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 September 30, 2017

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

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

(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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one)

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

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

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 November 9, 2017, was 60,987,597.

MYOVANT SCIENCES LTD.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2017

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

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

	September 30, 2017	March 31, 2017
Assets		
Current assets:		
Cash	$ 129,332	$ 180,838
Prepaid expenses and other current assets	3,738	3,221
Income tax receivable	—	105
Total current assets	133,070	184,164
Deferred tax assets	—	208
Furniture and equipment, net	965	906
Other assets	2,098	—
Total assets	$ 136,133	$ 185,278
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 1,354	$ 3,329
Income tax payable	456	—
Accrued expenses	14,547	11,978
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc.	731	3,030
Total current liabilities	17,088	18,337
Warrant liability	—	52
Deferred rent	326	113
Total liabilities	17,414	18,502
Commitments and contingencies (Note 7)		
Shareholders' equity:		
Common shares, par value $0.000017727 per share, 564,111,242 shares authorized, 60,849,236 and 60,275,757 issued and outstanding at September 30, 2017 and March 31, 2017, respectively	1	1
Common shares subscribed	(1)	(1)
Additional paid-in capital	256,875	251,733
Accumulated other comprehensive income	288	140
Accumulated deficit	(138,444)	(85,097)
Total shareholders' equity	118,719	166,776
Total liabilities and shareholders' equity	$ 136,133	$ 185,278

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

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

	Three Months Ended September 30,		Six Months Ended September 30,	
	2017	2016	2017	2016
Operating expenses:				
Research and development (includes $679 and $814 of share-based compensation expense for the three months ended September 30, 2017 and 2016 and $1,539 and $1,789 for the six months ended September 30, 2017 and 2016, respectively)	$ 24,170	$ 3,753	$ 41,878	$ 18,326
General and administrative (includes $2,070 and $1,336 of share-based compensation expense for the three months ended September 30, 2017 and 2016 and $3,411 and $2,982 for the six months ended September 30, 2017 and 2016, respectively)	6,141	2,967	10,323	5,529
Total operating expenses	30,311	6,720	52,201	23,855
Changes in the fair value of the warrant liability	—	27,984	—	29,817
Other (income) expense	(138)	—	204	—
Loss before provision for income taxes	(30,173)	(34,704)	(52,405)	(53,672)
Income tax (benefit) expense	(265)	8	820	11
Net loss	$ (29,908)	$ (34,712)	$ (53,225)	$ (53,683)
Net loss per common share — basic and diluted	$ (0.50)	$ (0.82)	$ (0.90)	$ (1.29)
Weighted average common shares outstanding — basic and diluted	59,459,500	42,512,254	59,353,966	41,646,657

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

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

	Three Months Ended September 30,		Six Months Ended September 30,	
	2017	2016	2017	2016
Net loss	$ (29,908)	$ (34,712)	$ (53,225)	$ (53,683)
Other comprehensive (loss) income:				
Foreign currency translation adjustment	(116)	—	148	—
Total other comprehensive (loss) income	(116)	—	148	—
Comprehensive loss	$ (30,024)	$ (34,712)	$ (53,077)	$ (53,683)

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

MYOVANT SCIENCES LTD.
Condensed Consolidated Statement of Shareholders' Equity
(unaudited, in thousands, except share data)

	Common Shares		Common Shares Subscribed	Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount					
Balance at March 31, 2017	60,275,757	$ 1	$ (1)	$ 251,733	$ 140	$ (85,097)	$ 166,776
Adjustment to adopt ASU 2016-09	—	—	—	122	—	(122)	—
Shares issued to settle the warrant liability to Takeda	4,432	—	—	58	—	—	58
Share-based compensation expense	564,111	—	—	4,473	—	—	4,473
Capital contribution — share-based compensation	—	—	—	477	—	—	477
Translation adjustment	—	—	—	—	148	—	148
Stock option exercises	4,936	—	—	12	—	—	12
Net loss	—	—	—	—	—	(53,225)	(53,225)
Balance at September 30, 2017	60,849,236	$ 1	$ (1)	$ 256,875	$ 288	$ (138,444)	$ 118,719

