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

FORM 10-Q

(Mark One)

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

For the quarterly period ended December 31, 2016

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 001-37929

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

Bermuda	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
20-22 Bedford Row London, United Kingdom WC1R 4JS	**Not Applicable**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **+44 203 318 9709**

Clarendon House
2 Church Street
Hamilton HM 11, Bermuda
(former name, former address and former fiscal year, if changed since last report)

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

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

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 of the Exchange Act. (Check one)

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	x (Do not check if a smaller reporting company)	Smaller reporting company	o

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

The number of shares outstanding of the Registrant's common shares, $0.000017727 par value per share, on February 10, 2017, was 60,255,821.

MYOVANT SCIENCES LTD.

QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED DECEMBER 31, 2016

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	December 31, 2016	March 31, 2016
Assets		
Current assets:		
Cash	$ 192,322	$ —
Prepaid expenses and other current assets	1,153	—
Income tax receivable	15	—
Total current assets	193,490	—
Property and equipment, net	471	—
Other assets	100	—
Total assets	$ 194,061	$ —
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accrued expenses and accounts payable	$ 3,890	$ 223
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc.	2,448	—
Total current liabilities	6,338	223
Warrant liability	1,655	—
Total liabilities	7,993	223
Commitments and contingencies (Note 9)		
Shareholders' equity (deficit):		
Common shares, par value $0.000017727 per share, 564,111,242 shares authorized, 60,250,094 and 37,231,342 issued and outstanding at December 31, 2016 and March 31, 2016, respectively	1	1
Common shares subscribed	(1)	(1)
Additional paid-in capital	249,491	1,434
Accumulated deficit	(63,423)	(1,657)
Total shareholders' equity (deficit)	186,068	(223)
Total liabilities and shareholders' equity (deficit)	$ 194,061	$ —

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

MYOVANT SCIENCES LTD.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(*unaudited, in thousands, except share and per share data*)

	Three Months Ended December 31, 2016	Nine Months Ended December 31, 2016
Operating expenses:		
Research and development (includes $1,060 and $2,849 of share-based compensation expense for the three and nine months ended December 31, 2016, respectively)	$ 6,158	$ 24,484
General and administrative (includes $950 and $3,932 of share-based compensation expense for the three and nine months ended December 31, 2016, respectively)	2,898	8,427
Total operating expenses	9,056	32,911
Other income (expense):		
Changes in the fair value of the warrant liability	1,002	(28,815)
Loss before provision for income tax expense	(8,054)	(61,726)
Income tax expense	29	40
Net loss and comprehensive loss	$ (8,083)	$ (61,766)
Net loss per common share — basic and diluted	$ (0.15)	$ (1.34)
Weighted average common shares outstanding — basic and diluted	54,447,203	45,929,021

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

MYOVANT SCIENCES LTD.
Condensed Consolidated Statement of Shareholders' Equity
For the Nine Months Ended December 31, 2016
(unaudited, in thousands, except share data)

	Common Shares		Common Shares Subscribed	Additional Paid in Capital	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount				
Balance at March 31, 2016	37,231,342	$ 1	(1)	$ 1,434	$ (1,657)	$ (223)
Sale of common shares in initial public offering ($15.00 per share), net of underwriting discounts and commissions and offering expenses of $17,536	14,500,000	—	—	199,964	—	199,964
Shares issued to Takeda under the Takeda license agreement	5,077,001	—	—	7,740	—	7,740
Shares issued to settle the warrant liability to Takeda	2,313,529	—	—	32,537	—	32,537
Share-based compensation expense	1,128,222	—	—	2,223	—	2,223
Capital contribution — share-based compensation	—	—	—	4,558	—	4,558
Capital contribution	—	—	—	1,035	—	1,035
Net loss	—	—	—	—	(61,766)	(61,766)
Balance at December 31, 2016	60,250,094	$ 1	(1)	$ 249,491	$ (63,423)	$ 186,068

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

MYOVANT SCIENCES LTD.
Condensed Consolidated Statement of Cash Flows
(unaudited, in thousands)

	Nine Months Ended December 31, 2016
Cash flows from operating activities:	
Net loss	$ (61,766)
Adjustments to reconcile net loss to net cash used in operating activities:	
Share-based compensation	6,781
Depreciation	9
Purchase of in-process research and development expense	13,117
Changes in the fair value of the warrant liability	28,815
Changes in operating assets and liabilities:	
Prepaid expenses and other current assets	(1,153)
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc.	3,301
Other assets	(100)
Accrued expenses and accounts payable	3,461
Income tax receivable	(15)
Net cash used in operating activities	(7,550)
Cash flows from investing activities:	
Purchase of property and equipment	(369)
Net cash used in investing activities	(369)
Cash flows from financing activities:	
Cash proceeds from issuance of common shares in initial public offering, net of underwriting discount	202,275
Initial public offering costs paid	(2,091)
Cash capital contribution from Roivant Sciences Ltd.	1,036
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc. for amounts paid on behalf of the Company	(979)
Net cash provided by financing activities	200,241
Net change in cash	192,322
Cash—beginning of period	—
Cash—end of period	$ 192,322
Non-cash financing activities:	
Deferred initial public offering costs, unpaid	$ 220
Purchase of in-process research and development	$ 13,117
Supplemental disclosure of cash paid:	
Taxes	$ 55

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

MYOVANT SCIENCES LTD.
Notes to Condensed Consolidated Financial Statements

Note 1—Description of Business

Myovant Sciences Ltd. (together with its wholly-owned 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, MVT-602 (formerly known as 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"). In August 2016, the Company incorporated as its wholly-owned subsidiaries Myovant Holdings Limited ("MHL"), a private limited company incorporated under the laws of England and Wales, and Myovant Sciences GmbH ("MSG"), a company with limited liability formed under the laws of Switzerland. In November 2016, the Company moved its principal executive office from Bermuda to the United Kingdom and became a U.K. tax resident, and the Company assigned all of its intellectual property rights to MSG. MSG is the Company's principal operating subsidiary and the Company remains incorporated in Bermuda.

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 MVT-602, under development which were licensed from Takeda Pharmaceuticals International AG ("Takeda") on April 29, 2016 (See Note 3).

Note 2—Summary of Significant Accounting Policies

(A) Basis of Presentation:

The Company's fiscal year ends on March 31, and its fiscal quarters end on June 30, September 30 and December 31.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. These interim unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements for the period from inception of February 2, 2016 through the period ended March 31, 2016, and unaudited consolidated financial statements for the three months ended June 30, 2016, included in the Company's final prospectus dated October 26, 2016 filed with the Securities and Exchange Commission ("SEC") on October 27, 2016. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary to present fairly the financial position of the Company and its results of operations and cash flows for the interim periods presented have been included. Operating results for the three and nine months ended December 31, 2016 are not necessarily indicative of the results that may be expected for the year ending March 31, 2017, for any other interim period or for any other future year.

Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). The condensed consolidated financial statements include the accounts of the Company and MSI, MHL and MSG, its wholly-owned subsidiaries. The Company has no unconsolidated subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

There have been no significant changes in the Company's accounting policies from those disclosed in its final prospectus filed with the SEC on October 27, 2016.

(B) Use of Estimates:

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. The Company regularly evaluates estimates and assumptions related to assets, liabilities, costs, and expenses, including compensation expense allocated to the Company under its services agreement with Roivant Sciences, Inc. ("RSI"), a wholly-owned subsidiary of RSL, as well as share-based compensation 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) Contingencies

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company continually assesses litigation to determine if an unfavorable outcome would lead to a probable loss or reasonably possible loss which could be estimated. In accordance with the guidance of the Financial Accounting Standards Board (FASB) on accounting for contingencies, the Company accrues for all contingencies at the earliest date at which the Company deems it probable that a liability has been incurred and the amount of such liability can be reasonably estimated. If the estimate of a probable loss is a range and no amount within the range is more likely than another, the Company accrues the minimum of the range. In the cases where the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the litigation, including an estimable range, if possible.

(E) Deferred Offering Costs:

Deferred offering costs, which consisted of direct costs related to the Company's initial public offering (the "IPO") of its common shares, were capitalized in other assets until the consummation of the IPO. These offering costs were reclassified to additional paid-in capital upon the closing of the IPO on November 1, 2016.

(F) 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.

(G) Warrant Liability:

The Company records the warrant liability at its estimated fair value as a liability in the condensed 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 condensed consolidated statement of operations and comprehensive loss as other (expense) income (See Note 8).

(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. 110. The risk-free interest rate is based on the rates paid on securities issued by the U.S. Treasury with a term approximating the expected life of the equity award. The expected share price volatility for the Company's common shares is estimated by taking the average historical price volatility for industry peers. 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 three and nine months ended December 31, 2016, 1,128,222 restricted share awards and 1,337,657 options to purchase common shares were not included in the calculation of diluted weighted-average common shares outstanding because they were anti-dilutive.

(K) Recently Issued Accounting Pronouncements:

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)" (ASU No. 2016-02), which is a comprehensive new lease standard that amends various aspects of existing accounting guidance for leases. The core principle of ASU No. 2016-02 will require lessees to present the assets and liabilities that arise from leases on their balance sheets. ASU No. 2016-02 is effective for annual periods beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company is currently evaluating the new standard and its impact on the Company's consolidated financial 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 MVT-602, in exchange for the following:

- The Company issued and delivered 5,077,001 common shares upon entry into the license agreement.
- The Company will pay Takeda a fixed, high single-digit royalty on net sales of relugolix and MVT-602 products in the Company's territory, subject to certain agreed reductions. Takeda will pay the Company a royalty at the same rate 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, unless earlier terminated upon a change in control.

For the consideration above, the Company also received a small quantity of relugolix and MVT-602, and certain historical research and development records. The Company did not hire, or receive, any Takeda workforce or employees working on relugolix and MVT-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 MVT-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 $13.1 million as research and development expense at the closing date of the acquisition of the rights, April 29, 2016, which consisted of $7.7 million for the estimated fair value of the 5,077,001 common shares issued and $5.4 million for the estimated fair value of warrant liability.

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. Under the Services Agreement, the Company pays or reimburses RSI for any expenses it, or third parties acting on its behalf, incurs for the Company. For any general and administrative and research and development activities performed by RSI employees, RSI charges back the employee compensation expense plus a pre-determined 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 are billed back at cost. The accompanying interim unaudited condensed consolidated financial statements include third-party expenses that have been paid by RSI and RSL.

During the three and nine months ended December 31, 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. Under the Services Agreement, for the three and nine months ended December 31, 2016, the Company incurred expenses of $2.7 million and $6.8 million, respectively, inclusive of the mark-up.

In February 2017, the Company and MSI amended and restated the Services Agreement, effective as of November 11, 2016, to include MSG as a services recipient. In addition, in February 2017, MSG entered into a separate services agreement with Roivant Sciences GmbH ("RSG"), a wholly-owned subsidiary of RSL, effective as of November 11, 2016, for the provisioning of services by RSG to MSG in relation to the identification of potential product candidates and project management of clinical trials, as well as, other services related to clinical development, administrative and financial activities.

(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 IPO 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—Shareholders' Equity

(A) Overview:

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

(B) Restricted Share Award and Options Granted:

During the nine months ended December 31, 2016, the Company granted a restricted share award for 1,128,222 common shares to the Company's Principal Executive Officer under the 2016 Equity Incentive Plan. During the nine months ended December 31, 2016, the Company granted options to its employees, consultants and directors to purchase 1,337,657 of its common shares.

(C) Initial Public Offering and Reverse 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. These interim unaudited condensed consolidated financial statements give retroactive effect to the reverse stock split for all periods presented.

On November 1, 2016, the Company completed its initial public offering ("IPO") of common shares. The Company sold 14,500,000 shares at a price of $15.00 per share, for gross proceeds of $217.5 million. The Company received net proceeds of $200.0 million, after deducting $15.2 million in underwriting discounts and commissions and $2.3 million in offering expenses. The cash proceeds from the IPO are currently deposited with one banking institution and are substantially in excess of federally insured levels.

(D) Warrant Liability:

During the nine months ended December 31, 2016, the Company issued 2,313,529 common shares to Takeda upon the automatic exercise of the warrant, which was due to the issuance of 153,846 common shares initiated by the grant of a restricted share award for 1,128,222 common shares, issuance of 182,414 common shares initiated by the grant of options to its employees, consultants and directors to purchase 1,337,657 common shares and the issuance of an additional 1,977,269 common shares to Takeda, upon the closing of its IPO, based upon the sale and issuance of 14,500,000 common shares to investors in the IPO.

Note 6—Income Taxes

The Company's provision for income taxes is based on income taxes in the United States, Switzerland and the United Kingdom. The Company is not subject to taxation under the laws of Bermuda since it was organized as a Bermuda Exempted Limited Company, for which there is no current tax regime. The Company's effective income tax rate for the three and nine months ended December 31, 2016 was (0.36)% and (0.06)%, respectively. As of December 31, 2016 and March 31, 2016, there were no uncertain tax positions.

Note 7—Share-Based Compensation

(A) Stock Options and Restricted Share Awards Granted to Employees, Consultants and Directors:

In June 2016, the Company adopted its 2016 Equity Incentive Plan (as amended, the "2016 Plan"), under which 4,512,889 common shares are reserved for grant. The Company's employees, directors, officers and consultants are eligible to receive non-qualified and incentive stock options, stock appreciation rights, restricted share awards, restricted share unit awards, and other share awards under the plan. 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.

In June 2016, the Company granted a restricted share award for 1,128,222 common shares to the Company's Principal Executive Officer under the 2016 Plan. In August 2016, the Company granted options to purchase 541,544 common shares to certain employees of the Company, with an exercise price of $2.38 under the 2016 Plan. In September 2016, the Company granted options to purchase 572,568 common shares to certain employees, officers and directors of the Company, with a weighted average exercise price of $4.00 under the 2016 Plan. During the nine months ended December 31, 2016, the Company granted options to purchase 1,276,458 common shares to certain employees and directors of the Company.

For the three and nine months ended December 31, 2016, share-based compensation expense related to the restricted share award was $0.4 million and $0.8 million, respectively.

For the three and nine months ended December 31, 2016, the Company recorded share-based compensation expense related to stock options issued to employees, officers and directors of $0.9 million and $1.2 million, respectively, and share-based compensation expense related to stock options issued to non-employees of $0.1 million and $0.2 million, respectively (Note 7(B)(1)). This share-based compensation expense is included in research and development and general and administrative expenses in the accompanying interim unaudited condensed consolidated statements of operations and comprehensive loss.

