other form of consideration, as determined by the Board and contained in the Stock Award Agreement evidencing such SAR.

(e) Transferability of Options and SARs. The Board may, in its sole discretion, impose such limitations on the transferability of Options and SARs as the Board will determine. In the absence of such a determination by the Board to the contrary, the following restrictions on the transferability of Options and SARs will apply:

(i) Restrictions on Transfer. An Option or SAR will not be transferable except by will or by the laws of descent and distribution (or pursuant to subsections (ii) and (iii) below), and will be exercisable during the lifetime of the Participant only by the Participant. The Board may permit transfer of the Option or SAR in a manner that is not prohibited by applicable tax and securities laws. Except as explicitly provided herein, neither an Option nor a SAR may be transferred for consideration.

(ii) Domestic Relations Orders. Subject to the approval of the Board or a duly authorized Officer, an Option or SAR may be transferred pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument as permitted by Treasury Regulation 1.421-1(b)(2). If an Option is an Incentive Stock Option, such Option may be deemed to be a Nonstatutory Stock Option as a result of such transfer.

(iii) Beneficiary Designation. Subject to the approval of the Board or a duly authorized Officer, a Participant may, by delivering written notice to the Company, in a form approved by the Company (or the designated broker), designate a third party who, upon the death of the Participant, will thereafter be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, upon the death of the Participant, the executor or administrator of the Participant's estate will be entitled to exercise the Option or SAR and receive the Common Stock or other consideration may prohibit designation of a beneficiary at any time, including due to any conclusion by the Company that such designation would be inconsistent with the provisions of applicable laws.

(f) Vesting Generally. The total number of shares of Common Stock subject to an Option or SAR may vest and become exercisable in periodic installments that may or may not be equal. The Option or SAR may be subject to such other terms and conditions on the time or times when it may or may not be exercised (which may be based on the satisfaction of Performance Goals or other criteria) as the Board may deem appropriate. The vesting provisions of individual Options or SARs may vary. The provisions of this Section 5(f) are subject to any Option or SAR provisions governing the minimum number of shares of Common Stock as to which an Option or SAR may be exercised.

(g) **Termination of Continuous Service.** Except as otherwise provided in the applicable Stock Award Agreement or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates (other than for Cause and other than

upon the Participant's death or Disability), the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Stock Award as of the date of termination of Continuous Service) within the period of time ending on the earlier of (i) the date three (3) months following the termination of the Participant's Continuous Service (or such longer or shorter period specified in the applicable Stock Award Agreement, and (ii) the expiration of the term of the Option or SAR as set forth in the Stock Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the applicable time frame, the Option or SAR (as applicable) will terminate.

(h) Extension of Termination Date. If the exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause and other than upon the Participant's death or Disability) would be prohibited at any time solely because the issuance of shares of Common Stock would violate the registration requirements under the Securities Act, then the Option or SAR will terminate on the earlier of (i) the expiration of a total period of time (that need not be consecutive) equal to the applicable post termination exercise period after the termination of the Participant's Continuous Service during which the exercise of the Option or SAR would not be in violation of such registration requirements, or (ii) the expiration of the term of the Option or SAR as set forth in the applicable Stock Award Agreement. In addition, unless otherwise provided in a Participant's Continuous Service (other than for Cause) would violate the Company's insider trading policy, then the Option or SAR will terminate on the earlier of (i) the expiration of a period of time (that need not be consecutive) equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service (other than for Cause) would violate the Company's insider trading policy, then the Option or SAR will terminate on the earlier of (i) the expiration of a period of time (that need not be consecutive) equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service during which the sale of the Common Stock received upon exercise of the Option or SAR would not be in violation of the Company's insider trading policy, or (ii) the expiration of the term of the Option or SAR would not be in violation of the Company's insider trading policy, or (ii) the expiration of the term of the Option or SAR as set forth in the applicable Stock Award Agreement.

(i) Disability of Participant. Except as otherwise provided in the applicable Stock Award Agreement or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates as a result of the Participant's Disability, the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Option or SAR as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date twelve (12) months following such termination of Continuous Service (or such longer or shorter period specified in the Stock Award Agreement), and (ii) the expiration of the term of the Option or SAR as set forth in the Stock Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the applicable time frame, the Option or SAR (as applicable) will terminate.

(j) Death of Participant. Except as otherwise provided in the applicable Stock Award Agreement or other agreement between the Participant and the Company, if (i) a Participant's Continuous Service terminates as a result of the Participant's death, or (ii) the Participant dies within the period (if any) specified in the Stock Award Agreement for exercisability after the termination of the Participant's Continuous Service (for a reason other than death), then the Option or SAR may be exercised (to the extent the Participant was entitled to exercise such Option or SAR as of the date of death) by the Participant's estate, by a person

who acquired the right to exercise the Option or SAR by bequest or inheritance or by a person designated to exercise the Option or SAR upon the Participant's death, but only within the period ending on the earlier of (i) the date eighteen (18) months following the date of death (or such longer or shorter period specified in the Stock Award Agreement), and (ii) the expiration of the term of such Option or SAR as set forth in the Stock Award Agreement. If, after the Participant's death, the Option or SAR is not exercised within the applicable time frame, the Option or SAR (as applicable) will terminate.

(k) Termination for Cause. Except as explicitly provided otherwise in a Participant's Stock Award Agreement or other individual written agreement between the Company or any Affiliate and the Participant, if a Participant's Continuous Service is terminated for Cause, the Option or SAR will terminate immediately upon such Participant's termination of Continuous Service, and the Participant will be prohibited from exercising his or her Option or SAR from and after the time of such termination of Continuous Service.