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

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

	Six Months Ended September 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	$ (53,225)	$ (53,683)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	4,950	4,771
Depreciation	104	1
Acquisition of in-process research and development	—	13,117
Changes in the fair value of the warrant liability	—	29,817
Unrealized currency translation	148	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(517)	(38)
Deferred tax assets	208	—
Other assets	(2,098)	(100)
Accounts payable	(1,975)	370
Income tax payable	561	1
Accrued expenses	2,569	1,043
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc.	(2,299)	4,014
Deferred rent	213	—
Net cash used in operating activities	(51,361)	(687)
Cash flows from investing activities:		
Purchases of furniture and equipment	(157)	—
Net cash used in investing activities	(157)	—
Cash flows from financing activities:		
Cash capital contribution from Roivant Sciences Ltd.	—	831
Stock option exercises	12	—
Deferred initial public offering costs	—	(71)
Net cash provided by financing activities	12	760
Net change in cash	(51,506)	73
Cash—beginning of period	180,838	—
Cash—end of period	$ 129,332	$ 73
Non-cash investing and financing activities:		
Deferred initial public offering costs, unpaid	$ —	$ 1,603
Acquisition of in-process research and development	$ —	$ 13,117

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

MYOVANT SCIENCES LTD.
Notes to Condensed Consolidated Financial Statements (Unaudited)

Note 1—Description of Business

Myovant Sciences Ltd. (or 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 and endocrine diseases. 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, for the treatment of female infertility as part of assisted reproduction.

The Company is an exempted limited company incorporated under the laws of Bermuda in February 2016 under the name Roivant Endocrinology Ltd. The Company changed its name to Myovant Sciences Ltd., or MSL, in May 2016. The Company has four wholly owned subsidiaries. Roivant Endocrinology Inc. was incorporated in Delaware in April 2016 and subsequently changed its name to Myovant Sciences, Inc., or MSI. Myovant Holdings Limited, or MHL, a private limited company incorporated under the laws of England and Wales, and Myovant Sciences GmbH, or MSG, a company with limited liability formed under the laws of Switzerland, were each organized in August 2016. Myovant Sciences Ireland Limited, or MSIL, a company with limited liability formed under the laws of Ireland, was organized in April 2017. MSG holds the Company's intellectual property rights and is the Company’s principal operating subsidiary.

Since its inception, the Company has devoted substantially all its efforts to organizing the Company, acquiring its product candidates, and preparing for and advancing the clinical development of its product candidates. The Company has two product candidates under development, relugolix and MVT-602, both of which were licensed from Takeda Pharmaceuticals International AG, or Takeda, on April 29, 2016.

The Company has determined that it has one operating and reporting segment as it allocates resources and assesses financial performance on a consolidated basis. The Company has incurred and expects to continue to incur significant and increasing operating losses and negative cash flows at least for the next several years. The Company does not expect to generate revenue unless and until it successfully completes development and obtains regulatory approval for one of its product candidates. The Company believes it currently has sufficient funds to meet its financial needs for at least the next 12 months. The Company may need to obtain further funding through other public or private offerings of its capital shares, debt financing, collaboration and licensing arrangements or other sources. Adequate additional funding may not be available to the Company on acceptable terms, or at all.

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, or 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 consolidated financial statements included in the Company’s Annual Report on Form 10-K for the fiscal year ended March 31, 2017, filed with the Securities and Exchange Commission, or SEC, on June 14, 2017. 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 six months ended September 30, 2017 are not necessarily indicative of the results that may be expected for the year ending March 31, 2018, for any other interim period or for any other future year. Certain prior year amounts have been reclassified to conform with the current period presentation. These reclassifications had no effect on the previously reported results of operations.

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

There have been no significant changes in the Company's accounting policies from those disclosed in its Annual Report on Form 10-K for the fiscal year ended March 31, 2017, filed with the SEC on June 14, 2017.

(B) Use of Estimates:

The preparation of unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions in certain circumstances that affect the amounts reported and disclosed in the unaudited 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 agreements with Roivant Sciences, Inc., or RSI, and Roivant Sciences GmbH, or RSG, each a wholly owned subsidiary of the Company's parent company, Roivant Sciences Ltd., or RSL, as well as share-based compensation, research and development, or R&D, costs, and income taxes. The Company bases its estimates and assumptions on historical experience and on various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities at the date of the unaudited condensed consolidated financial statements and the reported amounts of expenses during the reporting period, that are not readily apparent from other sources. Actual results could differ from those estimates.