In connection with the IPO and after preliminary discussions with the underwriters, the Company reassessed the fair value of: (1) 1,128,222 restricted common shares issued to our Principal Executive Officer in June 2016 with an initial fair value of $1.52 per common share; (2) 602,743 common shares underlying stock options granted in August 2016 (including options to purchase 61,199 common shares granted to certain consultants as described below in Note 7(B)(1)) with an exercise price of $2.38 per common share; and (3) 572,568 common shares underlying stock options granted in September 2016 to the Company's employees, officers and directors with a weighted-average exercise price of $4.00 per common share. As a result, the Company determined that the reassessed fair value of the restricted common shares was $5.10 per common share and the reassessed fair value of the common shares underlying the stock options granted in August and September 2016 was $15.00 per common share, which was the initial public offering price of the Company's common shares in the IPO. The use of this higher fair value per common share increased the weighted-average fair value of the stock options granted in August and September 2016 to $13.44 per common share and $12.78 per common share, respectively. Prior to the IPO, the fair value of the common shares underlying the Company's stock options was estimated on each grant date by the Board of Directors. In order to determine the fair value of the Company's common shares underlying granted stock options, the Board of Directors considered, among other things, timely valuations of the 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. The use of this higher share price increased both recognized and unrecognized share-based compensation expense.

At December 31, 2016, total unrecognized compensation expense related to non-vested options for employees, officers and directors was $14.6 million and is expected to be recognized over the remaining weighted-average service period of 3.67 years.

(B) Share-Based Compensation for Related Parties:

(1) Stock Options Granted to Non-Employees:

During the nine months ended December 31, 2016, the Company granted options to purchase 61,199 common shares to certain consultants, who are also employees of RSI, with an exercise price of $2.38 under the 2016 Plan. As discussed above in Note 7(A), the use of the higher fair value per common share of $15.00, which was reassessed in conjunction with the IPO and after preliminary discussions with the underwriters, increased both recognized and unrecognized share-based compensation expense. For the three and nine months ended December 31, 2016, share-based compensation expense related to stock options granted to consultants was $0.1 million and $0.2 million, respectively. At December 31, 2016, total unrecognized compensation expense related to stock options granted to consultants was $0.5 million, which is expected to be recognized over 1.19 years.

(2) Share-Based Compensation Allocated to the Company by RSL:

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 $0.6 million and $4.6 million, respectively, for the three and nine months ended December 31, 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.

The following table sets forth the Company's assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2016 and March 31, 2016, by level, within the fair value hierarchy:

	As of December 31, 2016				As of March 31, 2016			
				(in thousands)				
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 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 March 31, 2016
Assets:								
Total assets at fair value	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ —
Liabilities:								
Warrant liability	$ —	$ —	$ 1,655	$ 1,655	$ —	$ —	$ —	$ —
Total liabilities at fair value	$ —	$ —	$ 1,655	$ 1,655	$ —	$ —	$ —	$ —

There were no transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy that occurred during the nine months ended December 31, 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 interim unaudited condensed consolidated statements of operations and comprehensive loss.

The warrant liability may change significantly as additional data are 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 December 31, 2016 was calculated using the following significant unobservable inputs:

Input	Range or Point Estimate Used
Projected time frame to an equity financing	January 2017 - April 2017
Probability of a successful equity financing	2.0%
Annualized equity volatility	73.4%
Risk-free interest rate	0.44% - 0.55%

The changes in fair value of the Company's Level 3 warrant liability during the nine months ended December 31, 2016 were as follows (in thousands):

Balance at March 31, 2016	$	—
Fair value of the warrant liability issued		5,377
Changes in the fair value of the warrant liability, included in net loss		28,815
Settlements		(32,537)
Balance at December 31, 2016	$	1,655

For the nine months ended December 31, 2016, changes in the carrying value of the warrant liability resulted from settlements related to the fair value of the warrant exercised, partially offset by changes in the fair value of the warrant liability primarily due to the 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), amended its services agreement with RSI and entered into a separate service agreement with RSG (See Note 4(A)). As of March 31, 2016 and December 31, 2016, the Company did not have any ongoing material financial commitments. The Company expects to enter into other commitments as the business further develops.

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company accrues for loss contingencies when available information indicates that it is probable that a liability has been incurred and the amount of such loss can be reasonably estimated. In the cases where the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the litigation, including an estimable range, if possible.

Currently, the Company is party to a legal proceeding as described in Part II, Item 1, Legal Proceedings, of this Quarterly Report on Form 10-Q. The Company believes that it is not probable that a liability has been incurred and that the amount of any such liability cannot be reasonably estimated. As a result, the Company has not recorded a loss contingency related to this legal proceeding. While it is not possible to determine the outcome of the matter, the Company believes the resolution of such matter will not have a material adverse effect on its business, financial condition or results of operations.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition, results of operations and cash flows should be read in conjunction with (1) the unaudited interim condensed consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q, and (2) the audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the period from February 2, 2016 (date of inception) through March 31, 2016 and the unaudited interim consolidated financial statements for the three months ended June 30, 2016 included in our final prospectus, filed with the Securities and Exchange Commission, or the SEC, on October 27, 2016 pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Securities Act.

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements are often identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "project," "will," "would" or the negative or plural of these words or similar expressions or variations. Such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, and those discussed in the section titled "Risk Factors," set forth in Part II, Item 1A of this Quarterly Report on Form 10-Q and in our other filings with the SEC. You should not rely upon forward-looking statements as predictions of future events. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

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, ("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 study participants to date in Phase 1 and multiple large, randomized Phase 2 clinical trials. In January 2017, we initiated a Phase 3 clinical program consisting of two international clinical trials, LIBERTY 1 and LIBERTY 2, to evaluate the safety and efficacy of relugolix in women with heavy menstrual bleeding associated with uterine fibroids. The U.S. Investigational New Drug application, ("IND"), in support of this program was filed with the U. S. Food and Drug Administration, ("the FDA"), in November 2016. In the first half of 2017, we also plan to initiate two replicate multinational Phase 3 trials for relugolix in women with endometriosis-associated pain. 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 second quarter of 2017. To increase benefit and reduce side effects in the women's health indications, relugolix at a maximally estrogen-suppressive dose (40 mg once daily) is being co-administered with low-dose hormonal add-back therapy to fully suppress estrogen and then add-back a low dose of estrogen and progestin to reduce bone mineral density loss and hot flashes. In the first quarter of 2017, we also plan to initiate a Phase 3 clinical study of relugolix in men with advanced prostate cancer. 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 MVT-602 (formerly known as RVT-602), an oligopeptide kisspeptin analog, for the treatment of female infertility as part of assisted reproduction. Both relugolix and MVT-602 are licensed to us by Takeda Pharmaceuticals International AG, ("Takeda").

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 MVT-602 and preparing for and advancing our product candidates into clinical development. To date, we have not generated any revenue.

In November 2016, we completed our initial public offering, or ("IPO"), in which we sold 14,500,000 common shares at a price of $15.00 per share. The net proceeds to us were approximately $200.0 million, after deducting $15.2 million in underwriting discounts and commissions and $2.3 million in offering expenses. We intend to use these proceeds to fund our clinical program for relugolix and MVT-602. As of December 31, 2016, we had an accumulated deficit of $63.4 million. For the three and nine months ended December 31, 2016, we recorded net losses of $8.1 million and $61.8 million, respectively.

Recent Developments

In January 2017, we initiated a Phase 3 clinical program of relugolix in women with heavy menstrual bleeding associated with uterine fibroids, consisting of two clinical trials, LIBERTY 1 and LIBERTY 2. These trials are double-blind, placebo-controlled Phase 3 international clinical trials in women with heavy menstrual bleeding associated with uterine fibroids that will be conducted at up to 200 sites. Each of the two clinical trials is expected to enroll approximately 390 women aged 18 to 50 years with a diagnosis of uterine fibroids confirmed by ultrasound and heavy menstrual bleeding attributed to uterine fibroids. Eligible women will be randomized to one of three groups: relugolix 40 mg orally once daily co-administered with low-dose hormonal add-back therapy (1 mg estradiol/0.5 mg norethindrone acetate) for 24 weeks, relugolix 40 mg orally once daily monotherapy for 12 weeks followed by relugolix 40 mg once daily co-administered with hormonal add-back therapy for an additional 12 weeks, or placebo once daily for a period of 24 weeks. Patients completing the initial 24-week blinded assessment will be offered an active treatment extension with relugolix 40 mg once daily co-administered with hormonal add-back therapy for an additional 24-week period, or a total treatment period of up to 48 weeks, to evaluate the safety of longer-term treatment.

The primary efficacy outcome of the study is a clinically-meaningful reduction in menstrual blood loss based upon the alkaline hematin method, a standardized centrally-assessed quantitative measurement of menstrual blood loss. Safety outcomes, including bone mineral density changes as measured by dual-energy x-ray absorptiometry, will also be assessed.

Takeda has announced that, as of January 2017, it has completed enrollment in both of the Phase 3 clinical trials it is conducting in Japan. The first trial is a 12-week non-inferiority Phase 3 study of relugolix (also known as TAK-385) and leuprolide in women with heavy menstrual bleeding associated with uterine fibroids. The second Phase 3 study evaluates relugolix compared with placebo for 12 weeks in women with pain symptoms associated with uterine fibroids. Takeda has stated that top-line results from these trials are expected in the third and fourth quarters of 2017.

Services Agreements with Roivant Sciences, Inc. and Roivant Sciences GmbH

Effective as of April 29, 2016, we and our wholly-owned subsidiary, Myovant Sciences, Inc. ("MSI"), entered into a services agreement with Roivant Sciences, Inc. ("RSI"), a wholly-owned subsidiary of RSL, pursuant to which RSI provides us with services in relation to the identification of potential product candidates and project management of clinical trials, as well as other services related to our development, administrative and financial activities. In February 2017, in connection with the contribution and assignment of all of our intellectual property rights to Myovant Sciences GmbH ("MSG"), we amended and restated this services agreement effective as of November 11, 2016, as a result of which MSG was added as a recipient of these services from RSI. In February 2017, MSG also entered into a separate services agreement with Roivant Sciences GmbH ("RSG"), a wholly-owned subsidiary of RSL, effective as of November 11, 2016, for the provision of services by RSG to MSG in relation to the identification of potential product candidates and project management of clinical trials, as well as other services related to development, administrative and financial activities. Under the terms of both services agreements (collectively the "Services Agreements"), we are obligated to pay or reimburse RSI and RSG for the costs they, or third parties acting on their behalf, incur in providing services to us. In addition, we are obligated to pay to RSI and RSG a pre-determined markup, currently equal to 10%, on costs incurred by them in connection with any general and administrative and support services as well as research and development services.

Under the services agreement in effect as of December 31, 2016, we incurred expenses of $2.7 million and $6.8 million for the three months and nine months ended December 31, 2016, respectively, inclusive of the mark-up. We have recorded these charges as research and development expense and general and administrative expense in our condensed consolidated statement of operations.

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 MVT-602.

Research and Development Expense

Since our incorporation, our operations have primarily been limited to the license of the rights to relugolix and MVT-602 and products containing these compounds. Our research and development expenses 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 Agreements;

• expenses incurred under or in connection with agreements with contract research organizations, ("CROs"), as well as consultants and other vendors that conduct or participate in clinical and nonclinical studies designed to further the development of our product candidates;

• manufacturing costs in connection with conducting nonclinical 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. We expect our research and development expenses to increase significantly 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 MVT-602 and prepare to seek regulatory approval for our product candidates. 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.

The duration, costs and timing of clinical trials of relugolix, MVT-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 who participate in the trials;

• the number of sites included in the trials;

• the countries in which the trials are conducted;

• the length of time required to enroll eligible patients;

• the number of patients who fail to meet the study's inclusion and exclusion criteria;

• the number of study drugs that patients receive;

• the drop-out or discontinuation rates of patients;

• the potential additional safety monitoring or other studies requested by regulatory agencies;

• the duration of patient follow-up;

• the timing and receipt of regulatory approvals;

• the costs of clinical trial material; and

• the efficacy and safety profile of the product candidate.

In addition, the probability of success for relugolix, MVT-602 and any other product candidates 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 Agreements 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 New York Stock Exchange, or NYSE, rules and SEC requirements, insurance and investor relations costs. In addition, if relugolix or MVT-602 obtains regulatory approval for marketing, we expect that we would incur expenses associated with building a sales and marketing team.

Results of Operations for the Three and Nine Months Ended December 31, 2016

The following table summarizes our results of operations for the three and nine months ended December 31, 2016 (in thousands):

	Three Months Ended December 31, 2016	Nine Months Ended December 31, 2016
Operating expenses:		
Research and development (includes $1,060 and $2,849 of share-based compensation expense for the three and nine months ended December 31, 2016, respectively)	$ 6,158	$ 24,484
General and administrative (includes $950 and $3,932 of share-based compensation expense for the three and nine months ended December 31, 2016, respectively)	2,898	8,427
Total operating expenses	9,056	32,911
Changes in the fair value of the warrant liability	1,002	(28,815)
Income tax expense	29	40
Net loss and comprehensive loss	$ 8,083	$ 61,766

Research and Development Expenses

Research and development expenses were $6.2 million for the three months ended December 31, 2016, and consisted primarily of costs billed to us under the Services Agreement of $2.3 million, including personnel expenses and third-party costs associated with the preparation of our clinical and other research programs and share-based compensation expense of $1.1 million, $0.4 million of which was allocated to us by RSL.

Research and development expenses were $24.5 million for the nine months ended December 31, 2016, and consisted primarily of in-process research and development expenses of $13.1 million, which were related to our acquisition of the rights to our product candidates from Takeda and consisted of $7.7 million for the estimated fair value of the 5,077,001 common shares issued to Takeda and $5.4 million for the estimated fair value of the warrant liability. The remainder consisted of costs billed to us under the Services Agreement of $5.5 million, including personnel expenses and third-party costs associated with the preparation of our clinical and other research programs and share-based compensation expense of $2.8 million, $1.9 million of which was allocated to us by RSL.

General and Administrative Expenses

General and administrative expenses were $2.9 million for the three months ended December 31, 2016, and consisted primarily of share-based compensation expense of $0.9 million, including $0.2 million allocated to us by Roivant Sciences, Ltd., other personnel-related and general overhead expenses of $0.9 million, legal and professional fees of $0.7 million and costs of $0.4 million billed to us under the Services Agreement, including personnel expenses, overhead allocations and third-party costs.

General and administrative expenses were $8.4 million for the nine months ended December 31, 2016, and consisted primarily of share-based compensation expense of $3.9 million, including $2.6 million allocated to us by Roivant Sciences, Ltd., and legal and professional fees of $2.0 million, costs of $1.3 million billed to us under the Services Agreement, including personnel expenses, overhead allocations and third-party costs. The remainder consisted primarily of other personnel-related and general overhead expenses of $1.2 million.