(I) Non-Exempt Employees. If an Option or SAR is granted to an Employee who is a non-exempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, the Option or SAR will not be first exercisable for any shares of Common Stock until at least six (6) months following the date of grant of the Option or SAR (although the Stock Award may vest prior to such date). Consistent with the provisions of the Worker Economic Opportunity Act, (i) if such non-exempt Employee dies or suffers a Disability, (ii) upon a Transaction in which such Option or SAR is not assumed, continued, or substituted, (iii) upon a Change in Control, or (iv) upon the Participant's retirement (as such term may be defined in the Participant's Stock Award Agreement, in another agreement between the Participant and the Company, or, if no such definition, in accordance with the Company's then current employment policies and guidelines), the vested portion of any Options and SARs may be exercised earlier than six (6) months following the date of grant. The foregoing provision is intended to operate so that any income derived by a non-exempt employee in connection with the exercise or vesting of an Option or SAR will be exempt from his or her regular rate of pay. To the extent permitted and/or required for compliance with the Worker Economic Opportunity Act to ensure that any income derived by a non-exempt employee in connection 5(1) will apply to all Stock Awards and are hereby incorporated by reference into such Stock Award Agreements.

6. PROVISIONS OF STOCK AWARDS OTHER THAN OPTIONS AND SARS.

(a) Restricted Stock Awards. Each Restricted Stock Award Agreement will be in such form and will contain such terms and conditions as the Board deems appropriate. To the extent consistent with the Company's bylaws, at the Board's election, shares of Common Stock underlying a Restricted Stock Award may be (i) held in book entry form subject to the Company's instructions until any restrictions relating to the Restricted Stock Award lapse; or (ii) evidenced by a certificate, which certificate will be held in such form and manner as determined by the Board. The terms and conditions of Restricted Stock Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Award Agreements need not be identical. Each Restricted Stock Award Agreement will conform to (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. A Restricted Stock Award may be awarded in consideration for (A) cash, check, bank draft or money order payable to the Company, (B) past services to the Company or an Affiliate, or (C) any other form of legal consideration that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) Vesting. Shares of Common Stock awarded under the Restricted Stock Award Agreement may be subject to forfeiture to the Company in accordance with a vesting schedule to be determined by the Board.

(iii) Termination of Participant's Continuous Service. If a Participant's Continuous Service terminates, the Company may receive through a forfeiture condition or a repurchase right, any or all of the shares of Common Stock held by the Participant as of the date of termination of Continuous Service under the terms of the Restricted Stock Award Agreement.

(iv) Transferability. Rights to acquire shares of Common Stock under the Restricted Stock Award Agreement will be transferable by the Participant only upon such terms and conditions as are set forth in the Restricted Stock Award Agreement, as the Board will determine in its sole discretion, so long as Common Stock awarded under the Restricted Stock Award Agreement remains subject to the terms of the Restricted Stock Award Agreement.

(v) Dividends. A Restricted Stock Award Agreement may provide that any dividends paid on Restricted Stock will be subject to the same vesting and forfeiture restrictions as apply to the shares subject to the Restricted Stock Award to which they relate.

(b) Restricted Stock Unit Awards. Each Restricted Stock Unit Award Agreement will be in such form and will contain such terms and conditions as the Board deems appropriate. The terms and conditions of Restricted Stock Unit Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Unit Award Agreements need not be identical. Each Restricted Stock Unit Award Agreement will conform to (through incorporation of the provisions hereof by reference in the Agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. At the time of grant of a Restricted Stock Unit Award, the Board will determine the consideration, if any, to be paid by the Participant upon delivery of each share of Common Stock subject to the Restricted Stock Unit Award. The consideration to be paid (if any) by the Participant for each share of Common Stock subject to a Restricted Stock Unit Award may be paid in any form of legal consideration that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) Vesting. At the time of the grant of a Restricted Stock Unit Award, the Board may impose such restrictions on or conditions to the vesting of the Restricted Stock Unit Award as it, in its sole discretion, deems appropriate.

(iii) **Payment.** A Restricted Stock Unit Award may be settled by the delivery of shares of Common Stock, their cash equivalent, any combination thereof or in any other form of consideration, as determined by the Board and contained in the Restricted Stock Unit Award Agreement.

(iv) Additional Restrictions. At the time of the grant of a Restricted Stock Unit Award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the shares of Common Stock (or their cash equivalent) subject to a Restricted Stock Unit Award to a time after the vesting of such Restricted Stock Unit Award.

(v) Dividend Equivalents. Dividend equivalents may be credited in respect of shares of Common Stock covered by a Restricted Stock Unit Award, as determined by the Board and contained in the Restricted Stock Unit Award Agreement. At the sole discretion of the Board, such dividend equivalents may be converted into additional shares of Common Stock covered by the Restricted Stock Unit Award in such manner as determined by the Board. Any additional shares covered by the Restricted Stock Unit Award credited by reason of such dividend equivalents will be subject to all of the same terms and conditions of the underlying Restricted Stock Unit Award Agreement to which they relate.

(vi) Termination of Participant's Continuous Service. Except as otherwise provided in the applicable Restricted Stock Unit Award Agreement, such portion of the Restricted Stock Unit Award that has not vested will be forfeited upon the Participant's termination of Continuous Service.

(c) Performance Awards.