(C) Net Loss per Common Share:

Basic net loss per common share is computed by dividing net loss applicable to common shareholders by the weighted-average number of common shares outstanding during the period, reduced where applicable for outstanding yet unvested shares of restricted common stock. 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 six months ended September 30, 2017, 1.3 million restricted share awards and restricted stock units and 2.2 million options to purchase common shares were not included in the calculation of diluted weighted-average common shares outstanding because they were anti-dilutive given the net loss of the Company. For the three and six months ended September 30, 2016, 1.1 million restricted share awards and 1.2 million options to purchase common shares were not included in the calculation of diluted weighted-average common shares outstanding because they were anti-dilutive given the net loss of the Company.

(D) Financial Instruments:

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

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

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

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

The Company's financial instruments include cash and accounts payable. These financial instruments are stated at their respective historical carrying amounts, which approximate fair value due to their short-term nature.

(E) Recently Issued Accounting Pronouncements:

In February 2016, the FASB issued ASU No. 2016-02, "*Leases* (Topic 842)," or ASU No. 2016-02, which is a comprehensive new lease standard that amends various aspects of existing accounting guidance for leases. The core principle of ASU No. 2016-02 will require lessees to present the assets and liabilities that arise from leases on their 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*,'' or ASU No. 2016-09. This ASU makes several modifications to Topic 718 related to the accounting for forfeitures, employer tax withholding on share-based compensation, and the 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 Company has adopted this guidance as of April 1, 2017 using a modified retrospective transition method. As a result of the adoption of this standard, the Company elected to change its accounting policy from estimating forfeitures to recognizing forfeitures when they occur and, as a result, recorded an adjustment of $0.1 million to accumulated deficit with a corresponding offset to additional paid-in-capital as of April 1, 2017. The other amended requirements of ASU No. 2016-09 did not have a material impact on the Company's unaudited condensed consolidated financial statements and related disclosures.

Note 3—Accrued Expenses

As of September 30, 2017, and March 31, 2017, accrued expenses consisted of the following (in thousands):

	September 30, 2017	March 31, 2017
Accrued research and development expenses	$ 11,992	$ 9,737
Accrued compensation-related expenses	1,014	797
Accrued legal expenses	1,174	481
Accrued other expenses	367	963
Total accrued expenses	$ 14,547	$ 11,978

Note 4—Related Party Transactions

In July 2016, the Company entered into a formal services agreement with RSI, effective April 29, 2016, under which RSI agreed to provide certain administrative and R&D services to the Company. Under this services agreement, the Company pays or reimburses RSI for any expenses it, or third parties acting on its behalf, incurs for the Company. For any general and administrative, or G&A, and R&D activities performed by RSI employees, RSI charges the Company the employee compensation expense plus a pre-determined mark-up. RSI also provided such services prior to the formalization of this services agreement, and such costs have been recognized by the Company in the period in which the services were rendered. Employee compensation expense, inclusive of base salary and fringe benefits, is determined based upon the relative percentage of time utilized on Company matters. All other costs are billed back at cost. The accompanying interim unaudited condensed consolidated financial statements include third-party expenses that have been paid by RSI and RSL.

In February 2017, the Company and MSI amended and restated this 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 RSG, effective as of November 11, 2016, for the provisioning of services by RSG to MSG in relation to services related to clinical development, administrative and financial activities. The Company refers to the amended and restated services agreement with RSI and the services agreement with RSG, collectively, as the Services Agreements.

Under the Services Agreements, for the three months ended September 30, 2017 and 2016, the Company incurred expenses of $1.0 million and $3.1 million, respectively, inclusive of the pre-determined mark-up. For the six months ended September 30, 2017 and 2016, the Company incurred expenses of $2.1 million and $4.1 million, respectively, inclusive of the pre-determined mark-up.

Note 5—Income Taxes

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 provision for income taxes is primarily based on income taxes in the United States for federal, state and local income taxes. The effective income tax rate for the Company for the three months ended September 30, 2017 and 2016 was 0.88% and (0.02)%, respectively. The effective income tax rate for the Company for the six months ended September 30, 2017 and 2016 was (1.56)% and (0.02)%, respectively. The Company's effective income tax rate for all periods presented differs from the Bermuda federal statutory rate of 0% primarily due to the U.S. permanent unfavorable tax differences, and a valuation allowance that effectively eliminates the Company's net deferred tax assets in the United States.

The Company assesses the realizability of its deferred tax assets at each balance sheet date based on available positive and negative evidence to determine the amount which is more likely than not to be realized and records a valuation allowance as necessary.