Changes in the Fair Value of the Warrant Liability

The change in the fair value of the warrant liability was recorded as $1.0 million of income for the three months ended December 31, 2016, as the fair value of the warrant liability decreased to $1.7 million at December 31, 2016 from $32.6 million at September 30, 2016, primarily due to $29.9 million related to the fair value of the warrant exercised during the three months ended December 31, 2016, primarily as a result of issuance of an additional 1,977,269 common shares to Takeda, pursuant to the automatic exercise of the warrant, based upon the sale and issuance of 14,500,000 common shares to investors in the IPO supplemented by changes in the assumptions regarding probabilities of successful financing events used to estimate the fair value of the liability.

The change in the fair value of the warrant liability was recorded as $28.8 million of expense for the nine months ended December 31, 2016, as the fair value of the warrant liability decreased to $1.7 million at December 31, 2016 from $5.4 million at April 29, 2016, the date of issuance of the warrant to Takeda, primarily due to $32.5 million related to the fair value of the warrant exercised during the nine months ended December 31, 2016, primarily as a result of issuance of an additional 1,977,269 common shares to Takeda, pursuant to the automatic exercise of the warrant, based upon the sale and issuance of 14,500,000 common shares to investors in the IPO, partially offset by changes in the assumptions regarding probabilities of successful financing events used to estimate the fair value of the liability.

Liquidity and Capital Resources

Overview

In November 2016, we received the proceeds from our IPO, in which we sold 14,500,000 common shares at a price of $15.00 per share, for gross proceeds of $217.5 million. The net proceeds to us were approximately $200.0 million, after deducting $15.2 million in underwriting discounts and commissions and $2.3 million in offering expenses.

For the period from February 2, 2016 (date of inception) to March 31, 2016 and for the nine months ended December 31, 2016, we had net losses of $1.7 million and $61.8 million, respectively. As of December 31, 2016, we had $192.3 million of cash and had never generated any revenue.

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, MVT-602 or any future 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 MVT-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, regulatory, quality and administrative personnel;

• add operational, financial, quality and management information systems;

• 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

• operate as a public company.

Our primary use of cash is to fund the development of relugolix for the treatment of uterine fibroids, endometriosis and advanced prostate cancer. We expect that our existing cash, including net proceeds from our IPO, will be sufficient 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. 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, MVT-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 nine months ended December 31, 2016:

	(in thousands)
Net cash used in operating activities	$ (7,550)
Net cash used in investing activities	(369)
Net cash provided by financing activities	200,241

Operating Activities

For the nine months ended December 31, 2016, $7.6 million was used in operating activities. The net loss for the period of $61.8 million was partially offset by $13.1 million of non-cash in-process research and development expenses related to the acquisition of the rights to our product candidates, $6.8 million non-cash share-based compensation, $28.8 million non-cash changes in the fair value of the warrant liability, $3.3 million 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 $2.2 million other expenses.

Investing Activities

For the nine months ended December 31, 2016, $0.4 million was used in investing activities, all for the purchase of fixed assets.

Financing Activities

For the nine months ended December 31, 2016, $200.2 million was provided by financing activities. This was primarily due to the net proceeds of our IPO, which we completed on November 1, 2016.

Contractual Obligations

As of December 31, 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 condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S, under U.S GAAP. The preparation of these condensed 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 the Services Agreements, 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.

We believe the estimates and judgments involved in our warrant liability, research and development accruals, share-based compensation and income taxes have the greatest potential impact on our condensed consolidated financial statements, and consider these to be our critical accounting policies and estimates.

Our significant accounting policies are more fully described in Note 2 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. We believe there have been no material changes to our critical accounting policies and use of estimates as disclosed in the footnotes to our audited consolidated financial statements for the period from February 2, 2016 (date of inception) through March 31, 2016 included in our final prospectus filed with the SEC on October 27, 2016 pursuant to Rule 424(b)(4) under the Securities Act.

Recent Accounting Pronouncements

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, 2018, and interim periods within fiscal years beginning after December 15, 2018. Early adoption is permitted. We are currently evaluating the new standard and its impact on our consolidated financial 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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Market risk is the potential loss arising from adverse changes in market rates and market prices such as interest rates, foreign currency exchange rates, and changes in the market value of equity instruments. We do not believe we are currently exposed to any material market risk. As of December 31, 2016, we had cash of $192.3 million, consisting of non-interest bearing deposits denominated in the U.S. dollar and Swiss franc.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Security and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to a company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our Principal Executive Officer and our Principal Financial and Accounting Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2016, the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Principal Executive Officer and our Principal Financial and Accounting Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

(b) Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings relating to claims arising from the ordinary course of business. On January 27, 2017, in connection with preexisting litigation against an employee of MSI, Dr. Laura Williams, AbbVie Inc., or AbbVie filed an amended complaint that, among other things, seeks damages in an unspecified amount based on claims against MSI and Lynn Seely, M.D., our Principal Executive Officer, for tortious interference with contract and trade secret misappropriation. MSI and Dr. Seely have denied and filed a motion to dismiss both claims, and a hearing on this motion is scheduled to be held in March 2017. The case is pending in the Circuit Court of the Nineteenth Judicial Circuit, Lake County, Illinois. Prior to the filing of the amended complaint, the court had entered a temporary restraining order enjoining Dr. Williams from using or disclosing any of AbbVie's confidential information and/or trade secrets and from any involvement with the development of relugolix. These restrictions remained in place until January 30, 2017, at which time the court began a hearing regarding AbbVie's motion for a preliminary injunction against Dr. Williams. That hearing is ongoing and is expected to end during the week of February 13, 2017. A decision is expected from the court shortly thereafter. We do not expect the resolution of this matter to have a material adverse effect on our business, operating results or financial condition.

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to the other information contained in this Quarterly Report on Form 10-Q, including the section of this report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our condensed consolidated financial statements and related notes. If any of the events described in the following risk factors and the risks described elsewhere in this report occurs, our business, operating results and financial condition could be seriously harmed and the trading price of our common shares could decline. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this report.

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 MVT-602 (formerly known as 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 MVT-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 MVT-602, we do not know when relugolix or MVT-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 MVT-602;
- set an acceptable price for relugolix and MVT-602 and obtain coverage and adequate reimbursement from third-party payors;
- establish sales, marketing and distribution systems for relugolix and MVT-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 MVT-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 MVT-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.

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 MVT-602. Neither relugolix nor MVT-602 has been approved for marketing in the United States, and they may never receive such approval. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to generate product revenue and achieve profitability is dependent on our ability to complete the development of relugolix and MVT-602, obtain necessary regulatory approvals, and have relugolix and MVT-602 manufactured and successfully marketed. We cannot assure you that we will be profitable even if we successfully commercialize relugolix or MVT-602. If we do successfully obtain regulatory approval to market relugolix or MVT-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 MVT-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 MVT-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.

We expect our research and development expenses to be significant in connection with our development programs for relugolix and MVT-602. In addition, if we obtain regulatory approval for either relugolix or MVT-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.

We are heavily dependent on the success of relugolix and MVT-602, our only product candidates, which are still under clinical development, and if either relugolix or MVT-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 MVT-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 for either of the two women's health indications or for prostate cancer or MVT-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 MVT-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 country. 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.

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 MVT-602 for many reasons, including:

- we may not be able to demonstrate that relugolix or MVT-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 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 nonclinical 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 nonclinical 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 nonclinical 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 of relugolix 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 hormonal 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 MVT-602.

We expect to spend substantial amounts to complete the development of, seek regulatory approvals for and commercialize relugolix and MVT-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 MVT-602 and make significant royalty payments in connection with the sale of resulting products.

We will 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 our existing cash, including the net proceeds from our initial public offering, or our IPO, 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 MVT-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 MVT-602.

We have licensed the intellectual property rights covering our current product candidates, relugolix and MVT-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 MVT-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 a limited number of employees who are employed by our wholly-owned subsidiary, Myovant Sciences, Inc. ("MSI"), and we rely on Roivant Sciences, Inc. ("RSI") and Roivant Sciences GmbH ("RSG") to provide various administrative, research and development and other services.

As of December 31, 2016, we had no employees, and our wholly-owned subsidiary, Myovant Sciences, Inc., had twenty employees. We rely in part on the administrative support and research and development services provided by our affiliates, RSI and RSG, wholly-owned subsidiaries of RSL, pursuant to our Services Agreements with RSI and RSG. Personnel and support staff that provide services to us under the Services Agreements are not required to, and we do not expect that they will, have as their primary responsibility the management and administration of our business or act exclusively for us. Under the Services Agreements, RSI and RSG have the discretion to determine which of their employees will perform services under the agreement.

RSI and RSG have limited financing and accounting and other resources. If RSI or RSG fail to perform their obligations in accordance with the terms of the Services Agreements, it could be difficult for us to operate our business. In addition, the termination of our relationship with RSI or RSG and any delay in appointing or finding a suitable replacement provider, if one exists, could make it difficult for us to operate our business. Any failure by RSI or RSG to effectively manage the portion of 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 December 31, 2016, we had no employees, and our wholly-owned subsidiary, Myovant Sciences, Inc., had twenty 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, manufacturing, and 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 MVT-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 nonclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter 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 programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

Our computer systems, as well as those of RSI, RSG 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 nonclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of relugolix or MVT-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 MVT-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 MVT-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 MVT-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. 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, submitted our IND to the FDA, including Phase 3 protocols, in November 2016 and initiated our Phase 3 program for women with heavy menstrual bleeding associated with uterine fibroids in January 2017. 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 second quarter of 2017. The Phase 2 prostate cancer study of relugolix, C27002, did not meet the criteria for success for its primary endpoint specified in the statistical analysis plan, highlighting the importance of appropriate selection of the primary endpoint, powering of a clinical study and diligent oversight of the compliance of those patients enrolled into the trial. If we fail to execute these and other aspects of our planned Phase 3 prostate cancer trial effectively, the trial will not be successful. Further, we cannot predict with any certainty if or when we might submit an NDA for regulatory approval for relugolix or MVT-602 in any indication 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 MVT-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 MVT-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 nonclinical studies and initial clinical trials. The results of early clinical trials of relugolix and MVT-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 safety profiles, notwithstanding promising results in earlier trials.

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

- failure to obtain regulatory approval to commence a trial;
- unforeseen safety issues;
- 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 MVT-602 could be harmed, and our ability to generate product revenue from relugolix or MVT-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 MVT-602, we were not involved in the development of relugolix or MVT-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, prior to our acquisition of the rights to relugolix and MVT-602 we had no involvement or control over the nonclinical or clinical development of either relugolix or MVT-602. 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 MVT-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, one for the treatment of pain symptoms associated with uterine fibroids and one for the treatment of heavy menstrual bleeding associated with uterine fibroids. 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. Takeda is also completing an extension of the Phase 2 trial C27002 in prostate cancer. If safety data from this clinical trial or the Phase 3 clinical trials of uterine fibroids in women are unfavorable, it could negatively impact our ability to successfully complete our Phase 3 relugolix clinical trials.

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

Even if our clinical trials are completed as planned, we cannot be certain that their results will support the effectiveness or safety of relugolix or MVT-602. Success in nonclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and nonclinical 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 nonclinical, and early clinical studies of our product candidates may not be predictive of the results of later-stage nonclinical studies or clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical and initial clinical trials. A future 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 MVT-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 MVT-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 compel their actual performance.

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

Drug development is highly competitive and subject to rapid and significant technological advancements. 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. Should competitive new products become approved in regions where we are conducting our clinical trials, the time to completion and outcomes of these trials could be negatively impacted.

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 MVT-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 completed two Phase 3 trials with elagolix in women with endometriosis-associated pain and is expected to file an NDA for this indication in 2017. Furthermore, AbbVie has initiated a Phase 3 program evaluating elagolix with and without hormonal 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 hormonal add-back therapy in women with pain associated with endometriosis in 2017. Similarly, ObsEva SA, a Swiss-based clinical stage biopharmaceutical company, which completed its IPO in January 2017, intends to commence two Phase 3 clinical trials of OBE2109, also a GnRH receptor antagonist, in women with heavy menstrual bleeding associated with uterine fibroids in the first half 2017. Further, Allergan and Gedeon Richter announced in January 2017 positive results from the second of two pivotal Phase 3 clinical trials evaluating the efficacy and safety of ulipristal acetate in women with abnormal bleeding due to uterine fibroids. An NDA filing for ulipristal acetate is planned for the second half of 2017. Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Many of our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a 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 MVT-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 MVT-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 MVT-602, and our ability to generate product revenue will be materially impaired.

Relugolix and MVT-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 MVT-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 neither relugolix, MVT-602 nor 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 MVT-602, we will need to complete additional Phase1, 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 nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the safety and efficacy of relugolix and MVT-602 for the specified indication. Further, because we are exploring the use of relugolix co-administered with low-dose hormonal add-back therapy as a longer-term treatment for the heavy menstrual bleeding associated with uterine fibroids and of endometriosis-associated pain, we expect to submit data with respect to a large patient population. Even if we obtain approval for this patient population, we may not achieve labeling for longer than six months duration of therapy. 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 MVT-602 may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events caused by relugolix or MVT-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 MVT-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.

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 MVT-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 the 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 approval could result in difficulties and costs for us and require additional nonclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Even if we obtain regulatory approval for 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 MVT-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 MVT-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, third-party payors and others in the medical community. If it does not achieve an adequate level of acceptance, we may not generate significant product revenue 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 MVT-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 MVT-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 gain the necessary resources or 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 MVT-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 non-governmental 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 MVT-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 MVT-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 MVT-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 MVT-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 MVT-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 MVT-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 MVT-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 MVT-602, if approved, or any future product candidate in a timely fashion, in sufficient quantities or under acceptable terms;

- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- 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 nonclinical 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 nonclinical 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 nonclinical and nonclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP nonclinical 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 could be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If our relationships with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. 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, MVT-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, MVT-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, MVT-602 or any future product candidate, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates or companion diagnostic that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate 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, MVT-602 or any future product candidate, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize, future drugs. Any such outcome could have a materially adverse effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has 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, MVT-602 or any future product candidate, our competitors might be able to enter the market, which would have an adverse effect on our business.