(i) Performance Stock Awards. A Performance Stock Award is a Stock Award (covering a number of shares not in excess of that set forth in Section 3(d) above) that is payable or that may be granted, may vest or may be exercised, contingent upon the attainment during a Performance Period of certain Performance Goals. A Performance Stock Award may, but need not, require the Participant's completion of a specified period of Continuous Service. The length of any Performance Period, the Performance Goals to be achieved during the Performance Period, and the measure of whether and to what degree such Performance Goals have been attained will be conclusively determined by the Committee (or, if not required for compliance with Section 162(m) of the Code, the Board), in its sole discretion. In addition, to the extent permitted by applicable law and the applicable Award Agreement, the Board may determine that cash may be used in payment of Performance Stock Awards.

(ii) Performance Cash Awards. A Performance Cash Award is a cash award (for a dollar value not in excess of that set forth in Section 3(d) above) that is payable contingent upon the attainment during a Performance Period of certain Performance Goals. A Performance Cash Award may also require the completion of a specified period of Continuous Service. At the time of grant of a Performance Cash Award, the length of any Performance Period, the Performance Goals to be achieved during the Performance Period, and the measure of whether and to what degree such Performance Goals have been attained will be conclusively determined by the Committee (or, if not required for compliance with Section 162(m) of the Code, the Board), in its sole discretion. The Board may specify the form of payment of Performance Cash Awards, which may be cash or other property, or may provide for a Participant to have the option for his or her Performance Cash Award, or such portion thereof as the Board may specify, to be paid in whole or in part in cash or other property.

(iii) Board Discretion. The Board retains the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of Performance Goals and to define the manner of calculating the Performance Criteria it selects to use for a Performance Period. Partial achievement of the specified criteria may result in the payment or vesting corresponding to the degree of achievement as specified in the Stock Award Agreement or the written terms of a Performance Cash Award.

(iv) Section 162(m) Compliance. Unless otherwise permitted in compliance with the requirements of Section 162(m) of the Code with respect to an Award intended to qualify as "performance-based compensation" thereunder, the Committee will establish the Performance Goals applicable to, and the formula for calculating the amount payable under, the Award no later than the earlier of (a) the date 90 days after the commencement of the applicable Performance Period, and (b) the date on which 25% of the Performance Period has elapsed, and in any event at a time when the achievement of the applicable Performance Goals remains substantially uncertain. Prior to the payment of any compensation under an Award intended to qualify as "performance-based compensation" under Section 162(m) of the Code, the Committee will certify the extent to which any Performance Goals and any other material terms under such Award have been satisfied (other than in cases where such Performance Goals relate solely to the increase in the value of the Common Stock). Notwithstanding satisfaction of, or completion of any Performance Goals, the number of shares of Common Stock, Options, cash or other benefits granted, issued, retainable and/or vested under an Award on account of satisfaction of such Performance Goals may be reduced by the Committee on the basis of such further considerations as the Committee, in its sole discretion, will determine.

(d) Other Stock Awards. Other forms of Stock Awards valued in whole or in part by reference to, or otherwise based on, Common Stock, including the appreciation in value thereof (e.g., options or stock rights with an exercise price or strike price less than one hundred percent (100%) of the Fair Market Value of the Common Stock at the time of grant) may be granted either alone or in addition to Stock Awards provided for under Section 5 and the preceding provisions of this Section 6. Subject to the provisions of the Plan, the Board will have sole and complete authority to determine the persons to whom and the time or times at which such Other Stock Awards will be granted, the number of shares of Common Stock (or the cash equivalent thereof) to be granted pursuant to such Other Stock Awards and all other terms and conditions of such Other Stock Awards.

7. COVENANTS OF THE COMPANY.

(a) Availability of Shares. The Company will keep available at all times the number of shares of Common Stock reasonably required to satisfy then-outstanding Stock Awards.

(b) Securities Law Compliance. The Company will seek to obtain from each regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Stock Awards and to issue and sell shares of Common Stock upon exercise or vesting of the Stock Awards; provided, however, that this undertaking will not require the

Company to register under the Securities Act (or other applicable law) the Plan, any Stock Award or any Common Stock issued or issuable pursuant to any such Stock Award. If, after reasonable efforts and at a reasonable cost, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary for the lawful issuance and sale of Common Stock under the Plan, the Company will be relieved from any liability for failure to issue and sell Common Stock upon exercise of such Stock Awards unless and until such authority is obtained. A Participant will not be eligible for the grant of an Award or the subsequent issuance of cash or Common Stock pursuant to the Award if such grant or issuance would be in violation of any applicable securities law.

(c) No Obligation to Notify or Minimize Taxes. The Company will have no duty or obligation to any Participant to advise such holder as to the time or manner of exercising such Stock Award. Furthermore, the Company will have no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of an Award or a possible period in which the Award may not be exercised. The Company has no duty or obligation to minimize the tax consequences of an Award to the holder of such Award.

8. MISCELLANEOUS.

(a) Use of Proceeds from Sales of Common Stock. Proceeds from the sale of shares of Common Stock pursuant to Stock Awards will constitute general funds of the Company.

(b) Corporate Action Constituting Grant of Awards. Corporate action constituting a grant by the Company of an Award to any Participant will be deemed completed as of the date of such corporate action, unless otherwise determined by the Board, regardless of when the instrument, certificate, or letter evidencing the Award is communicated to, or actually received or accepted by, the Participant. In the event that the corporate records (e.g., Board consents, resolutions or minutes) documenting the corporate action constituting the grant contain terms (e.g., exercise price, vesting schedule or number of shares) that are inconsistent with those in the Award Agreement or related grant documents as a result of a clerical error in the papering of the Award Agreement or related grant documents, the corporate records will control and the Participant will have no legally binding right to the incorrect term in the Award Agreement or related grant documents.