Note 6—Share-Based Compensation

In June 2016, the Company adopted its 2016 Equity Incentive Plan, or as amended, the 2016 Plan, under which 4.5 million common shares were originally reserved for grant. On April 1, 2017, the number of common shares authorized for issuance increased automatically to 6.9 million in accordance with the 2016 Plan.

At September 30, 2017, a total of 2.0 million common shares were available for future grant under the 2016 Plan. At September 30, 2017, there were 3.2 million options outstanding with a weighted average exercise price of $9.22.

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

During the three and six months ended September 30, 2017, the Company granted options to purchase a total of 1.0 million and 1.9 million common shares, respectively, to its employees and directors under the 2016 Plan. During the three and six months ended September 30, 2016, the Company granted options to purchase a total of 1.1 million common shares to its employees and directors under the 2016 Plan. The Company recorded share-based compensation expense related to stock options issued to Company employees and directors of $1.5 million and $0.3 million, respectively, for the three months ended September 30, 2017 and 2016 and $2.8 million and $0.3 million, respectively, for the six months ended September 30, 2017 and 2016. At September 30, 2017, total unrecognized compensation expense related to unvested options issued to employees and directors was $24.9 million, which is expected to be recognized over the remaining weighted-average service period of 3.26 years.

During the six months ended September 30, 2017 and 2016, the Company granted a restricted share award for 0.6 million and 1.1 million, respectively, to the Company's Principal Executive Officer under the 2016 Plan. The restricted share award granted during the six months ended September 30, 2017 is a market-based award for which the grant date fair value was estimated using a Monte Carlo valuation model. The Company records expense ratably over the applicable vesting period regardless of whether the market condition is satisfied because the awards are subject to market conditions. During the three months ended September 30, 2017 and 2016, no restricted share awards were granted to employees or directors. During the three and six months ended September 30, 2017, the Company granted 10,000 restricted stock units to its Chief Medical Officer. During the three and six months ended September 30, 2016, no restricted stock units were granted to employees or directors. The Company recorded share-based compensation expense related to the restricted share awards and restricted stock units of $0.9 million and $0.4 million, respectively, for the three months ended September 30, 2017 and 2016 and $1.5 million and $0.4 million, respectively, for the six months ended September 30, 2017 and 2016. At September 30, 2017, total unrecognized compensation expense related to unvested restricted share awards and restricted stock units was $11.2 million, which is expected to be recognized over the remaining weighted-average service period of 4.05 years.

Share-based compensation expense is classified in R&D and G&A expenses in the accompanying interim unaudited condensed consolidated statements of operations consistent with the grantee's salary.

(B) Share-Based Compensation for Related Parties:

(1) Stock Options Granted to Non-Employees:

The Company recorded share-based compensation expense related to stock options granted to consultants of $0.1 million and $0.1 million, respectively, for the three months ended September 30, 2017 and 2016 and $0.2 million and $0.1 million, respectively, for the six months ended September 30, 2017 and 2016. At September 30, 2017, total unrecognized compensation expense related to stock options granted to consultants was $0.1 million, which is expected to be recognized over 2.88 years. This share-based compensation expense is included in R&D and G&A expenses in the accompanying interim unaudited condensed consolidated statements of operations. During the six months ended September 30, 2017, no options were granted to consultants under the 2016 Plan. During the six months ended September 30, 2016, 0.1 million options were granted to consultants under the 2016 Plan.

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

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.

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 $0.3 million and $1.4 million, respectively, for the three months ended September 30, 2017 and 2016 and $0.5 million and $4.0 million, respectively, for the six months ended September 30, 2017 and 2016.

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. As RSL is a non-public entity, the RSL common share awards are classified as a level 3 financial instrument within the fair value hierarchy due to their unobservable nature. 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). RSL estimated the fair value of each RSL option on the date of grant using the Black-Scholes closed-form option-pricing model.

Share-based compensation expense has been and will continue to be allocated to the Company over the requisite service period over which these RSL common share awards and RSL options are expected to vest based upon the relative percentage of time utilized by RSL and RSI employees on Company matters.

Note 7—Commitments and Contingencies

The Company entered into certain commitments under its license agreement with Takeda, or the Takeda Agreement, amended its services agreement with RSI and entered into a separate services agreement with RSG (See Note 4). In addition, the Company has entered into services agreements with third parties for pharmaceutical research and manufacturing activities and has a lease agreement for office space located in Brisbane, California. The manufacturing agreements can be terminated by the Company with 30 days written notice. Expenditures to contract research organizations, or CROs, and contract manufacturing organizations, or CMOs, represent significant costs in the Company's clinical development of its product candidates. Subject to required notice periods and the Company's obligations under binding purchase orders, the Company can elect to discontinue the work under these agreements at any time. The Company expects to enter into additional commitments as the business further develops.