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

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter partes review, and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous 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 MVT-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 MVT-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 were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our drugs or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

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

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the 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 that we have licensed or that we may obtain in the future.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting and defending patents covering relugolix, MVT-602 and any future product candidate throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the 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, MVT-602 and any future product candidates, and we expect to collaborate with third parties on the development of relugolix, MVT-602 and any future product candidates, we must, at times, share trade secrets with them. We also conduct joint 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 and our Principal Executive Officer are currently defendants in one lawsuit alleging such claims. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Risks Related to Our Common Shares

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

Prior to our IPO, there was no public market for our common shares. The trading market for our common shares may not be liquid enough for you to sell your shares quickly or at the prevailing 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 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, MVT-602 or those of our competitors;
- any delay in filing an NDA or similar application for relugolix or MVT-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, MVT-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, MVT-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, MVT-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.

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

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

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

Roivant Sciences Ltd. controls a majority of the voting power of our outstanding common shares. As a result, we are 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, including the requirements:

- that a majority of the board of directors consists of independent directors;
- for an annual performance evaluation of the nominating and corporate governance and compensation committees;
- that we have a nominating and corporate governance committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; and
- that we have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibility.

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

Roivant Sciences Ltd. owns a significant percentage of our common shares and is able to exert significant control over matters subject to shareholder approval.

Based on our common shares outstanding as of December 31, 2016, Roivant Sciences Ltd. beneficially owns approximately 61.8% of the voting power of our outstanding common shares. As a result, Roivant Sciences Ltd. has the ability to substantially influence us and exert significant control through this ownership position. For example, Roivant Sciences Ltd. is 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 depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If our financial performance fails to meet analyst estimates or one or more of the analysts who cover us downgrade our common shares or change their opinion of our common shares, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

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.

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

Sales of a substantial number of our common shares in the public market, or the perception 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. All of the shares sold in our IPO are freely transferable without restrictions or further registration under the Securities Act of 1933, as amended, or the Securities Act, except for common shares sold to Pfizer Inc. and BB Biotech AG, which are subject to lock-up agreements until April 21, 2017. The remaining 45,750,094 common shares outstanding as of December 31, 2016 are restricted as a result of securities laws, lock-up agreements or other contractual restrictions that restrict transfers until April 21, 2017.

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. Sales of these common shares may have an adverse effect on the trading price of our common shares. In addition, in the future we may issue common shares or other securities if we need to raise additional capital. 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.

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 expect 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.

As 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 fiscal year ending March 31, 2018. 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, we will be unable to assert that 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 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 November 1, 2021, (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 are held by non-affiliates exceeds $700.0 million as of the prior September 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

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

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

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

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

We are a Bermuda exempted company. As a result, the rights of our shareholders are governed by Bermuda law and our memorandum of association and bye-laws. The rights of shareholders under Bermuda law may differ from the rights of shareholders of companies incorporated in another jurisdiction. It may be difficult for investors to enforce in the 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.

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 66⅔% 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.

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 held, directly, indirectly or constructively, 9.5% or more of the total voting power of issued share capital immediately prior to the closing of our IPO, 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 MVT-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.

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 our IPO in our business. We believe that we were not a CFC prior to our IPO 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 fact-intensive 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

(a) **Recent Sales of Unregistered Equity Securities**

In August 2016, (1) we granted options to purchase 602,743 common shares to our employees and consultants, with an exercise price of $2.38 under the 2016 Plan and (2) we 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) we granted options to purchase 572,568 common shares to our employees, officers and directors, with an exercise price of $4.00 under the 2016 Plan and (2) we 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.

The sale and issuance of the securities listed above were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act or Rule 701 promulgated under Section 3(b) of the Securities Act, as transactions by an issuer not involving a public offering or transactions pursuant to compensatory benefit plans and contracts relating to compensation as provided under Rule 701.

(b) **Use of Proceeds**

On November 1, 2016, we closed our IPO, in which we issued and sold 14,500,000 common shares at a public offering price of $15.00 per common share, for gross proceeds of $217.5 million. All of the common shares issued and sold in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (Registration No. 333-213891), which was declared effective by the SEC on October 26, 2016. Citigroup Global Markets Inc., Cowen and Company, LLC, Evercore Group L.L.C. and Barclays Capital Inc. acted as book-running managers for our IPO. The net proceeds to us were approximately $200.0 million, after deducting $15.2 million in underwriting discounts and commissions and $2.3 million in offering expenses. Substantially all of the cash proceeds are currently deposited with one banking institution and is substantially all in excess of insured levels.

No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliates.

There has been no material change in the planned use of proceeds from our IPO from that described in the final prospectus filed by us with the SEC on October 27, 2016 pursuant to Rule 424(b) of the Securities Act.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

On February 13, 2017, in connection with the contribution and assignment of all of our intellectual property rights to MSG, we and our wholly-owned subsidiaries, MSI and MSG, entered into an amended and restated services agreement with RSI, effective as of November 11, 2016. As a result of the amended and restated agreement, MSG was included as a recipient of these services from RSI. On February 13, 2017, MSG also entered into a separate services agreement with RSG, effective as of November 11, 2016, for the provisioning of services by RSG to MSG in relation to the identification of potential product candidates and project management of clinical trials, as well as, other services related to clinical development, administrative and financial activities. Under the terms of both services agreements, we are obligated to pay or reimburse RSI and RSG for the costs they, or third parties acting on their behalf, incur in providing services to us, including administrative and support services, as well as, research and development services. In addition, we are obligated to pay to RSI and RSG a pre-determined mark-up on the costs incurred directly by RSI and RSG in connection with any general and administrative and research and development services.

Item 6. Exhibits.

The exhibits listed in the Exhibit Index to this Quarterly Report on Form 10-Q are incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

MYOVANT SCIENCES LTD.

By: /s/ Frank Karbe

Frank Karbe
(Duly Authorized Officer and Principal Financial and Accounting Officer)

Date: February 13, 2017

Exhibit Index

Exhibit Number	Description of Document
3.1	Certificate of Incorporation. (1)
3.2	Memorandum of Association. (2)
3.3	Amended and Restated Bye-laws. (3)
10.1	Amended and Restated Services Agreement, dated February 13, 2017, by and among Roivant Sciences, Inc., Myovant Sciences Ltd., Myovant Sciences, Inc. and Myovant Sciences GmbH.
10.2	Services Agreement, dated February 13, 2017, by and among Roivant Sciences GmbH and Myovant Sciences GmbH.
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS XBRL	Instance Document
101.SCH XBRL	Taxonomy Extension Schema
101.CAL XBRL	Taxonomy Extension Calculation Linkbase
101.DEF XBRL	Taxonomy Extension Definition Linkbase
101.LAB XBRL	Taxonomy Extension Label Linkbase
101.PRE XBRL	Taxonomy Extension Presentation Linkbase

(1) Incorporated herein by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-213891), filed on September 30, 2016.

(2) Incorporated herein by reference to Exhibit 3.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-213891), filed on September 30, 2016.

(3) Incorporated herein by reference to Exhibit 3.4 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-213891), filed on October 17, 2016.

* These certifications are being furnished solely to accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 10.1

EXECUTION COPY

AMENDED AND RESTATED SERVICES AGREEMENT

This Amended and Restated Services Agreement (the "Agreement") is entered into effective as of November 11, 2016 (the "Effective Date"), by and among Roivant Sciences, Inc., a corporation organized under the laws of the State of Delaware ("Service Provider"), Myovant Sciences GmbH, a company with limited liability organized under the laws of the country of Switzerland ("MSG"), Myovant Sciences, Inc. (f/k/a Roivant Endocrinology, Inc.), a corporation organized under the laws of the State of Delaware ("MSI"), and Myovant Sciences Ltd. (f/k/a Roivant Endocrinology Ltd.), an exempted limited company organized under the laws of the country of Bermuda ("MSL", and together with MSI and MSG, the "Service Recipients" and each a "Service Recipient").

RECITALS

WHEREAS, Service Provider, MSI and MSL entered into that certain Services Agreement, dated as of April 29, 2016 (the "Original Services Agreement"), pursuant to which MSI and MSL engaged the services of Service Provider in consideration for a fee;

WHEREAS, the Parties hereto desire to add MSG as one of the service recipients to the Original Services Agreement in connection with the contribution and assignment by MSL to MSG of certain assigned assets pursuant to that certain Asset Contribution Agreement, dated November 11, 2016, by and between MSL and MSG;

WHEREAS, the Parties hereto desire to amend and restate the Original Services Agreement in its entirety as set forth herein to reflect the addition of MSG as one of the service recipients to the Original Services Agreement;

WHEREAS, MSG is a biotechnology company focused on acquiring, developing and commercializing late-stage endocrinology drug candidates, including non-strategic endocrinology assets from large pharmaceutical companies, distressed endocrinology drug candidates from small biotech companies, endocrinology drugs or novel approaches from universities, and high-risk endocrinology projects abandoned by conventional biopharmaceutical firms;

WHEREAS, MSI has agreed to provide certain preparatory services in relation to the identification of potential endocrinology drug asset candidates, managing the performance of clinical trials or other research and development activities, performing or evaluating scientific and statistical analyses, and various administrative matters pursuant to that certain Amended and Restated Services Agreement among MSL, MSI and MSG, dated as of November 3, 2016 (the "MSL-MSI-MSG Services Agreement");

WHEREAS, Service Provider is capable of providing preparatory services in relation to the identification of potential endocrinology drug asset candidates, managing the performance of clinical trials or other research and development activities, performing or evaluating scientific and statistical analyses, and various administrative matters and is also capable of assisting MSI in providing such services in connection with the MSL-MSI-MSG Services Agreement; and

WHEREAS, Service Recipients desire to engage the services of Service Provider until such time as MSI is able to provide all of the services required by MSG in connection with the MSL-MSI-MSG Services Agreement, and the Service Provider is willing to provide such services in consideration for a fee.

NOW, THEREFORE, in consideration of the mutual covenants, rights and obligations set forth herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. DEFINITIONS

1.1 Affiliate. "Affiliate" shall mean any Person, whether de jure or de facto, other than a Party, that directly or indirectly owns, is owned by or is under common ownership with a Party to the extent of at least 50 percent of the equity having the power to vote on or direct the affairs of the entity, and any Person actually controlled by, controlling, or under common control with a Party.

1.2 Costs. "Costs" shall mean the fully-burdened cost incurred by the Service Provider and its Affiliates during any applicable month to provide the Services. For purposes of this definition, the fully-burdened cost includes without limitation: (i) the costs of any materials used in providing the Services; (ii) the salary, benefits (if any) (including without limitation, medical plans and 401(k) or other retirement plans), and employment taxes (if any) of all the Service Provider's employees involved in providing such services (excluding, however, any compensation that is provided to an employee or independent contractor in the form of equity instruments, options to acquire stock (stock options), rights with respect to (or determined by reference to) equity instruments or stock options, or any non-cash compensation provided by a third party to an employee or independent contractor); (iii) related overhead expenses (including, without limitation, cost of facilities and utilities costs, insurance, and the cost of all general support, operational and business services); (iv) any and all licensing fees paid or payable to Third Parties for any intellectual property incorporated into such services; and (v) any depreciation, amortization or other cost recovery for financial accounting purposes related to assets of the Service Provider to the extent such assets are used in providing the Services; provided, however, that the fully-burdened cost shall not include costs incurred by the Service Provider to engage a Third Party for the purpose of providing Services pursuant to Section 3.4 of the Agreement.

1.3 Marks. "Marks" shall mean and include trademarks, service marks, trade names, domain names, trade dress, logos, and similar designations, whether registered or unregistered, and all applications and registrations therefor.

1.4 Party. "Party" shall mean Service Provider or either Service Recipient, and "Parties" shall mean Service Provider and Service Recipients collectively.

1.5 Person. "Person" shall mean and include any individual, corporation, trust, estate, partnership, joint venture, company, association, governmental bureau or agency, or any other entity regardless of the type or nature thereof.

1.6 Third Party. "Third Party" shall mean any entity other than a Party or an Affiliate.

1.7 Works. “Works” shall mean any work product, technical knowledge, creations, know-how, formulations, recipes, specifications, rights, devices, drawings, instructions, expertise, trade practices, customer lists, computer data, source codes, analytical and quality control data, Marks, copyrights, commercial information, inventions, works of authorship, designs, methods, processes, technology, patterns, techniques, data, , patents, trade secrets, copyrights, related contracts, licenses and agreements and the like, and all other intellectual property created, authored, composed, invented, discovered, performed, perfected, provided, acquired or learned by the Service Provider, whether solely or jointly with others, whether patented, patentable or not, whether in written form or otherwise, whether disclosed to Service Provider by either Service Recipient or otherwise, in performing its obligations under this Agreement, in each case, that (i) relates to intellectual property or potential intellectual property originating from research and development of any of Service Recipient or its affiliate’s drug products or portfolio candidates, and (ii) arises out of services provided directly or indirectly (e.g., through an employee, consultant clinical research organization, other vendor or other Third Party engaged by the Service Provider) in connection with such research and development.

1.8 Year. “Year” shall mean the 12-month period ending on March 31.

2. ENGAGEMENT.

Subject to the terms of this Agreement, each Service Recipient hereby engages the Service Provider to perform the services it requires from among those set forth on Exhibit A attached hereto (the “Services”). Any additional services requested by a Service Recipient that are not included within the Services shall, if mutually agreed upon by the Parties, each in its sole discretion, be negotiated and included in this Agreement through amendments to Exhibit A hereto. The scope of the Service Provider’s authority shall be specifically limited to those activities outlined in this Agreement.

3. RELATIONSHIP OF THE PARTIES.

3.1 The Service Provider and the Service Recipients are each independent contractors and not joint venturers, partners, agents, or representatives of the other. The Service Provider shall perform the Services for the Service Recipients under this Agreement as an independent contractor and neither the Service Provider nor its employees, subcontractors or agents shall be deemed to be agents, servants or employees of either of the Service Recipients, nor shall the Service Provider and any of the Service Recipients be deemed or construed solely by this Agreement to be partners or joint venturers. The Service Provider shall have exclusive control over the direction and conduct of its employees in carrying out the activities required under this Agreement.

3.2 Neither the Service Provider nor its employees, subcontractors or agents shall have the authority to (i) negotiate the terms of or execute contracts and agreements of either of the Service Recipients (including letters of intent, even if non-binding), provided the Service Provider may suggest incorporating certain non-core agreement terms within the parameters and guidelines provided by the applicable Service Recipient; (ii) hire personnel for either of the Service Recipients; (iii) exercise binding authority with respect to the operations of either of the Service Recipients; (iv) make binding recommendations to either of the Service Recipients; (v) make decisions or have decision-making rights with respect to either of the Service Recipients; (vi) hold itself out as representing either of

the Service Recipients or as having the authority to negotiate the terms of or conclude contracts on behalf of either of the Service Recipients or (vii) perform services for either of the Service Recipients that are not covered by this Agreement.