(c) Shareholder Rights. No Participant will be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to an Award unless and until (i) such Participant has satisfied all requirements for exercise of, or the issuance of shares of Common Stock under, the Award pursuant to its terms, and (ii) the issuance of the Common Stock subject to the Award has been entered into the books and records of the Company.

(d) No Employment or Other Service Rights. Nothing in the Plan, any Award Agreement or any other instrument executed thereunder or in connection with any Stock Award granted pursuant thereto will confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Award was granted or will affect the right of the Company or an Affiliate to terminate (i) the employment of an Employee with or without notice and with or without cause, (ii) the service of a Consultant pursuant to the terms of

such Consultant's agreement with the Company or an Affiliate, or (iii) the service of a Director pursuant to the bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state or foreign jurisdiction in which the Company or the Affiliate is domiciled or incorporated, as the case may be.

(e) Change in Time Commitment. In the event a Participant's regular level of time commitment in the performance of his or her services for the Company and any Affiliates is reduced (for example, and without limitation, if the Participant is an Employee of the Company and the Employee has a change in status from a full-time Employee to a part-time Employee) after the date of grant of any Award to the Participant, the Board has the right in its sole discretion to (x) make a corresponding reduction in the number of shares or cash amount subject to any portion of such Award that is scheduled to vest or become payable after the date of such change in time commitment, and (y) in lieu of or in combination with such a reduction, extend the vesting or payment schedule applicable to such Award. In the event of any such reduction, the Participant will have no right with respect to any portion of the Award that is so reduced or extended.

(f) Incentive Stock Option Limitations. To the extent that the aggregate Fair Market Value (determined at the time of grant) of Common Stock with respect to which Incentive Stock Options are exercisable for the first time by any Optionholder during any calendar year (under all plans of the Company and any Affiliates) exceeds one hundred thousand dollars (\$100,000) (or such other limit established in the Code) or otherwise does not comply with the rules governing Incentive Stock Options, the Options or portions thereof that exceed such limit (according to the order in which they were granted) or otherwise do not comply with such rules will be treated as Nonstatutory Stock Options, notwithstanding any contrary provision of the applicable Option Agreement(s).

(g) Investment Assurances. The Company may require a Participant, as a condition of exercising or acquiring Common Stock under any Award, (i) to give written assurances satisfactory to the Company as to the Participant's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that he or she is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Award; and (ii) to give written assurances satisfactory to the Company stating that the Participant is acquiring Common Stock subject to the Award for the Participant's own account and not with any present intention of selling or otherwise distributing the Common Stock. The foregoing requirements, and any assurances given pursuant to such requirements, will be inoperative if (A) the issuance of the shares upon the exercise or acquisition of Common Stock under the Award has been registered under a then currently effective registration statement under the Securities Act, or (B) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the Common Stock.

(h) Withholding Obligations. Unless prohibited by the terms of an Award Agreement, the Company may, in its sole discretion, satisfy any federal, state or local tax withholding obligation relating to an Award by any of the following means or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Award; provided, however, that no shares of Common Stock are withheld with a value exceeding the minimum amount of tax required to be withheld by law (or such lesser amount as may be necessary to avoid classification of the Award as a liability for financial accounting purposes); (iii) withholding cash from an Award settled in cash; (iv) withholding payment from any amounts otherwise payable to the Participant; or (v) by such other method as may be set forth in the Award Agreement.

(i) Electronic Delivery. Any reference herein to a "written" agreement or document will include any agreement or document delivered electronically, filed publicly at www.sec.gov (or any successor website thereto) or posted on the Company's intranet (or other shared electronic medium controlled by the Company to which the Participant has access).

(j) Deferrals. To the extent permitted by applicable law, the Board, in its sole discretion, may determine that the delivery of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Stock Award may be deferred and may establish programs and procedures for deferral elections to be made by Participants. Deferrals by Participants will be made in accordance with Section 409A of the Code. Consistent with Section 409A of the Code, the Board may provide for distributions while a Participant is still an employee or otherwise providing services to the Company. The Board is authorized to make deferrals of Stock Awards and determine when, and in what annual percentages, Participants may receive payments, including lump sum payments, following the Participant's termination of Continuous Service, and implement such other terms and conditions consistent with the provisions of the Plan and in accordance with applicable law.

(k) Compliance with Section 409A of the Code. Unless otherwise expressly provided for in an Award Agreement, the Plan and Award Agreements will be interpreted to the greatest extent possible in a manner that makes the Plan and the Awards granted hereunder exempt from Section 409A of the Code, and, to the extent not so exempt, in compliance with Section 409A of the Code. If the Board determines that any Award granted hereunder is not exempt from and is therefore subject to Section 409A of the Code, the Award Agreement evidencing such Award will incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code, and to the extent an Award Agreement is silent on terms necessary for compliance, such terms are hereby incorporated by reference into the Award Agreement. Notwithstanding anything to the contrary in this Plan (and unless the Award Agreement specifically provides otherwise), if the shares of Common Stock are publicly traded, and if a Participant holding an Award that constitutes "deferred compensation" under Section 409A of the Code is a "specified employee" for purposes of Section 409A of the Code, no distribution or payment of any amount that is due because of a "separation from service" (as defined in Section 409A of the Code without regard to alternative definitions thereunder) will be issued or paid before the date that is six (6) months following the date of such Participant's "separation from service" or, if earlier, the date of the Participant's death, unless such distribution or payment can be made in a manner that complies with Section 409A of the Code, and any amounts so deferred will be paid in a lump sum on the day after such six (6) month period elapses, with the balance paid thereafter on the original schedule.