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

During the six months ended September 30, 2017, there were no other material changes outside the ordinary course of business to the specified contractual obligations set forth in the contractual obligations table included in the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2017, filed with the SEC on June 14, 2017. In October 2017, the Company obtained financing commitments of up to $140.0 million from NovaQuest Capital Management and Hercules Capital, which require the Company to make interest and principal payments at various intervals. The financing commitments are described further in "Note 8—Subsequent Events."

Note 8—Subsequent Events

In October 2017, the Company and NovaQuest Capital Management, or NovaQuest, entered into (i) a Securities Purchase Agreement, or the NovaQuest Securities Purchase Agreement, and (ii) an Equity Purchase Agreement, or the NovaQuest Equity Purchase Agreement. Pursuant to the NovaQuest Securities Purchase Agreement the Company has committed, at its discretion, to issue up to $60.0 million aggregate principal amount of notes to NovaQuest through December 31, 2018. The Company has agreed that it will issue at least $30.0 million aggregate principal amount of notes through December 31, 2018, subject to certain terms and conditions. The notes bear interest at 15% per annum, of which 5% is payable quarterly, and 10% is payable on a deferred basis. The notes mature on October 16, 2023. The Company will be required to amortize the principal amount of the notes in equal quarterly installments commencing on November 1, 2020, subject to extension at the option of the Company to November 1, 2021, provided certain terms and conditions are met as set forth in the NovaQuest Securities Purchase Agreement. Early redemption of the notes is subject to a prepayment penalty. Concurrent with each issuance of notes, NovaQuest is obligated to purchase common shares with a value equal to one third of the note issuance amount or up to $20.0 million in total, subject to certain terms and conditions as set forth in the NovaQuest Securities Purchase Agreement. Pursuant to the NovaQuest Equity Purchase Agreement, NovaQuest has committed to purchase up to an additional $20.0 million of the Company’s common shares from time to time at the discretion of the Company through December 31, 2018, with an option to extend through December 31, 2019, subject to certain terms and conditions as set forth in the NovaQuest Equity Purchase Agreement. The Company has agreed that it will exercise its option to sell and issue a minimum of $10.0 million of the Company’s common shares through December 31, 2018, subject to certain terms and conditions. The purchase price for the common shares issued pursuant to the NovaQuest Securities Purchase Agreement and the NovaQuest Equity Purchase Agreement will be equal to 105% of the average of the volume-weighted average price for the five consecutive trading days immediately prior to the relevant purchase date.

In October 2017, the Company and Hercules Capital, Inc., or Hercules, entered into a Loan Agreement, or the Hercules Loan Agreement, which provides up to $40.0 million principal amount of term loans, or the Term Loans. A first tranche of $25.0 million principal amount was funded upon execution of the Hercules Loan Agreement on October 16, 2017 and the remaining $15.0 million principal amount is available at the Company’s discretion through March 31, 2018. The Term Loans bear interest at a variable per annum rate at the greater of either (i) the prime rate plus 4.00% and (ii) 8.25%. The Term Loans mature on May 1, 2021, subject to extension to November 1, 2021 if certain milestones are met. The Company is obligated to make monthly payments of accrued interest until June 1, 2019, or the Interest-only Period, followed by monthly installments of principal and interest through the maturity date. The Interest-only Period may be extended until June 1, 2020 if certain milestones are met. Prepayment of the Term Loans is subject to a prepayment charge.

Concurrent with each funding of the Term Loans, the Company is required to issue to Hercules a warrant, or the Warrants, to purchase a number of the Company’s common shares equal to 3% of the principal amount of the relevant Term Loan funded divided by the exercise price, which will be based on the lowest three-day volume-weighted average price for the three consecutive trading days prior to the funding date for such Term Loan. The Warrants may be exercised on a cashless basis, and are immediately exercisable through the seventh anniversary of the applicable funding date. In connection with the first tranche funded under the Hercules Loan Agreement, the Company issued a warrant to Hercules exercisable for an aggregate of 49,800 of the Company’s common shares at an exercise price of $15.06 per share.

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 interim unaudited 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 fiscal year ended March 31, 2017 included in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission, or SEC, on June 14, 2017. Unless the context requires otherwise, references in this report to "Myovant," the "Company," "we," "us," and "our" refer to Myovant Sciences Ltd. and its subsidiaries.