3.3 The Service Provider and its employees, subcontractors or agents shall have the authority to (i) provide advice, assistance, direction and recommendations to the Service Recipients with respect to the operation of MSG; (ii) make recommendations on key points of contracts, without having the power to negotiate the terms of or conclude contracts or agreements on behalf of either of the Service Recipients; (iii) participate in discussions on contracts and agreements; (iv) arrange transactions between a Service Recipient and other parties, provided that the Service Provider does not make any actual decisions or participate in substantive activities, such as negotiations with respect to the terms of such transactions, provided the Service Provider may suggest incorporating certain non-core agreement terms within the parameters and guidelines provided by the applicable Service Recipient; and (v) contact banks in connection with raising capital for the Service Recipient, without having, in any circumstance, the power to negotiate the terms of or conclude contracts or agreements on behalf of either of the Service Recipients in connection with raising capital for MSG.

3.4 Engagement of Third Parties. The Service Provider may, with the prior consent of the applicable Service Recipient, engage such persons, corporations, or other entities as it reasonably deems necessary for the purpose of performing Services under this Agreement; provided, however, that the Service Provider shall remain responsible for the performance of all such Services and shall be considered to engage with such persons, corporations, or other entities in its own name and on its own behalf.

4. FEES AND EXPENSES.

4.1 Each Service Recipient shall pay the Service Provider a fee in accordance with Exhibit B attached hereto for the Services provided to such Service Recipient hereunder. The rates specified in Exhibit B attached hereto shall be reviewed and may be updated from time to time by the Parties. Fees for Services performed by the Service Provider will be billed by the Service Provider to the applicable Service Recipient on a monthly basis. All other costs for Third Party services shall be billed, by or on behalf of the Service Provider, to the applicable Service Recipient, in such manner and format and with such supporting information as the Parties may reasonably agree from time to time. Payment for undisputed invoices received by the applicable Service Recipient shall be due within sixty (60) days after the billing date. Any fees and expenses not paid by the due date thereof shall accrue interest at the safe harbor interest rate based on the applicable Federal rate as set forth in U.S. Treasury Regulations Section 1.482-2(a)(2)(iii)(B). All fees and expenses shall be invoiced and payable in U.S. dollars.

4.2 Yearly Reconciliation. The Parties shall perform a yearly reconciliation for the compensation amounts paid as follows:

a. Administrative Services Yearly Reconciliation.

i. As soon as reasonably practicable following the close of each Year during the Term of this Agreement, the Parties will calculate the total service fee with respect to the activities listed in Exhibit A, subsection 1 ("Administrative and Support Services") owing under this Agreement by each Service Recipient for the Year (the "Exhibit B Administrative Services Fees") by calculating the Service Provider's Costs with respect to such services provided to the applicable Service Recipient and applying the mutually agreed mark-up percentage for such services determined in accordance with Exhibit B, and adding the amount of any third-party costs reimbursable under Exhibit B paragraph (c) that relate to such services. As soon as reasonably practicable following the close of each Year, the Parties shall also calculate the total amount of service fees actually paid by each Service Recipient for the Year under Section 4.1 with respect to the activities listed in Exhibit A, subsection 1 ("Administrative and Support Services"), adding the amount of any third-party costs reimbursable under Exhibit B paragraph (c) that relate to such services (the "Actual Administrative Services Fees").

ii. If, for any Year, the total Actual Administrative Services Fees paid by a Service Recipient is greater than the Exhibit B Administrative Services Fees for such Service Recipient, there shall be deemed to exist an excess of service fee in an amount equal to the difference between the total Actual Administrative Services Fees paid by such Service Recipient and the total Exhibit B Administrative Services Fees for such Service Recipient for the Year (hereinafter "Administrative Services Excess").

iii. If, for any Year, the total Actual Administrative Services Fees paid by a Service Recipient is less than the total Exhibit B Administrative Services Fees for such Service Recipient, there shall be deemed to exist a shortfall in an amount equal to the difference between the total Exhibit B Administrative Services Fees for such Service Recipient and the total Actual Administrative Services Fees paid by such Service Recipient (hereinafter "Administrative Services Shortfall").

b. Other Services Yearly Reconciliation.

i. As soon as reasonably practicable following the close of each Year during the Term of this Agreement, the Parties will calculate the total service fee with respect to the activities listed in Exhibit A, subsection 2 ("Other Services") owing under this Agreement by each Service Recipient for the Year (the "Exhibit B Other Services Fees") by calculating the Service Provider's Costs with respect to such services provided to the applicable Service Recipient and applying the mutually agreed mark-up percentage for such services determined in accordance with Exhibit B, and adding the amount of any third-party costs reimbursable under Exhibit B paragraph (c) that relate to such services. As soon as reasonably practicable following the close of each Year, the Parties shall also calculate the total amount of service fees actually paid by each Service Recipient for the Year under Section 4.1 with respect to the activities listed in Exhibit A, subsection 1 ("Other Services"), adding the amount of any third-party costs reimbursable under Exhibit B paragraph (c) that relate to such services (the "Actual Other Services Fees").

ii. If, for any Year, the total Actual Other Services Fees paid by a Service Recipient is greater than the Exhibit B Other Services Fees for such Service Recipient, there shall be deemed to exist an excess of service fee in an amount equal to the difference between the total Actual Other Services Fees paid by such Service Recipient and the total Exhibit B Other Services Fees for such Service Recipient for the Year (hereinafter "Other Services Excess").

iii. If, for any Year, the total Actual Other Services Fees paid by a Service Recipient is less than the total Exhibit B Other Services Fees for such Service Recipient, there shall be deemed to exist a shortfall in an amount equal to the difference between the total Exhibit B Other Services Fees for such Service Recipient and the total Actual Other Services Fees paid by such Service Recipient (hereinafter "Other Services Shortfall").

c. Settlement of Excess or Shortfall Amounts.

i. If, for any Year, (1) the sum of the Administrative Services Shortfall for a Service Recipient and the Other Services Shortfall for such Service Recipient exceeds (2) the sum of the Administrative Services Excess for such Service Recipient and the Other Services Excess for such Service Recipient (such excess amount, the "Net Shortfall"), such Service Recipient shall pay such Net Shortfall to Service Provider within thirty (30) days after the Exhibit B Administrative Services Fees, Exhibit B Other Services Fees, Actual Administrative Services Fees, and Actual Other Services Fees have been calculated for such Year.

ii. If, for any Year, (1) the sum of the Administrative Services Excess for a Service Recipient and the Other Services Excess for such Service Recipient exceeds (2) the sum of the Administrative Services Shortfall for such Service Recipient and the Other Services Shortfall for such Service Recipient (such excess amount, the "Net Excess"), the Service Provider may (x) treat such Net Excess, in whole or in part, as a contribution to the capital of the Service Provider; or (y) treat such Net Excess, in whole or in part, as an overpayment to the Service Provider that must be repaid to such Service Recipient within 30 days after the end of the Year.

4.3 Withholding. The Service Recipients shall be entitled to deduct from any payments to Service Provider the amount of any withholding taxes with respect to such amounts payable, or any taxes in each case required to be withheld by the applicable Service Recipient to the extent that such Service Recipient pays to the appropriate governmental authority on behalf of Service Provider such taxes, levies, or charges. Such Service Recipient shall, upon the request of Service Provider, deliver to Service Provider proof of payment of all such taxes, levies, and other charges and the appropriate documentation that is necessary to obtain a tax credit, to the extent such tax credit can be obtained.

5. ACCESS TO BOOKS AND RECORDS.

Service Provider shall maintain books and records pertaining to the Services provided in any Year pursuant to this Agreement for ten (10) Years following the performance of such Services and shall make them available for inspection and audit, at the applicable Service Recipient's expense, by a mutually acceptable independent certified public accounting firm during normal business hours upon reasonable prior written notice to Service Provider.

6. CONFIDENTIAL INFORMATION

6.1 Obligations. The Parties acknowledge that, from time to time, one Party (the "Disclosing Party") may disclose to another Party (the "Receiving Party") information that is marked as "proprietary," or "confidential," or which would, under the circumstances, be understood by a reasonable person to be proprietary and nonpublic ("Confidential Information"). The Receiving Party shall retain such Confidential Information in confidence. Each Party shall use at least the same procedures and degree of care that it uses to protect its own Confidential Information of like importance, including those procedures used when disclosing Confidential Information to Third Parties, and in no event less than reasonable care.

6.2 Exceptions. Nothing in this Agreement shall prevent the disclosure by the Receiving Party or its employees of Confidential Information that:

a. Prior to the transmittal thereof to Receiving Party was of general public knowledge;

b. Becomes, subsequent to the time of transmittal to Receiving Party, a matter of general public knowledge otherwise than as a consequence of a breach by Receiving Party of any obligation under this Agreement;

c. Is made public by Disclosing Party;

d. Was in the possession of Receiving Party in documentary form prior to the time of disclosure thereof to Receiving Party by Disclosing Party, and is held by Receiving Party free of any obligation of confidence to Disclosing Party or any Third Party; or

e. Is received in good faith from a Third Party having the right to disclose it, who, to the best of Receiving Party's knowledge, did not obtain the same from Disclosing Party and who imposed no obligation of secrecy on Receiving Party with respect to such information.

6.3 No Unauthorized Use. The Receiving Party shall refrain from using or exploiting any and all Confidential Information for any purposes or activities other than those contemplated in this Agreement or any other written agreement entered into by and between the Parties.

6.4 Survival. The Parties' obligations under this Article 6 shall survive the termination of this Agreement for any reason whatsoever.

7. OWNERSHIP OF INTANGIBLE PROPERTY

Service Provider agrees that all right, title and interest in and to any and all Works will be owned exclusively by MSG. All Works, as applicable, shall be considered "works made for hire" to the extent permitted under applicable copyright law and will be considered the sole property of MSG. To the extent such Works are not considered "works made for hire," all right, title, and interest to such Works, including, but not limited to, all copyrights, patents, trademarks, rights of publicity, and trade secrets, is hereby assigned by Service Provider to MSG and the Service Provider agrees, at MSG's expense, to execute any documents requested by MSG or any successor in interest to MSG, at any time in relation to such assignment. Service Provider further acknowledges and agrees that any and all derivative works, developments, or improvements based on the Works, shall also be deemed Works and all right, title and interest therein shall be exclusively owned by MSG. Service Provider shall cooperate with MSG and any of its Affiliates, at no additional cost to such parties (whether during or after the term of this Agreement), in the confirmation, registration, protection and enforcement of the rights and property of MSG and its successors in interest in such Works. The Service Provider shall be entitled to use the Works only for purposes of performing the Services. The Service Provider shall not at any time do or cause to be done, or fail to do or cause to be done, any act or thing, directly or indirectly, contesting or in any way impairing either MSG's right, title, or interest in the Intangible Property. Every use of any Works (and any derivative works, developments, or improvements based on the Works) by Service Provider shall inure to the benefit of MSG.

8. USE OF TRADEMARKS

Each Service Recipient shall grant the Service Provider a right to use its Marks only in connection with the Services, provided that if a Service Recipient provides the Service Provider with reasonable written trademark guidelines governing the use of such Service Recipient's Marks (which guidelines may be updated by such Service Recipient from time to time with prior written notice to the Service Provider), the Service Provider's use of such Marks shall be subject to such written guidelines so provided. Notwithstanding the foregoing, the Service Provider will comply with all of such Service Recipient's reasonable instructions and quality control requirements regarding such Service Provider's use of its Marks. The Service Provider acknowledges that any of a Service Recipient's Marks are owned and licensed solely and exclusively by such Service Recipient, and agrees to use such Marks only in the form and with appropriate legends as described by such Service Recipient. All use of a Service Recipient's Marks and associated goodwill will inure to the benefit of such Service Recipient. All rights not expressly granted are reserved to the applicable Service Recipient. The Service Provider shall not remove, cover, or modify any proprietary rights notice or legend placed by the other party on materials used in connection with this Agreement.

9. INDEMNIFICATION; LIMITATION OF LIABILITY

9.1 The Service Provider, to the maximum extent permitted by law, shall defend, protect, indemnify and hold the Service Recipients and their officers, employees and directors, as the case may be ("Indemnified Parties"), harmless from and against any and all losses, demands, damages (including, without limitation, special, consequential and punitive damages awarded to Third Parties), claims, liabilities, interest, awards, actions or causes of action, suits, judgments, settlements and compromises relating thereto, and all reasonable attorney's fees and other fees and expenses in connection therewith ("Losses") which may be incurred by an Indemnified Party, arising out of, due to, or in connection with, directly or indirectly, the provision of the Services or failure to provide the Services under this Agreement, except to the extent that such Losses are the result of the gross negligence or willful misconduct of an Indemnified Party.

9.2 The Service Provider's liability for aggregate Losses under this Agreement for any cause whatsoever, and regardless of the form of action, whether in contract or in tort, shall be limited to the payments made by the Service Recipients under this Agreement for the specific Service that allegedly caused or was related to the Losses during the period in which the alleged Losses were incurred. In no event shall the Service Provider be liable for any Losses caused by a Service Recipient's failure to perform such Service Recipient's obligations under this Agreement.

9.3 NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT OR AT LAW OR IN EQUITY, IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR PUNITIVE, SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES TO THE OTHER PARTY OR ANY OTHER PERSON (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF BUSINESS PROFITS, BUSINESS INTERRUPTION, ACTIONS OF THIRD PARTIES OR ANY OTHER LOSS) ARISING FROM OR RELATING TO ANY CLAIM MADE UNDER THIS AGREEMENT OR THE PROVISION OR THE FAILURE TO PROVIDE THE SERVICES.

10. TERM AND TERMINATION

10.1 Term. This Agreement shall commence on the Effective Date and continue until terminated by a Party in accordance with this Section 10.1. A Party may terminate this Agreement at its discretion by giving written notice to the other Parties at least sixty (60) days before the proposed termination date. Section 12.14 and Article 6 shall survive the termination of this Agreement. The Service Recipients hereby specifically agree and acknowledge that all obligations of the Service Provider to provide any and all Services shall immediately cease upon termination of this Agreement. The Service Provider hereby specifically agrees and acknowledges that all of its rights to use Marks pursuant to Article 8 of this Agreement shall immediately cease upon termination of this Agreement. To the extent permitted by applicable law, no Party shall be liable to another Party for, and each Party hereby expressly waives any right to, any termination compensation of any kind or character whatsoever, to which such Party may be entitled solely by virtue of termination of this Agreement.

10.2 Rights and Duties on Termination. Upon termination of this Agreement for any reason, each Party shall cease all use of the other Party's Confidential Information, and the Service Recipients shall pay Service Provider all accrued and unpaid fees for Services performed through the date of termination.