(I) Clawback/Recovery. All Awards granted under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Board may impose such other clawback, recovery or recoupment provisions in an Award Agreement as the Board determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired shares of Common Stock or other cash or property upon the occurrence of an event constituting Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for "good reason" or "constructive termination" (or similar term) under any agreement with the Company or an Affiliate.

9. ADJUSTMENTS UPON CHANGES IN COMMON STOCK; OTHER CORPORATE EVENTS.

(a) Capitalization Adjustments. In the event of a Capitalization Adjustment, the Board will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a), (ii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of Incentive Stock Options pursuant to Section 3(c), (iii) the class(es) and maximum number of securities that may be awarded to any person pursuant to Sections 3.(d), and (iv) the class(es) and number of securities and price per share of stock subject to outstanding Stock Awards. The Board will make such adjustments, and its determination will be final, binding and conclusive.

(b) Dissolution. Except as otherwise provided in the Stock Award Agreement, in the event of a Dissolution of the Company, all outstanding Stock Awards (other than Stock Awards consisting of vested and outstanding shares of Common Stock not subject to a forfeiture condition or the Company's right of repurchase) will terminate immediately prior to the completion of such Dissolution, and the shares of Common Stock subject to the Company's repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the holder of such Stock Award is providing Continuous Service, *provided, however*, that the Board may, in its sole discretion, cause some or all Stock Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Stock Awards have not previously expired or terminated) before the Dissolution is completed but contingent on its completion.

(c) Transactions. The following provisions will apply to Stock Awards in the event of a Transaction unless otherwise provided in the Stock Award Agreement or any other written agreement between the Company or any Affiliate and the Participant or unless otherwise expressly provided by the Board at the time of grant of a Stock Award. In the event of a Transaction, then, notwithstanding any other provision of the Plan, the Board may take one or more of the following actions with respect to Stock Awards, contingent upon the closing or completion of the Transaction:

(i) arrange for the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) to assume or continue the Stock Award or to substitute a similar stock award for the Stock Award (including, but not limited to, an award to acquire the same consideration paid to the shareholders of the Company pursuant to the Transaction);

(ii) arrange for the assignment of any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to the Stock Award to the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company);

(iii) accelerate the vesting, in whole or in part, of the Stock Award (and, if applicable, the time at which the Stock Award may be exercised) to a date prior to the effective time of such Transaction as the Board determines (or, if the Board does not determine such a date, to the date that is five (5) days prior to the effective date of the Transaction), with such Stock Award terminating if not exercised (if applicable) at or prior to the effective time of the Transaction; provided, however, that the Board may require Participants to complete and deliver to the Company a notice of exercise before the effective date of a Transaction, which exercise is contingent upon the effectiveness of such Transaction;

(iv) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by the Company with respect to the Stock Award;

(v) cancel or arrange for the cancellation of the Stock Award, to the extent not vested or not exercised prior to the effective time of the Transaction, in exchange for such cash consideration (or no consideration), if any, as the Board, in its sole discretion, may consider appropriate; and

(vi) make a payment, in such form as may be determined by the Board equal to the excess, if any, of (A) the value of the property the Participant would have received upon the exercise of the Stock Award immediately prior to the effective time of the Transaction, over (B) any exercise price payable by such holder in connection with such exercise. For clarity, this payment may be zero (\$0) if the value of the property is equal to or less than the exercise price. Payments under this provision may be delayed to the same extent that payment of consideration to the holders of the Company's Common Stock in connection with the Transaction is delayed as a result of escrows, earn outs, holdbacks or any other contingencies.

The Board need not take the same action or actions with respect to all Stock Awards or portions thereof or with respect to all Participants. The Board may take different actions with respect to the vested and unvested portions of a Stock Award.

(d) Change in Control. A Stock Award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the Stock Award Agreement for such Stock Award or as may be provided in any other written agreement between the Company or any Affiliate and the Participant, but in the absence of such provision, no such acceleration will occur.

10. PLAN TERM; EARLIER TERMINATION OR SUSPENSION OF THE PLAN.

(a) Plan Term. The Board may suspend or terminate the Plan at any time. No Incentive Stock Option will be granted after the tenth (10th) anniversary of the earlier of (i) the date the Plan is adopted by the Board, or (ii) the date the Plan is approved by the shareholders of the Company. No Stock Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

11. EFFECTIVE DATE OF PLAN.

This Plan will become effective on the Effective Date.

12. CHOICE OF LAW.

To the extent that United States federal laws do not otherwise control, this Plan and all determinations made and actions taken pursuant to this Plan shall be governed by the internal laws of the State of New York, and construed accordingly, except for those matters subject to The Companies Act, 1981 of Bermuda (as amended), which shall be governed by Bermuda law, without giving effect to principles of conflicts of laws, and construed accordingly.

13. Definitions. As used in the Plan, the following definitions will apply to the capitalized terms indicated below:

(a) "*Affiliate*" means, at the time of determination, any "parent" or "subsidiary" of the Company as such terms are defined in Rule 405. The Board will have the authority to determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

- (b) "Award" means a Stock Award or a Performance Cash Award.
- (c) "Award Agreement" means a written agreement between the Company and a Participant evidencing the terms and conditions of an Award.
- (d) "Board" means the Board of Directors of the Company.