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements are often identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "project," "will," "would" or the negative or plural of these words or similar expressions or variations, although not all forward-looking statements contain these identifying words. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those projected in the forward-looking statements.

The forward-looking statements in this Quarterly Report on Form 10-Q include, but are not limited to, statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things:

- the success and timing of our ongoing clinical trials for our lead product candidate, relugolix;
- our plans to develop and commercialize relugolix;
- the anticipated start dates, durations and completion dates of our ongoing and future nonclinical studies and clinical trials;
- the anticipated designs of our future clinical trials;
- anticipated future regulatory submissions and the timing of, and our ability to, obtain and maintain regulatory approvals for our product candidates;
- the rate and degree of market acceptance and clinical utility of any approved product candidate;
- our ability to quickly and efficiently identify and develop product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- continued service of our key scientific or management personnel;
- our ability to obtain, maintain and enforce intellectual property rights for our product candidates;
- our anticipated future cash position and cash burn rate;
- the anticipated receipt of funding under our new financing commitments;
- our estimates regarding our results of operations, financial condition, liquidity, capital requirements, prospects, growth and strategies; and
- the success of competing drugs that are or may become available.

We have based these forward-looking statements largely on our current expectations and projections about future events, including the responses we expect from the U.S. Food and Drug Administration, or FDA, and other regulatory authorities and financial trends that we believe may affect our financial condition, results of operations, business strategy, nonclinical studies and clinical trials and financing needs. Such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors known and unknown that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, 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. These risks are not exhaustive. 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. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. 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 and endocrine diseases. Our goal is to be the leading global biopharmaceutical company focused on women's health and endocrine diseases in areas of high unmet medical need. Our lead product candidate is relugolix, an oral, once-daily, small molecule that acts as a gonadotropin-releasing hormone, or GnRH, receptor antagonist. We are advancing relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids, endometriosis-associated pain and advanced prostate cancer. In addition, we are developing MVT-602, an oligopeptide kisspeptin agonist, for the treatment of female infertility as part of the hormonal preparation used in assisted reproduction. Both relugolix and MVT-602 were licensed to us by Takeda.

We were incorporated in February 2016 and our operations to date have been limited to organizing and staffing our company, raising capital, acquiring the rights to relugolix and MVT-602, and preparing for and advancing the clinical development of our product candidates. To date, we have not generated any revenue. We have never been profitable, have incurred net losses in each period since inception and do not anticipate that we will achieve profitability in the near term. We expect our net losses and negative cash flows to increase as we continue the clinical development of, and seek regulatory approval for, our product candidates.

In November 2016, we completed our initial public offering, or IPO, in which we raised net proceeds of approximately $200.0 million. As of September 30, 2017, and March 31, 2017, we had an accumulated deficit of $138.4 million and $85.1 million, respectively. We recorded net losses of $29.9 million and $34.7 million for the three months ended September 30, 2017 and 2016, respectively, and net losses of $53.2 million and $53.7 million for the six months ended September 30, 2017 and 2016, respectively. We have determined that we have one operating and reporting segment.

Our Product Candidates

Relugolix

Our lead product candidate, relugolix, is currently being developed for the treatment of heavy menstrual bleeding associated with uterine fibroids, endometriosis-associated pain, and advanced prostate cancer. As a GnRH receptor antagonist, relugolix has a clinically-validated mechanism of action in each of our three target indications. Lowering estrogen levels decreases heavy menstrual bleeding in women with uterine fibroids and improves the pelvic pain associated with endometriosis. Decreasing testosterone slows the growth and progression of advanced prostate cancer and is the central objective of treatment once the disease has recurred following definitive treatment with prostatectomy or radiation therapy or in men presenting with advanced prostate cancer. Myovant Sciences GmbH, or MSG, our wholly owned subsidiary, holds global commercial rights to relugolix, excluding Japan, China, Hong Kong, Indonesia, Korea, Malaysia, Philippines, Singapore, Taiwan, Thailand, and Vietnam, and, in each case, the territories and possessions of each of the foregoing.