11. COMPLIANCE WITH LAWS

11.1 General Compliance. The Parties shall at all times strictly comply with all applicable laws, rules, regulations, and governmental orders, now or hereafter in effect, relating to their performance of this Agreement. Each Party further agrees to make, obtain, and maintain in force at all times during the term of this Agreement, all filings, registrations, reports, licenses, permits, and authorizations (collectively, "Authorizations") required under applicable law, regulation, or order for such Party to perform its obligations under this Agreement. The Service Recipients shall provide Service Provider with such assistance as Service Provider may reasonably request in making or obtaining any such Authorizations.

12. GENERAL PROVISIONS

12.1 Notices. Any and all notices, elections, offers, acceptances, and demands permitted or required to be made under this Agreement shall be in writing, signed by the Party giving such notice, election, offer, acceptance, or demand and shall be delivered personally, by messenger, courier service, telecopy, first class mail or similar transmission, to the Party, at its address on file with the Party giving such notice, election, offer, acceptance or demand or at such other address as may be supplied in writing. The date of personal delivery or the date of mailing, as the case may be, shall be the date of such notice, election, offer, acceptance, or demand.

12.2 Force Majeure. If the performance of any part of this Agreement by a Party, or of any obligation under this Agreement, is prevented, restricted, interfered with, or delayed by reason of any cause beyond the reasonable control of the Party liable to perform, unless conclusive evidence to the contrary is provided, the Party so affected shall, on giving written notice to the other Parties, be excused from such performance to the extent of such prevention, restriction, interference, or delay, provided that the affected Party shall use its reasonable best efforts to avoid or remove such causes of nonperformance and shall continue performance with the utmost dispatch whenever such causes are removed. When such circumstances arise, the Parties shall discuss what, if any, modification of the terms of this Agreement may be required in order to arrive at an equitable solution.

12.3 Successors and Assigns. This Agreement may not be assigned or otherwise conveyed by any Party without the prior written consent of the other Parties; provided however that such prior written consent will not be required for an assignment to an Affiliate of a Party. This Agreement shall be binding on and inure to the benefit of the Parties hereto and their respective successors, successors in title and assigns to the extent that such assignment is permitted under this paragraph.

12.4 Entire Agreement, Amendments. This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof, and supersedes all prior agreements, understandings, and communications between the Parties, whether oral or written, relating to the same subject matter. No change, modification, or amendment of this Agreement shall be valid or binding on the Parties unless such change or modification shall be in writing signed by the Party or Parties against whom the same is sought to be enforced.

12.5 Remedies Cumulative. The remedies of the Parties under this Agreement are cumulative and shall not exclude any other remedies to which the Party may be lawfully entitled.

12.6 Other Persons. Nothing in this Agreement shall be construed to prevent or prohibit the Service Provider from providing services to any other Person or from engaging in any other business activity.

12.7 Not for the Benefit of Third Parties. This Agreement is for the exclusive benefit of the Parties to this Agreement and not for the benefit of any Third Party.

12.8 Further Assurances. Each Party hereby covenants and agrees that it shall execute and deliver such deeds and other documents as may be required to implement any of the provisions of this Agreement.

12.9 No Waiver. The failure of any Party to insist on strict performance of a covenant hereunder or of any obligation hereunder shall not be a waiver of such Party’s right to demand strict compliance therewith in the future, nor shall the same be construed as a novation of this Agreement.

12.10 Integration. This Agreement constitutes the full and complete agreement of the Parties.

12.11 Captions. Titles or captions of articles and paragraphs contained in this Agreement are inserted only as a matter of convenience and for reference, and in no way define, limit, extend, or describe the scope of this Agreement or the intent of any provision hereof.

12.12 Number and Gender. Whenever required by the context, the singular number shall include the plural, the plural number shall include the singular, and the gender of any pronoun shall include all genders.

12.13 Counterparts. This Agreement may be executed in multiple copies, each one of which shall be an original and all of which shall constitute one and the same document, binding on the Parties, and each Party hereby covenants and agrees to execute all duplicates or replacement counterparts of this Agreement as may be required.

12.14 Governing Law and Jurisdiction. THIS AGREEMENT AND THE LEGAL RELATIONS BETWEEN THE PARTIES HERETO SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK, WITHOUT REGARD TO ANY CONFLICT OF LAWS RULES. THE COURTS LOCATED WITHIN THE STATE OF NEW YORK SHALL HAVE EXCLUSIVE JURISDICTION OVER ANY AND ALL DISPUTES BETWEEN THE PARTIES HERETO, WHETHER IN LAW OR EQUITY, ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE AGREEMENTS, INSTRUMENTS AND DOCUMENTS CONTEMPLATED HEREBY AND THE PARTIES CONSENT TO AND AGREE TO SUBMIT TO THE EXCLUSIVE JURISDICTION OF SUCH COURTS. EACH OF THE PARTIES HEREBY WAIVES AND AGREES NOT TO ASSERT IN ANY SUCH DISPUTE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY CLAIM THAT (A) SUCH PARTY IS NOT PERSONALLY SUBJECT TO THE JURISDICTION OF SUCH COURTS, (B) SUCH PARTY AND SUCH PARTY'S PROPERTY IS IMMUNE FROM ANY LEGAL PROCESS ISSUED BY SUCH COURTS OR (C) ANY LITIGATION OR OTHER PROCEEDING COMMENCED IN SUCH COURTS IS BROUGHT IN AN INCONVENIENT FORUM.

12.15 Computation of Time. Whenever the last day for the exercise of any privilege or the discharge of any duty hereunder shall fall on a Saturday, Sunday, or any public or legal holiday, whether local or national, the Party having such privilege or duty shall have until 5:00 p.m. (EST or, if in effect in New York, EDT) on the next succeeding business day to exercise such privilege, or to discharge such duty.

12.16 Severability. In the event any provision, clause, sentence, phrase, or word hereof, or the application thereof in any circumstances, is held to be invalid or unenforceable, such invalidity or unenforceability shall not affect the validity or enforceability of the remainder hereof, or of the application of any such provision, sentence, clause, phrase, or word in any other circumstances.

12.17 Costs and Expenses. Unless otherwise provided in this Agreement, each Party shall bear all fees and expenses incurred in performing its obligations under this Agreement.

12.18 Provisions of Law. A reference in this Agreement to a provision of law, regulation, rule, official directive, request, or guideline (whether or not having the force of law) of any governmental, intergovernmental or supranational body, agency, department or regulatory, self-regulatory, or other authority or organization is a reference to that provision as amended or re-enacted currently or in the future.

12.19 Meaning in Notices. Unless a contrary indication appears, a term used in any notice given under or in connection with this Agreement has the same meaning in that notice as in this Agreement.

(The remainder of this page has been intentionally left blank)

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized officers effective as of the date first above written.

MYOVANT SCIENCES LTD.	ROIVANT SCIENCES, INC.
/s/ Marianne L. Romeo	/s/ Matthew Gline
By: Marianne L. Romeo	By: Matthew Gline
Title: Head, Global Transaction & Risk Management	Title: SVP, Finance and Business Operations
Date: 13 February 2017	Date: February 13, 2017

MYOVANT SCIENCES, INC.	MYOVANT SCIENCES GMBH
/s/ Lynn Seely	/s/ Ruben Masar
By: Lynn Seely	By: Ruben Masar
Title: President and Chief Executive Officer	Title: Secretary
Date: February 13, 2017	Date: 13 February 2017

EXHIBIT A

SERVICES PROVIDED

1. Administrative and Support Services. Various administrative and supportive services, which may include, but are not limited to:

(a) Payroll
(b) Accounts Receivable
(c) Accounts Payable
(d) General Administrative
(e) Corporate and Public Relations (including advertising, investor relations and/or financial marketing)
(f) Meeting Coordination and Travel Planning
(g) Accounting and Auditing
(h) Tax
(i) Budgeting
(j) Treasury Activities
(k) Staffing and Recruiting
(l) Training and Employee Development
(m) Benefits
(n) Information and Technology Services
(o) Legal Services
(p) Insurance Claims Management
(q) Purchasing

And other similar services.

2. Other Services

Administrative, research and development services whether provided directly or by engaging employees, agents, consultants, contract research organizations, vendors or any other Third Party, including, but not limited to:

(a) Preparatory assistance in respect of the identification/location of potential drug asset candidates

(b) Perform/oversee due diligence to evaluate a drug candidate (including, but not limited to, studying the compound, market demand, potential opportunities and competitive landscape with respect to such drug candidate and probability of commercial success of such drug candidate)

(c) Engage, manage and oversee external consultants, whether individuals or consulting companies, in connection with in-depth analyses of potential drug investment opportunities and other activities relating to drugs and drug candidates

(d) Form recommendations regarding potential drug investment opportunities and deliver recommendations to the board of directors of either of the Service Recipients

(e) Provide the board of directors of either of the Service Recipients with advice in connection with the acquisition of drug assets and, if necessary, assist in communications between the board of directors of the applicable Service Recipient and the sellers of the relevant drug asset in order for MSG to negotiate and conclude agreements to acquire drug assets and related intellectual property

(f) Participate in meetings with regulatory authorities related to drug assets of MSG (within the parameters and guidelines provided by MSG)

(g) Develop a plan for clinical testing with respect to a drug asset, identify appropriate contract research organizations to be used in connection with such clinical testing and contract with such contract research organizations (within the parameters and guidelines provided by MSG)

(h) Select manufacturers to manufacture small batch sample of drug product for purposes of clinical trials and contract with such manufacturers (within the parameters and guidelines provided by MSG)

(i) Manage and oversee clinical trials and drug manufacturing to the extent such clinical trials and drug manufacturing costs do not exceed established cost parameters set by MSG

(j) Gather and analyze data obtained in connection with clinical trials and present such information to the board of directors of MSG

(k) Conduct final filings to obtain regulatory approvals with respect to a drug asset

The Service Provider shall provide such other services as are agreed with the Service Recipients from time to time.

EXHIBIT B

CALCULATION OF COMPENSATION FOR SERVICES PROVIDED

The fees set forth in this Exhibit B represent the entire amount to be paid by the Service Recipients in connection with the Service Provider's provision of the Services, and any and all other costs and expenses associated with the Services or the Agreement. In addition, the fees set forth in this Exhibit B include any and all applicable federal, state or local sales or use tax payable in connection with the Services or the Agreement.

Except as otherwise agreed to by the Parties from time to time, the Service Recipients shall compensate Service Provider for its Services rendered and Costs incurred under this Agreement in accordance with the following:

(a) The applicable Service Recipient shall reimburse Service Provider for its Costs, excluding third-party costs as provided in (c), incurred in providing the Administrative and Support Services described in Exhibit A to such Service Recipient or in making, obtaining, and maintaining in force the Authorizations as described in Section 11.1 for such Service Recipient and shall further pay Service Provider a mark-up on such costs. The mark-up shall be based on the mark-up percentage that the Parties mutually agree is consistent with the financial returns of independent companies performing similar services. The Parties shall review and (if necessary) update the mark-up percentage on an annual basis.

(b) The applicable Service Recipient shall reimburse Service Provider for its Costs, excluding third-party costs as provided in (c), incurred in providing the Other Services described in Exhibit A to such Service Recipient, and shall further pay Service Provider a mark-up on such costs. The mark-up shall be based on the mark-up percentage that the Parties mutually agree is consistent with the financial returns of independent companies performing similar services. The Parties shall review and (if necessary) update the mark-up percentage on an annual basis.

(c) If the Service Provider engages a third party pursuant to Section 3.4 hereof, the applicable Service Recipient shall reimburse the Service Provider for all reasonable and actual out-of-pocket costs incurred by the Service Provider in connection with such engagement to the extent such Service Recipient is the beneficiary of the services performed by such third party.

Exhibit 10.2

EXECUTION COPY

SERVICES AGREEMENT

This Services Agreement (the "Agreement") is entered into effective as of November 11, 2016 (the "Effective Date"), by and between Roivant Sciences GmbH, a company with limited liability organized under the laws of the country of Switzerland ("Service Provider") and Myovant Sciences GmbH, a company with limited liability organized under the laws of the country of Switzerland ("Service Recipient").

RECITALS

WHEREAS, Service Recipient is a biotechnology company focused on acquiring, developing and commercializing late-stage endocrinology drug candidates, including non-strategic endocrinology assets from large pharmaceutical companies, distressed endocrinology drug candidates from small biotech companies, endocrinology drugs or novel approaches from universities, and high-risk endocrinology projects abandoned by conventional biopharmaceutical firms;

WHEREAS, Service Provider is capable of providing preparatory services in relation to the identification of potential endocrinology drug asset candidates, managing the performance of clinical trials or other research and development activities, performing or evaluating scientific and statistical analyses, and various administrative matters; and

WHEREAS, Service Recipient desires to engage the services of Service Provider, and the Service Provider is willing to provide such services in consideration for a fee.

NOW, THEREFORE, in consideration of the mutual covenants, rights and obligations set forth herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. DEFINITIONS

1.1 Affiliate. "Affiliate" shall mean any Person, whether de jure or de facto, other than a Party, that directly or indirectly owns, is owned by or is under common ownership with a Party to the extent of at least 50 percent of the equity having the power to vote on or direct the affairs of the entity, and any Person actually controlled by, controlling, or under common control with a Party.

1.2 Costs. “Costs” shall mean the fully-burdened cost incurred by the Service Provider and its Affiliates during any applicable month to provide the Services. For purposes of this definition, the fully-burdened cost includes without limitation: (i) the costs of any materials used in providing the Services; (ii) the salary, benefits (if any) (including without limitation, medical plans and 401(k) or other retirement plans), and employment taxes (if any) of all the Service Provider’s employees involved in providing such services (excluding, however, any compensation that is provided to an employee or independent contractor in the form of equity instruments, options to acquire stock (stock options), rights with respect to (or determined by reference to) equity instruments or stock options, or any non-cash compensation provided by a third party to an employee or independent contractor); (iii) related overhead expenses (including, without limitation, cost of facilities and utilities costs, insurance, and the cost of all general support, operational and business services); (iv) any and all licensing fees paid or payable to Third Parties for any intellectual property incorporated into such services; and (v) any depreciation, amortization or other cost recovery for financial accounting purposes related to assets of the Service Provider to the extent such assets are used in providing the Services; provided, however, that the fully-burdened cost shall not include costs incurred by the Service Provider to engage a Third Party for the purpose of providing Services pursuant to Section 3.4 of the Agreement.

1.3 Marks. “Marks” shall mean and include trademarks, service marks, trade names, domain names, trade dress, logos, and similar designations, whether registered or unregistered, and all applications and registrations therefor.