(e) "*Capitalization Adjustment*" means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Stock Award after the Effective Date without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or any similar equity restructuring transaction, as that term is used in Statement of Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.

(f) "*Cause*" will have the meaning ascribed to such term in any written agreement between the Participant and the Company defining such term and, in the absence of such

agreement, such term means, with respect to a Participant, the occurrence of any of the following events: (i) such Participant's willful failure substantially to perform his or her duties and responsibilities to the Company or deliberate violation of a Company policy; (ii) such Participant's commission of any act of fraud, embezzlement, dishonesty or any other willful misconduct that has caused or is reasonably expected to result in material injury to the Company; (iii) unauthorized use or disclosure by such Participant of any proprietary information or trade secrets of the Company or any other party to whom the Participant owes an obligation of nondisclosure as a result of his or her relationship with the Company; or (iv) such Participant's willful breach of any of his or her obligations under any written agreement or covenant with the Company. The determination that a termination of the Participant's Continuous Service is either for Cause or without Cause will be made by the Company, in its sole discretion. Any determination by the Company that the Continuous Service of a Participant was terminated with or without Cause for the purposes of outstanding Stock Awards held by such Participant will have no effect upon any determination of the rights or obligations of the Company or such Participant for any other purpose.

(g) "Change in Control" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control will not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company, (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company's securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities, (C) on account of the acquisition of securities of the Company by any individual who is, on the IPO Date, either an executive officer or a Director (either, an "IPO Investor") and/or any entity in which an IPO Investor has a direct or indirect interest (whether in the form of voting rights or participation in profits or capital contributions) of more than 50% (collectively, the "IPO Entities") or on account of the IPO Entities continuing to hold shares that come to represent more than 50% of the combined voting power of the Company's then outstanding securities as a result of the conversion of any class of the Company's securities into another class of the Company's securities having a different number of votes per share pursuant to the conversion provisions set forth in the Company's Amended and Restated Certificate of Incorporation; or (D) solely because the level of Ownership held by any Exchange Act Person (the "Subject Person") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control will be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the shareholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction; *provided, however*, that a merger, consolidation or similar transaction if the outstanding voting securities representing more than 50% of the combined voting power of the surviving power of the surviving Entity or its parent are owned by the IPO Entities;

(iii) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are Owned by shareholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; *provided, however*, that a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries will not constitute a Change in Control under this prong of the definition if the outstanding voting securities representing more than 50% of the combined voting power of the acquiring Entity or its parent are owned by the IPO Entities; or

(iv) individuals who, on the date the Plan is adopted by the Board, are members of the Board (the "*Incumbent Board*") cease for any reason to constitute at least a majority of the members of the Board; *provided, however*, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member will, for purposes of this Plan, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing definition or any other provision of the Plan, (A) the term Change in Control will not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company, and (B) the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant will supersede the foregoing definition with respect to Awards subject to such agreement; *provided, however*, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition will apply.

(h) "Code" means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(i) "Committee" means a committee of two (2) or more Directors to whom authority has been delegated by the Board in accordance with Section 2(c).

(j) "Common Stock" means the common shares of the Company.

(k) "*Company*" means Myovant Sciences Ltd., an exempted limited company incorporated under the laws of Bermuda, with its registered office at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda, or any successor to all or substantially all of its businesses by merger, amalgamation, consolidation, purchase of assets, or otherwise.

(1) "Consultant" means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, will not cause a Director to be considered a "Consultant" for purposes of the Plan. Notwithstanding the foregoing, a person is treated as a Consultant under this Plan only if a Form S-8 Registration Statement under the Securities Act is available to register either the offer or the sale of the Company's securities to such person.

(m) "Continuous Service" means that the Participant's service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Director or Consultant or a change in the Entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant's service with the Company or an Affiliate, will not terminate a Participant's Continuous Service; *provided*, *however*, that if the Entity for which a Participant is rendering services ceases to qualify as an Affiliate, as determined by the Board in its sole discretion, such Participant's Continuous Service will be considered to have terminated on the date such Entity ceases to qualify as an Affiliate. For example, a change in status from an Employee of the Company to a Consultant of an Affiliate or to a Director will not constitute an interruption of Continuous Service. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service will be considered in the case of (i) any leave of absence approved by the Board or chief executive officer, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, an Affiliate, or their successors. Notwithstanding the foregoing, a leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law. In addition, to the extent required for exemption from or compliance with Section 409A of the Code, the determination of whether there has been a termination of Continuous Service will be made, and such term will be construed, in a manner that is consistent with the definition of "separation from service" as defined under Treasury Regulation Section 1.409A-1(h) (without regard to any alternative definit

(n) "*Corporate Transaction*" means a sale of all or substantially all of the Company's assets, or a merger, consolidation or other capital reorganization or business combination transaction of the Company with or into another corporation, entity or person, or the direct or

indirect acquisition (including by way of a tender or exchange offer) by any person, or persons acting as a group, of beneficial ownership or a right to acquire beneficial ownership of shares representing a majority of the voting power of the then outstanding shares of capital stock of the Company.

(o) "Covered Employee" will have the meaning provided in Section 162(m)(3) of the Code.

(p) "Director" means a member of the Board.