Relugolix for the Treatment of Uterine Fibroids

We initiated a Phase 3 clinical program in January 2017, evaluating relugolix in women with heavy menstrual bleeding associated with uterine fibroids. The program consists of two international, replicate pivotal clinical trials (LIBERTY 1 and LIBERTY 2). Each trial randomizes women 1:1:1 to one of three treatment arms: relugolix 40 mg once daily co-administered with commercially available low-dose hormonal add-back therapy for 24 weeks, relugolix 40 mg once daily monotherapy for 12 weeks followed by relugolix 40 mg once daily co-administered with hormonal add-back therapy for an additional 12 weeks, or placebo once daily for a period of 24 weeks. We expect to enroll approximately 390 women in each of the two replicate LIBERTY 1 and LIBERTY 2 trials. Eligible women completing the initial 24-week period will be offered an active treatment extension with relugolix 40 mg once daily co-administered with hormonal add-back therapy for an additional 28-week period, or a total treatment period of 52 weeks, to evaluate the safety of longer-term treatment.

In October 2017, Takeda reported positive top-line results from its Phase 3 trial in Japan evaluating the efficacy and safety of relugolix compared with leuprorelin for the treatment of heavy menstrual bleeding associated with uterine fibroids. In this trial, relugolix met the primary endpoint, achieving 82.2% response rate and was observed to be statistically non-inferior to leuprorelin ($p = 0.0013$), meeting the trial's primary endpoint, the proportion of patients achieving a pre-defined reduction in menstrual bleeding. Additionally, in November 2017, Takeda reported positive top-line results from its Phase 3 trial in Japan evaluating the efficacy and safety of relugolix for the treatment of pain associated with uterine fibroids. Takeda reported that the primary endpoint was met with 57.6% of women with uterine fibroids treated with relugolix demonstrating a marked improvement in pain symptoms compared to 3.1% of women receiving placebo ($p < 0.0001$). Adverse events in both the studies were consistent with the mechanism of action of relugolix and adverse events observed in previous clinical studies. The Phase 3 data from each of these trials will be available to us, and may be used to support our New Drug Application, or NDA. Takeda plans to submit the data from both of these trials to regulatory authorities in Japan for marketing authorization of relugolix for the treatment of uterine fibroids. We will be solely responsible for obtaining FDA approval for relugolix in the United States.

Relugolix for the Treatment of Endometriosis

We initiated a Phase 3 clinical program in June 2017 consisting of two international, replicate pivotal clinical trials (SPIRIT 1 and SPIRIT 2), evaluating relugolix in women with endometriosis-associated pain. Each trial randomizes women 1:1:1 to one of three treatment arms: relugolix 40 mg once daily co-administered with low-dose hormonal add-back therapy for 24 weeks, relugolix 40 mg once daily monotherapy for 12 weeks followed by relugolix 40 mg once daily co-administered with hormonal add-back therapy for an additional 12 weeks, or placebo once daily for a period of 24 weeks. We expect to enroll approximately 600 women in each of the two replicate SPIRIT 1 and SPIRIT 2 trials. Eligible women completing the initial 24-week period will be offered an active treatment extension with relugolix 40 mg once daily co-administered with hormonal add-back therapy for an additional 28-week period, or a total treatment period of 52 weeks, to evaluate the safety of longer-term treatment.

Relugolix for the Treatment of Advanced Prostate Cancer

We initiated a Phase 3 clinical trial, the HERO study, in March of 2017, for relugolix in men with advanced prostate cancer. Our Phase 3 HERO trial is enrolling men with advanced prostate cancer who require androgen deprivation therapy and randomizes men to treatment with either oral relugolix 120 mg once daily (after a single oral loading dose of 360 mg) or a depot injection of leuprolide (per national or regional product label) for a period of at least 48 weeks. We expect to enroll approximately 1,125 men into this trial, with approximately 750 men enrolled into the active treatment arm and 375 men into the leuprolide arm. Based on FDA discussions, we are only required to conduct one Phase 3 trial with a single relugolix arm to gain approval for relugolix in men with advanced prostate cancer in the United States; however, we have designed the trial to include a second arm with leuprolide to demonstrate that treatment with relugolix is noninferior to leuprolide in achieving sustained suppression of testosterone to castrate levels over 48 weeks, an outcome expected to be required for approval in other major markets.