1.4 Party. “Party” shall mean Service Provider or Service Recipient, and “Parties” shall mean Service Provider and Service Recipient collectively.

1.5 Person. “Person” shall mean and include any individual, corporation, trust, estate, partnership, joint venture, company, association, governmental bureau or agency, or any other entity regardless of the type or nature thereof.

1.6 Third Party. “Third Party” shall mean any entity other than a Party or an Affiliate.

1.7 Works. “Works” shall mean any work product, technical knowledge, creations, know-how, formulations, recipes, specifications, rights, devices, drawings, instructions, expertise, trade practices, customer lists, computer data, source codes, analytical and quality control data, Marks, copyrights, commercial information, inventions, works of authorship, designs, methods, processes, technology, patterns, techniques, data, , patents, trade secrets, copyrights, related contracts, licenses and agreements and the like, and all other intellectual property created, authored, composed, invented, discovered, performed, perfected, provided, acquired or learned by the Service Provider, whether solely or jointly with others, whether patented, patentable or not, whether in written form or otherwise, whether disclosed to Service Provider by either Service Recipient or otherwise, in performing its obligations under this Agreement, in each case, that (i) relates to intellectual property or potential intellectual property originating from research and development of Service Recipient or its affiliate’s drug products or portfolio candidates, and (ii) arises out of services provided directly or indirectly (e.g., through an employee, consultant clinical research organization, other vendor or other Third Party engaged by the Service Provider) in connection with such research and development.

1.8 Year. “Year” shall mean the 12-month period ending on March 31.

2. ENGAGEMENT.

Subject to the terms of this Agreement, the Service Recipient hereby engages the Service Provider to perform the services set forth on Exhibit A attached hereto (the “Services”). Any additional services requested by the Service Recipient that are not included within the Services shall, if mutually agreed upon by the Parties, each in its sole discretion, be negotiated and included in this Agreement through amendments to Exhibit A hereto. The scope of the Service Provider’s authority shall be specifically limited to those activities outlined in this Agreement.

3. RELATIONSHIP OF THE PARTIES.

3.1 The Parties are each independent contractors and not joint venturers, partners, agents, or representatives of the other. The Service Provider shall perform the Services for the Service Recipient under this Agreement as an independent contractor and neither the Service Provider nor its employees, subcontractors or agents shall be deemed to be agents, servants or employees of the Service Recipient, nor shall the Service Provider and the Service Recipient be deemed or construed solely by this Agreement to be partners or joint venturers. The Service Provider shall have exclusive control over the direction and conduct of its employees in carrying out the activities required under this Agreement.

3.2 Neither the Service Provider nor its employees, subcontractors or agents shall have the authority to (i) negotiate the terms of or execute contracts and agreements of the Service Recipient (including letters of intent, even if non-binding), provided the Service Provider may suggest incorporating certain non-core agreement terms within the parameters and guidelines provided by Service Recipient; (ii) hire personnel for the Service Recipient; (iii) exercise binding authority with respect to the operations of the Service Recipient; (iv) make binding recommendations to the Service Recipient; (v) make decisions or have decision-making rights with respect to the Service Recipient; (vi) hold itself out as representing the Service Recipient or as having the authority to negotiate the terms of or conclude contracts on behalf of the Service Recipient or (vii) perform services for the Service Recipient that are not covered by this Agreement.

3.3 The Service Provider and its employees, subcontractors or agents shall have the authority to (i) provide advice, assistance, direction and recommendations to the Service Recipient with respect to its operations; (ii) make recommendations on key points of contracts, without having the power to negotiate the terms of or conclude contracts or agreements on behalf of the Service Recipient; (iii) participate in discussions on contracts and agreements; (iv) arrange transactions between the Service Recipient and other parties, provided that the Service Provider does not make any actual decisions or participate in substantive activities, such as negotiations with respect to the terms of such transactions, provided the Service Provider may suggest incorporating certain non-core agreement terms within the parameters and guidelines provided by Service Recipient; and (v) contact banks in connection with raising capital for the Service Recipient, without having, in any circumstance, the power to negotiate the terms of or conclude contracts or agreements on behalf of the Service Recipient in connection with raising capital for the Service Recipient.

3.4 Engagement of Third Parties. The Service Provider may, with the prior consent of the Service Recipient, engage such persons, corporations, or other entities as it reasonably deems necessary for the purpose of performing Services under this Agreement; provided, however, that the Service Provider shall remain responsible for the performance of all such Services and shall be considered to engage with such persons, corporations, or other entities in its own name and on its own behalf.

4. FEES AND EXPENSES.

4.1 The Service Recipient shall pay the Service Provider a fee in accordance with Exhibit B attached hereto for the Services provided hereunder. The rates specified in Exhibit B attached hereto shall be reviewed and may be updated from time to time by the Parties. Fees for Services performed by the Service Provider will be billed by the Service Provider on a monthly basis. All other costs for Third Party services shall be billed, by or on behalf of the Service Provider, to the Service Recipient, in such manner and format and with such supporting information as the Parties may reasonably agree from time to time. Payment for undisputed invoices received by the Service Recipient shall be due within sixty (60) days after the billing date. Any fees and expenses not paid by the due date thereof shall accrue interest at the safe harbor interest rate based on the applicable Federal rate as set forth in U.S. Treasury Regulations Section 1.482-2(a)(2)(iii)(B). All fees and expenses shall be invoiced and payable in U.S. dollars.

4.2 Yearly Reconciliation. The Parties shall perform a yearly reconciliation for the compensation amounts paid as follows:

a. Administrative Services Yearly Reconciliation.

i. As soon as reasonably practicable following the close of each Year during the Term of this Agreement, the Parties will calculate the total service fee with respect to the activities listed in Exhibit A, subsection 1 (“Administrative and Support Services”) owing under this Agreement for the Year (the “Exhibit B Administrative Services Fees”) by calculating the Service Provider’s Costs with respect to such services and applying the mutually agreed mark-up percentage for such services determined in accordance with Exhibit B, and adding the amount of any third-party costs reimbursable under Exhibit B paragraph (c) that relate to such services. As soon as reasonably practicable following the close of each Year, the Parties shall also calculate the total amount of service fees actually paid for the Year under Section 4.1 with respect to the activities listed in Exhibit A, subsection 1 (“Administrative and Support Services”), adding the amount of any third-party costs reimbursable under Exhibit B paragraph (c) that relate to such services (the “Actual Administrative Services Fees”).

ii. If, for any Year, the total Actual Administrative Services Fees is greater than the Exhibit B Administrative Services Fees for such services, there shall be deemed to exist an excess of service fee in an amount equal to the difference between the total Actual Administrative Services Fees and the total Exhibit B Administrative Services Fees for the Year (hereinafter “Administrative Services Excess”).

iii. If, for any Year, the total Actual Administrative Services Fees is less than the total Exhibit B Administrative Services Fees, there shall be deemed to exist a shortfall in an amount equal to the difference between the total Exhibit B Administrative Services Fees and the total Actual Administrative Services Fees (hereinafter "Administrative Services Shortfall").

b. Other Services Yearly Reconciliation.

i. As soon as reasonably practicable following the close of each Year during the Term of this Agreement, the Parties will calculate the total service fee with respect to the activities listed in Exhibit A, subsection 2 ("Other Services") owing under this Agreement for the Year (the "Exhibit B Other Services Fees") by calculating the Service Provider's Costs with respect to such services and applying the mutually agreed mark-up percentage for such services determined in accordance with Exhibit B, and adding the amount of any third-party costs reimbursable under Exhibit B paragraph (c) that relate to such services. As soon as reasonably practicable following the close of each Year, the Parties shall also calculate the total amount of service fees actually paid for the Year under Section 4.1 with respect to the activities listed in Exhibit A, subsection 1 ("Other Services"), adding the amount of any third-party costs reimbursable under Exhibit B paragraph (c) that relate to such services (the "Actual Other Services Fees").

ii. If, for any Year, the total Actual Other Services Fees is greater than the Exhibit B Other Services Fees for such services, there shall be deemed to exist an excess of service fee in an amount equal to the difference between the total Actual Other Services Fees and the total Exhibit B Other Services Fees for the Year (hereinafter "Other Services Excess").

iii. If, for any Year, the total Actual Other Services Fees is less than the total Exhibit B Other Services Fees, there shall be deemed to exist a shortfall in an amount equal to the difference between the total Exhibit B Other Services Fees and the total Actual Other Services Fees (hereinafter "Other Services Shortfall").

c. Settlement of Excess or Shortfall Amounts.

i. If, for any Year, (1) the sum of the Administrative Services Shortfall and the Other Services Shortfall exceeds (2) the sum of the Administrative Services Excess and the Other Services Excess (such excess amount, the "Net Shortfall"), the Service Recipient shall pay such Net Shortfall to Service Provider within thirty (30) days after the Exhibit B Administrative Services Fees, Exhibit B Other Services Fees, Actual Administrative Services Fees, and Actual Other Services Fees have been calculated for such Year.

ii. If, for any Year, (1) the sum of the Administrative Services Excess and the Other Services Excess exceeds (2) the sum of the Administrative Services Shortfall and the Other Services Shortfall (such excess amount, the "Net Excess"), the Service Provider may (x) treat such Net Excess, in whole or in part, as a contribution to the capital of the Service Provider; or (y) treat such Net Excess, in whole or in part, as an overpayment to the Service Provider that must be repaid to the Service Recipient within 30 days after the end of the Year.

4.3 Withholding. Service Recipient shall be entitled to deduct from any payments to Service Provider the amount of any withholding taxes with respect to such amounts payable, or any taxes in each case required to be withheld by Service Recipient to the extent that Service Recipient pays to the appropriate governmental authority on behalf of Service Provider such taxes, levies, or charges. Service Recipient shall, upon the request of Service Provider, deliver to Service Provider proof of payment of all such taxes, levies, and other charges and the appropriate documentation that is necessary to obtain a tax credit, to the extent such tax credit can be obtained.

5. ACCESS TO BOOKS AND RECORDS.

Service Provider shall maintain books and records pertaining to the Services provided in any Year pursuant to this Agreement for ten (10) Years following the performance of such Services and shall make them available for inspection and audit, at Service Recipient's expense, by a mutually acceptable independent certified public accounting firm during normal business hours upon reasonable prior written notice to Service Provider.

6. CONFIDENTIAL INFORMATION

6.1 Obligations. The Parties acknowledge that, from time to time, one Party (the "Disclosing Party") may disclose to the other Party (the "Receiving Party") information that is marked as "proprietary," or "confidential," or which would, under the circumstances, be understood by a reasonable person to be proprietary and nonpublic ("Confidential Information"). The Receiving Party shall retain such Confidential Information in confidence. Each Party shall use at least the same procedures and degree of care that it uses to protect its own Confidential Information of like importance, including those procedures used when disclosing Confidential Information to Third Parties, and in no event less than reasonable care.

6.2 Exceptions. Nothing in this Agreement shall prevent the disclosure by the Receiving Party or its employees of Confidential Information that:

a. Prior to the transmittal thereof to Receiving Party was of general public knowledge;

b. Becomes, subsequent to the time of transmittal to Receiving Party, a matter of general public knowledge otherwise than as a consequence of a breach by Receiving Party of any obligation under this Agreement;

c. Is made public by Disclosing Party;

d. Was in the possession of Receiving Party in documentary form prior to the time of disclosure thereof to Receiving Party by Disclosing Party, and is held by Receiving Party free of any obligation of confidence to Disclosing Party or any Third Party; or

e. Is received in good faith from a Third Party having the right to disclose it, who, to the best of Receiving Party's knowledge, did not obtain the same from Disclosing Party and who imposed no obligation of secrecy on Receiving Party with respect to such information.

6.3 No Unauthorized Use. The Receiving Party shall refrain from using or exploiting any and all Confidential Information for any purposes or activities other than those contemplated in this Agreement or any other written agreement entered into by and between the Parties.

6.4 Survival. The Parties' obligations under this Article 6 shall survive the termination of this Agreement for any reason whatsoever.

7. OWNERSHIP OF INTANGIBLE PROPERTY

Service Provider agrees that all right, title and interest in and to any and all Works will be owned exclusively by the Service Recipient. All Works, as applicable, shall be considered "works made for hire" to the extent permitted under applicable copyright law and will be considered the sole property of the Service Recipient. To the extent such Works are not considered "works made for hire," all right, title, and interest to such Works, including, but not limited to, all copyrights, patents, trademarks, rights of publicity, and trade secrets, is hereby assigned by Service Provider to the Service Recipient and the Service Provider agrees, at the Service Recipient's expense, to execute any documents requested by the Service Recipient or any successor in interest to the Service Recipient, at any time in relation to such assignment. Service Provider further acknowledges and agrees that any and all derivative works, developments, or improvements based on the Works, shall also be deemed Works and all right, title and interest therein shall be exclusively owned by the Service Recipient. Service Provider shall cooperate with the Service Recipient and any of its Affiliates, at no additional cost to such parties (whether during or after the term of this Agreement), in the confirmation, registration, protection and enforcement of the rights and property of the Service Recipient and its successors in interest in such Works. The Service Provider shall be entitled to use the Works only for purposes of performing the Services. The Service Provider shall not at any time do or cause to be done, or fail to do or cause to be done, any act or thing, directly or indirectly, contesting or in any way impairing Service Recipient's right, title, or interest in the Intangible Property. Every use of any Works (and any derivative works, developments, or improvements based on the Works) by Service Provider shall inure to the benefit of Service Recipient.

8. USE OF TRADEMARKS

The Service Recipient shall grant the Service Provider a right to use its Marks only in connection with the Services, provided that if the Service Recipient provides the Service Provider with reasonable written trademark guidelines governing the use of the Service Recipient's Marks (which guidelines may be updated by the Service Recipient from time to time with prior written notice to the Service Provider), the Service Provider's use of such Marks shall be subject to such written guidelines so provided. Notwithstanding the foregoing, the Service Provider will comply with all of the Service Recipient's reasonable instructions and quality control requirements regarding Service Provider's use of the Marks. The Service Provider acknowledges that any of the Service Recipient's Marks are owned and licensed solely and exclusively by the Service Recipient, and agrees to use such Marks only in the form and with appropriate legends as described by the Service Recipient. All use of the Marks and associated goodwill will inure to the benefit of the Service Recipient. All rights not expressly granted are reserved to the Service Recipient. The Service Provider shall not remove, cover, or modify any proprietary rights notice or legend placed by the other party on materials used in connection with this Agreement.