(q) "*Disability*" means, with respect to a Participant, the inability of such Participant to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than twelve (12) months as provided in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

(r) "*Dissolution*" means when the Company has completely wound up its affairs and dissolved in accordance with the Companies Act 1981 of Bermuda.

(s) "Effective Date" means the IPO Date.

(t) "*Employee*" means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an "Employee" for purposes of the Plan.

(u) "Entity" means a corporation, partnership, limited liability company or other entity.

(v) "Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(w) "*Exchange Act Person*" means any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that "Exchange Act Person" will not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, an underwriter temporarily holding securities pursuant to an offering of such securities, an Entity Owned, directly or indirectly, by the shareholders of the Company in substantially the same proportions as their Ownership of stock of the Company; or (v) any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the Effective Date, is the Owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities.

(x) "Fair Market Value" means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value of a share of Common Stock will be, unless otherwise determined by the Board, the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in a source the Board deems reliable.

(ii) Unless otherwise provided by the Board, if there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing selling price on the last preceding date for which such quotation exists.

(iii) In the absence of such markets for the Common Stock, the Fair Market Value will be determined by the Board in good faith and in a manner that complies with Sections 409A and 422 of the Code.

(y) "*Incentive Stock Option*" means an option granted pursuant to Section 5 of the Plan that is intended to be, and that qualifies as, an "incentive stock option" within the meaning of Section 422 of the Code.

(z) "IPO Date" means the date and time of execution of the underwriting agreement between the Company and the underwriter(s) managing the initial public offering of the Common Stock, pursuant to which the Common Stock is priced for the initial public offering.

(aa) "*Non-Employee Director*" means a Director who either (i) is not a current employee or officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly, from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act ("*Regulation S -K*")), does not possess an interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K; or (ii) is otherwise considered a "non-employee director" for purposes of Rule 16b-3.

(bb) "Nonstatutory Stock Option" means any option granted pursuant to Section 5 of the Plan that does not qualify as an Incentive Stock Option.

(cc) "Officer" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act.

(dd) "Option" means an Incentive Stock Option or a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to the Plan.

(ee) "*Option Agreement*" means a written agreement between the Company and an Optionholder evidencing the terms and conditions of an Option grant. Each Option Agreement will be subject to the terms and conditions of the Plan.

(**ff**) "*Optionholder*" means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

(gg) "Other Stock Award" means an award based in whole or in part by reference to the Common Stock which is granted pursuant to the terms and conditions of Section 6(c).

(hh) "Other Stock Award Agreement" means a written agreement between the Company and a holder of an Other Stock Award evidencing the terms and conditions of an Other Stock Award grant. Each Other Stock Award Agreement will be subject to the terms and conditions of the Plan.

(ii) "Outside Director" means a Director who either (i) is not a current employee of the Company or an "affiliated corporation" (within the meaning of Treasury Regulations promulgated under Section 162(m) of the Code), is not a former employee of the Company or an "affiliated corporation" who receives compensation for prior services (other than benefits under a tax-qualified retirement plan) during the taxable year, has not been an officer of the Company or an "affiliated corporation," and does not receive remuneration from the Company or an "affiliated corporation," either directly or indirectly, in any capacity other than as a Director, or (ii) is otherwise considered an "outside director" for purposes of Section 162(m) of the Code.

(jj) "Own," "Owned," "Owner," "Ownership" A person or Entity will be deemed to "Own," to have "Owned," to be the "Owner" of, or to have acquired "Ownership" of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(kk) "Participant" means a person to whom an Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Award.

(II) "Performance Cash Award" means an award of cash granted pursuant to the terms and conditions of Section 6.(c)(ii).

(mm) "*Performance Criteria*" means the one or more criteria that the Board or Committee (as applicable) will select for purposes of establishing the Performance Goals for a Performance Period. The Performance Criteria that will be used to establish such Performance Goals may be based on any one of, or combination of, the following as determined by the Board or Committee: (i) earnings (including earnings per share and net earnings); (ii) earnings before interest, taxes and depreciation; (iii) earnings before interest, taxes, depreciation and amortization; (iv) earnings before interest, taxes, depreciation, amortization and legal settlements; (v) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense) and stock-based compensation; (vii) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense), stock-based compensation and changes in deferred revenue; (viii) total shareholder return; (ix) return on equity or average shareholder's equity; (x) return on assets, investment, or capital employed; (xi) stock price; (xii) margin (including gross margin); (xiii) income (before or after taxes); (xiv) operating income; (xv) operating income after taxes; (xvi) pre-tax profit; (xvii) operating cash

flow; (xviii) sales or revenue targets; (xix) increases in revenue or product revenue; (xx) expenses and cost reduction goals; (xxi) improvement in or attainment of working capital levels; (xxii) economic value added (or an equivalent metric); (xxiii) market share; (xxiv) cash flow; (xxv) cash flow per share; (xxvi) share price performance; (xxvii) debt reduction; (xxviii) implementation or completion of projects or processes; (xxix) employee retention; (xxx) shareholders' equity; (xxxi) capital expenditures; (xxxii) debt levels; (xxxiii) operating profit or net operating profit; (xxxiv) workforce diversity; (xxxv) growth of net income or operating income; (xxxvi) billings; (xxxvii) bookings; (xxxviii) initiation or completion of phases of clinical trials and/or studies by specified dates; (xxxix) patient enrollment rates, (xxxx) budget management; (xxxxi) regulatory body and/or pricing approval with respect to products, studies and/or trials; (xxxxii) commercial launch of products; (xxxiii) progress of partnered programs; (xxxix) strategic partnerships or transactions; and (xxxxx) to the extent that an Award is not intended to comply with Section 162(m) of the Code, other measures of performance selected by the Board or Committee.

(nn) "Performance Goals" means, for a Performance Period, the one or more goals established by the Board or Committee (as applicable) for the Performance Period based upon the Performance Criteria. Performance Goals may be based on a Company-wide basis, with respect to one or more business units, divisions, Affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by the Board or Committee (i) in the Award Agreement at the time the Award is granted or (ii) in such other document setting forth the Performance Goals at the time the Performance Goals are established, the Board or Committee will appropriately make adjustments in the method of calculating the attainment of Performance Goals for a Performance Period as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the dilutive effects of acquisitions or joint ventures; (6) to assume that any business divested by the Company achieved performance objectives at targeted levels during the balance of a Performance Period following such divestiture; (7) to exclude the effect of any change in the outstanding shares of common stock of the Company by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spinoff, combination or exchange of shares or other similar corporate change, or any distributions to common shareholders other than regular cash dividends; (8) to exclude the effects of stock based compensation and the award of bonuses under the Company's bonus plans; (9) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to expensed under generally accepted accounting principles; (10) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles; (11) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (12) to exclude the effect of any other unusual, non-recurring gain or loss; (13) to exclude the effects of the timing of acceptance for review and/or approval of submissions to the Food and Drug Administration or any other regulatory body and (14) to exclude the effects of entering into or achieving milestones involved in licensing, collaboration, or other business development transactions. In addition, the Board or Committee retains the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of Performance Goals and to define the manner of calculating the Performance Criteria it selects to

use for such Performance Period. Partial achievement of the specified criteria may result in the payment or vesting corresponding to the degree of achievement as specified in the Stock Award Agreement or the written terms of a Performance Cash Award.

(oo) "*Performance Period*" means the period of time selected by the Board or Committee (as applicable) over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Participant's right to and the payment of a Stock Award or a Performance Cash Award. Performance Periods may be of varying and overlapping duration, at the sole discretion of the Board or Committee.

(pp) "Performance Stock Award" means a Stock Award granted under the terms and conditions of Section 6.(c)(i).

(qq) "Plan" means this Myovant Sciences Ltd. 2016 Equity Incentive Plan.

(rr) "Restricted Stock Award" means an award of shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(a).

(ss) "*Restricted Stock Award Agreement*" means a written agreement between the Company and a holder of a Restricted Stock Award evidencing the terms and conditions of a Restricted Stock Award grant. Each Restricted Stock Award Agreement will be subject to the terms and conditions of the Plan.

(tt) "*Restricted Stock Unit Award*" means a right to receive shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(b).

(uu) "*Restricted Stock Unit Award Agreement*" means a written agreement between the Company and a holder of a Restricted Stock Unit Award evidencing the terms and conditions of a Restricted Stock Unit Award grant. Each Restricted Stock Unit Award Agreement will be subject to the terms and conditions of the Plan.

(vv) "*Rule 16b-3*" means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

(ww) "Rule 405" means Rule 405 promulgated under the Securities Act.

(xx) "Securities Act" means the Securities Act of 1933, as amended.

(yy) "*Stock Appreciation Right*" or "*SAR*" means a right to receive the appreciation on Common Stock that is granted pursuant to the terms and conditions of Section 5.

(zz) "Stock Appreciation Right Agreement" means a written agreement between the Company and a holder of a Stock Appreciation Right evidencing the terms and conditions of a Stock Appreciation Right grant. Each Stock Appreciation Right Agreement will be subject to the terms and conditions of the Plan.

(aaa) "*Stock Award*" means any right to receive Common Stock granted under the Plan, including an Incentive Stock Option, a Nonstatutory Stock Option, a Restricted Stock Award, a Restricted Stock Unit Award, a Stock Appreciation Right, a Performance Stock Award, or any Other Stock Award.

(bbb) "*Stock Award Agreement*" means a written agreement between the Company and a Participant evidencing the terms and conditions of a Stock Award grant. Each Stock Award Agreement will be subject to the terms and conditions of the Plan.

(ccc) "*Subsidiary*" means, with respect to the Company, (i) any corporation of which more than fifty percent (50%) of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation will have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than fifty percent (50%).

(ddd) "*Ten Percent Shareholder*" means a person who Owns (or is deemed to Own pursuant to Section 424(d) of the Code) shares possessing more than ten percent (10%) of the total combined voting power of all classes of shares of the Company or any Affiliate.

(eee) "*Transaction*" means a Corporate Transaction or a Change in Control. To the extent required for compliance with Section 409A of the Code, in no event will a Transaction be deemed to have occurred if such transaction is not also a "change in the ownership or effective control of" the Company or "a change in the ownership of a substantial portion of the assets of" the Company as determined under Treasury Regulations Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder). The Board may, in its sole discretion and without a Participant's consent, amend the definition of "Transaction" to conform to the definition of "Change in Control" under Section 409A of the Code, and the regulations thereunder, to the extent required for compliance with Section 409A of the Code.

^{28.}

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated July 8, 2016 (except for Note 11, as to which the date is October 19, 2016), in Amendment No. 3 to the Registration Statement on Form S-1 (File No. 333-213891) and related Prospectus of Myovant Sciences Ltd. for the registration of its common shares.

/s/ Ernst & Young LLP Metro Park, New Jersey October 19, 2016