9. INDEMNIFICATION; LIMITATION OF LIABILITY

9.1 The Service Provider, to the maximum extent permitted by law, shall defend, protect, indemnify and hold the Service Recipient and its officers, employees and directors, as the case may be ("Indemnified Parties"), harmless from and against any and all losses, demands, damages (including, without limitation, special, consequential and punitive damages awarded to Third Parties), claims, liabilities, interest, awards, actions or causes of action, suits, judgments, settlements and compromises relating thereto, and all reasonable attorney's fees and other fees and expenses in connection therewith ("Losses") which may be incurred by an Indemnified Party, arising out of, due to, or in connection with, directly or indirectly, the provision of the Services or failure to provide the Services under this Agreement, except to the extent that such Losses are the result of the gross negligence or willful misconduct of an Indemnified Party.

9.2 The Service Provider's liability for aggregate Losses under this Agreement for any cause whatsoever, and regardless of the form of action, whether in contract or in tort, shall be limited to the payments made by the Service Recipient under this Agreement for the specific Service that allegedly caused or was related to the Losses during the period in which the alleged Losses were incurred. In no event shall the Service Provider be liable for any Losses caused by the Service Recipient's failure to perform the Service Recipient's obligations under this Agreement.

9.3 NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT OR AT LAW OR IN EQUITY, IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR PUNITIVE, SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES TO THE OTHER PARTY OR ANY OTHER PERSON (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF BUSINESS PROFITS, BUSINESS INTERRUPTION, ACTIONS OF THIRD PARTIES OR ANY OTHER LOSS) ARISING FROM OR RELATING TO ANY CLAIM MADE UNDER THIS AGREEMENT OR THE PROVISION OR THE FAILURE TO PROVIDE THE SERVICES.

10. TERM AND TERMINATION

10.1 Term. This Agreement shall commence on the Effective Date and continue until terminated by either Party in accordance with this Section 10.1. Either party may terminate this Agreement at its discretion by giving written notice to the other party at least sixty (60) days before the proposed termination date. Section 12.14 and Article 6 shall survive the termination of this Agreement. The Service Recipient hereby specifically agrees and acknowledges that all obligations of the Service Provider to provide any and all Services shall immediately cease upon termination of this Agreement. The Service Provider hereby specifically agrees and acknowledges that all of its rights to use Marks pursuant to Article 8 of this Agreement shall immediately cease upon termination of this Agreement. To the extent permitted by applicable law, neither Party shall be liable to the other Party for, and each Party hereby expressly waives any right to, any termination compensation of any kind or character whatsoever, to which such Party may be entitled solely by virtue of termination of this Agreement.

10.2 Rights and Duties on Termination. Upon termination of this Agreement for any reason, each Party shall cease all use of the other Party's Confidential Information, and Service Recipient shall pay Service Provider all accrued and unpaid fees for Services performed through the date of termination.

11. COMPLIANCE WITH LAWS

11.1 General Compliance. The Parties shall at all times strictly comply with all applicable laws, rules, regulations, and governmental orders, now or hereafter in effect, relating to their performance of this Agreement. Each Party further agrees to make, obtain, and maintain in force at all times during the term of this Agreement, all filings, registrations, reports, licenses, permits, and authorizations (collectively, "Authorizations") required under applicable law, regulation, or order for such Party to perform its obligations under this Agreement. Service Recipient shall provide Service Provider with such assistance as Service Provider may reasonably request in making or obtaining any such Authorizations.

12. GENERAL PROVISIONS

12.1 Notices. Any and all notices, elections, offers, acceptances, and demands permitted or required to be made under this Agreement shall be in writing, signed by the Party giving such notice, election, offer, acceptance, or demand and shall be delivered personally, by messenger, courier service, telecopy, first class mail or similar transmission, to the Party, at its address on file with the other Party or at such other address as may be supplied in writing. The date of personal delivery or the date of mailing, as the case may be, shall be the date of such notice, election, offer, acceptance, or demand.

12.2 Force Majeure. If the performance of any part of this Agreement by either Party, or of any obligation under this Agreement, is prevented, restricted, interfered with, or delayed by reason of any cause beyond the reasonable control of the Party liable to perform, unless conclusive evidence to the contrary is provided, the Party so affected shall, on giving written notice to the other Party, be excused from such performance to the extent of such prevention, restriction, interference, or delay, provided that the affected Party shall use its reasonable best efforts to avoid or remove such causes of nonperformance and shall continue performance with the utmost dispatch whenever such causes are removed. When such circumstances arise, the Parties shall discuss what, if any, modification of the terms of this Agreement may be required in order to arrive at an equitable solution.

12.3 Successors and Assigns. This Agreement may not be assigned or otherwise conveyed by any Party without the prior written consent of the other Party; provided however that such prior written consent will not be required for an assignment to an Affiliate of either Party. This Agreement shall be binding on and inure to the benefit of the Parties hereto and their respective successors, successors in title and assigns to the extent that such assignment is permitted under this paragraph.

12.4 Entire Agreement, Amendments. This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof, and supersedes all prior agreements, understandings, and communications between the Parties, whether oral or written, relating to the same subject matter. No change, modification, or amendment of this Agreement shall be valid or binding on the Parties unless such change or modification shall be in writing signed by the Party or Parties against whom the same is sought to be enforced.

12.5 Remedies Cumulative. The remedies of the Parties under this Agreement are cumulative and shall not exclude any other remedies to which the Party may be lawfully entitled.

12.6 Other Persons. Nothing in this Agreement shall be construed to prevent or prohibit the Service Provider from providing services to any other Person or from engaging in any other business activity.

12.7 Not for the Benefit of Third Parties. This Agreement is for the exclusive benefit of the Parties to this Agreement and not for the benefit of any Third Party.

12.8 Further Assurances. Each Party hereby covenants and agrees that it shall execute and deliver such deeds and other documents as may be required to implement any of the provisions of this Agreement.

12.9 No Waiver. The failure of any Party to insist on strict performance of a covenant hereunder or of any obligation hereunder shall not be a waiver of such Party’s right to demand strict compliance therewith in the future, nor shall the same be construed as a novation of this Agreement.

12.10 Integration. This Agreement constitutes the full and complete agreement of the Parties.

12.11 Captions. Titles or captions of articles and paragraphs contained in this Agreement are inserted only as a matter of convenience and for reference, and in no way define, limit, extend, or describe the scope of this Agreement or the intent of any provision hereof.

12.12 Number and Gender. Whenever required by the context, the singular number shall include the plural, the plural number shall include the singular, and the gender of any pronoun shall include all genders.

12.13 Counterparts. This Agreement may be executed in multiple copies, each one of which shall be an original and all of which shall constitute one and the same document, binding on the Parties, and each Party hereby covenants and agrees to execute all duplicates or replacement counterparts of this Agreement as may be required.

12.14 Governing Law and Jurisdiction. THIS AGREEMENT AND THE LEGAL RELATIONS BETWEEN THE PARTIES HERETO SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK, WITHOUT REGARD TO ANY CONFLICT OF LAWS RULES. THE COURTS LOCATED WITHIN THE STATE OF NEW YORK SHALL HAVE EXCLUSIVE JURISDICTION OVER ANY AND ALL DISPUTES BETWEEN THE PARTIES HERETO, WHETHER IN LAW OR EQUITY, ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE AGREEMENTS, INSTRUMENTS AND DOCUMENTS CONTEMPLATED HEREBY AND THE PARTIES CONSENT TO AND AGREE TO SUBMIT TO THE EXCLUSIVE JURISDICTION OF SUCH COURTS. EACH OF THE PARTIES HEREBY WAIVES AND AGREES NOT TO ASSERT IN ANY SUCH DISPUTE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY CLAIM THAT (A) SUCH PARTY IS NOT PERSONALLY SUBJECT TO THE JURISDICTION OF SUCH COURTS, (B) SUCH PARTY AND SUCH PARTY'S PROPERTY IS IMMUNE FROM ANY LEGAL PROCESS ISSUED BY SUCH COURTS OR (C) ANY LITIGATION OR OTHER PROCEEDING COMMENCED IN SUCH COURTS IS BROUGHT IN AN INCONVENIENT FORUM.

12.15 Computation of Time. Whenever the last day for the exercise of any privilege or the discharge of any duty hereunder shall fall on a Saturday, Sunday, or any public or legal holiday, whether local or national, the Party having such privilege or duty shall have until 5:00 p.m. (EST or, if in effect in New York, EDT) on the next succeeding business day to exercise such privilege, or to discharge such duty.

12.16 Severability. In the event any provision, clause, sentence, phrase, or word hereof, or the application thereof in any circumstances, is held to be invalid or unenforceable, such invalidity or unenforceability shall not affect the validity or enforceability of the remainder hereof, or of the application of any such provision, sentence, clause, phrase, or word in any other circumstances.

12.17 Costs and Expenses. Unless otherwise provided in this Agreement, each Party shall bear all fees and expenses incurred in performing its obligations under this Agreement.

12.18 Provisions of Law. A reference in this Agreement to a provision of law, regulation, rule, official directive, request, or guideline (whether or not having the force of law) of any governmental, intergovernmental or supranational body, agency, department or regulatory, self-regulatory, or other authority or organization is a reference to that provision as amended or re-enacted currently or in the future.

12.19 Meaning in Notices. Unless a contrary indication appears, a term used in any notice given under or in connection with this Agreement has the same meaning in that notice as in this Agreement.

(The remainder of this page has been intentionally left blank)

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized officers effective as of the date first above written.

ROIVANT SCIENCES GMBH

/s/ Marianne Romeo Dinsmore

By: Marianne Romeo Dinsmore
Title: Managing Director
Date: 13 February 2017

MYOVANT SCIENCES GMBH

/s/ Ruben Masar

By: Ruben Masar
Title: Secretary
Date: 13 February 2017

EXHIBIT A

SERVICES PROVIDED

1. Administrative and Support Services. Various administrative and supportive services, which may include, but are not limited to:

(a) Payroll
(b) Accounts Receivable
(c) Accounts Payable
(d) General Administrative
(e) Corporate and Public Relations (including advertising, investor relations and/or financial marketing)
(f) Meeting Coordination and Travel Planning
(g) Accounting and Auditing
(h) Tax
(i) Budgeting
(j) Treasury Activities
(k) Staffing and Recruiting
(l) Training and Employee Development
(m) Benefits
(n) Information and Technology Services
(o) Legal Services
(p) Insurance Claims Management
(q) Purchasing

And other similar services.

2. Other Services

Administrative, research and development services whether provided directly or by engaging employees, agents, consultants, contract research organizations, vendors or any other Third Party, including, but not limited to:

(a) Preparatory assistance in respect of the identification/location of potential drug asset candidates

(b) Perform/oversee due diligence to evaluate a drug candidate (including, but not limited to, studying the compound, market demand, potential opportunities and competitive landscape with respect to such drug candidate and probability of commercial success of such drug candidate)

(c) Engage, manage and oversee external consultants, whether individuals or consulting companies, in connection with in-depth analyses of potential drug investment opportunities and other activities relating to drugs and drug candidates

(d) Form recommendations regarding potential drug investment opportunities and deliver recommendations to the board of directors of the Service Recipient

(e) Provide the board of directors of the Service Recipient with advice in connection with the acquisition of drug assets and, if necessary, assist in communications between the board of directors of the Service Recipient and the sellers of the relevant drug asset in order for the Service Recipient to negotiate and conclude agreements to acquire drug assets and related intellectual property

(f) Participate in meetings with regulatory authorities related to drug assets of Service Recipient (within the parameters and guidelines provided by Service Recipient)

(g) Develop a plan for clinical testing with respect to a drug asset, identify appropriate contract research organizations to be used in connection with such clinical testing and contract with such contract research organizations (within the parameters and guidelines provided by Service Recipient)

(h) Select manufacturers to manufacture small batch sample of drug product for purposes of clinical trials and contract with such manufacturers (within the parameters and guidelines provided by Service Recipient)

(i) Manage and oversee clinical trials and drug manufacturing to the extent such clinical trials and drug manufacturing costs do not exceed established cost parameters set by Service Recipient

(j) Gather and analyze data obtained in connection with clinical trials and present such information to the board of directors of the Service Recipient

(k) Conduct final filings to obtain regulatory approvals with respect to a drug asset

The Service Provider shall provide such other services as are agreed with the Service Recipient from time to time.

EXHIBIT B

CALCULATION OF COMPENSATION FOR SERVICES PROVIDED

The fees set forth in this Exhibit B represent the entire amount to be paid by the Service Recipient in connection with the Service Provider's provision of the Services, and any and all other costs and expenses associated with the Services or the Agreement. In addition, the fees set forth in this Exhibit B include any and all applicable federal, state or local sales or use tax payable in connection with the Services or the Agreement.

Except as otherwise agreed to by the Parties from time to time, Service Recipient shall compensate Service Provider for its Services rendered and Costs incurred under this Agreement in accordance with the following:

(a) Service Recipient shall reimburse Service Provider for its Costs, excluding third-party costs as provided in (c), incurred in providing the Administrative and Support Services described in Exhibit A or in making, obtaining, and maintaining in force the Authorizations as described in Section 11.1, and shall further pay Service Provider a mark-up on such costs. The mark-up shall be based on the mark-up percentage that the Parties mutually agree is consistent with the financial returns of independent companies performing similar services. The Parties shall review and (if necessary) update the mark-up percentage on an annual basis.

(b) Service Recipient shall reimburse Service Provider for its Costs, excluding third-party costs as provided in (c), incurred in providing the Other Services described in Exhibit A, and shall further pay Service Provider a mark-up on such costs. The mark-up shall be based on the mark-up percentage that the Parties mutually agree is consistent with the financial returns of independent companies performing similar services. The Parties shall review and (if necessary) update the mark-up percentage on an annual basis.

(c) If the Service Provider engages a third party pursuant to Section 3.4 hereof, the Service Recipient shall reimburse the Service Provider for all reasonable and actual out-of-pocket costs incurred by the Service Provider in connection with such engagement.

Exhibit 31.1

CERTIFICATION

I, Lynn Seely, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Myovant Sciences Ltd.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 13, 2017

By: /s/ Lynn Seely

Lynn Seely

Principal Executive Officer

Exhibit 31.2

CERTIFICATION

I, Frank Karbe, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Myovant Sciences Ltd.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 13, 2017

By: /s/ Frank Karbe
Frank Karbe
Principal Financial and Accounting Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Myovant Sciences Ltd. (the "Company") for the period ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Lynn Seely, Principal Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to her knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: February 13, 2017

By: /s/ Lynn Seely

Lynn Seely

Principal Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Myovant Sciences Ltd. (the "Company") for the period ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Frank Karbe, Principal Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: February 13, 2017

By: /s/ Frank Karbe

Frank Karbe

Principal Financial Officer