MVT-602

MVT-602, our second product candidate, is an oligopeptide kisspeptin agonist. Kisspeptin is a naturally-occurring peptide that stimulates GnRH release and is required for puberty and maintenance of normal reproductive function, including production of sperm, follicular maturation and ovulation, and production of estrogen and progesterone in women and testosterone in men. MSG, our wholly owned subsidiary, holds global commercial rights to MVT-602. In a Phase 1 study in healthy female volunteers conducted in the second half of 2017, a single injection of MVT-602 was observed to cause a dose-dependent luteinizing hormone surge. We intend to conduct additional Phase 1 evaluation in women to further characterize the pharmacokinetic and pharmacodynamic profile of MVT-602 prior to the initiation of a Phase 2 proof-of-concept clinical trial in 2018. MVT-602 is being developed as a potential treatment for female infertility in women as part of assisted reproduction, such as in vitro fertilization.

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, MVT-602 or a potential future product candidate.

Research and Development Expense

Since inception, our operations have primarily been limited to the license of the rights to relugolix and MVT-602, the expansion of our team, and the initiation of our Phase 3 programs. Our research and development, or R&D, expenses include:

- employee-related expenses, such as salaries, share-based compensation, benefits and travel expenses for our R&D personnel;
- costs allocated to us under the Services Agreements;
- expenses incurred under or in connection with agreements with contract research organizations, or CROs, as well as consultants and other vendors who conduct or participate in clinical and nonclinical studies designed to further the development of our product candidates;
- manufacturing and supply costs in connection with conducting nonclinical and clinical studies;
- costs for sponsored research; and
- depreciation expense for assets used in R&D activities.

R&D activities will continue to be central to our business model. We expect our R&D expenses to increase significantly in the future as we conduct our Phase 3 programs for relugolix, expand our employee base and increase personnel related expenses, conduct further Phase 1 evaluation 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. We expect our share-based compensation expense to increase as we continue to increase our number of employees and hire additional senior executives.

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. As a result, we are unable to determine the duration and completion costs of our programs or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates. Our R&D activities may be subject to change from time to time as we evaluate our priorities and available resources.

General and Administrative Expense

General and administrative, or G&A, expenses consist primarily of personnel related expenses, share-based compensation, legal and accounting fees, general overhead expenses and costs billed to us under our Services Agreements and consulting services relating to our formation and corporate matters.

We anticipate that our G&A expenses will increase in the future to support the growth of our operations and the costs of operating as a public company. These increases will likely include costs related to the hiring of additional personnel and fees to outside consultants, lawyers, and accountants, expenses related to maintaining compliance with New York Stock Exchange, or NYSE, rules and SEC requirements, and insurance and investor relations costs and information technology costs. We expect our share-based compensation expense to increase as we continue to increase our number of employees and hire additional senior executives. In addition, if relugolix or MVT-602 obtains regulatory approval for marketing, we expect that we would incur expenses associated with building medical affairs, sales and marketing teams.

Results of Operations for the Three and Six Months Ended September 30, 2017 and 2016

The following table summarizes our results of operations for the three and six months ended September 30, 2017 and 2016 (in thousands):

	Three Months Ended September 30,		Six Months Ended September 30,	
	2017	2016	2017	2016
Operating expenses:				
Research and development (includes $679 and $814 of share-based compensation expense for the three months ended September 30, 2017 and 2016 and $1,539 and $1,789 for the six months ended September 30, 2017 and 2016, respectively)	$ 24,170	$ 3,753	$ 41,878	$ 18,326
General and administrative (includes $2,070 and $1,336 of share-based compensation expense for the three months ended September 30, 2017 and 2016 and $3,411 and $2,982 for the six months ended September 30, 2017 and 2016, respectively)	6,141	2,967	10,323	5,529
Total operating expenses	30,311	6,720	52,201	23,855
Changes in the fair value of the warrant liability	—	27,984	—	29,817
Other (income) expense	(138)	—	204	—
Income tax (benefit) expense	(265)	8	820	11
Net loss	$ (29,908)	$ (34,712)	$ (53,225)	$ (53,683)

Research and Development Expenses

R&D expenses increased by $20.4 million, to $24.2 million, in the three months ended September 30, 2017 compared to the three months ended September 30, 2016, primarily due to increases in expenses for the ongoing LIBERTY 1 and LIBERTY 2, SPIRIT 1 and SPIRIT 2, and HERO trials. R&D expenses for the three months ended September 30, 2017 consisted primarily of contract resource organization, or CRO, and clinical drug supply costs of $19.7 million, personnel expenses of $3.0 million, share-based compensation expense of $0.7 million, $0.1 million of which was allocated to us by RSL, and costs billed to us under the Services Agreements of $0.5 million, including personnel expenses and third-party costs associated with the preparation of our clinical and other research programs. R&D expenses were $3.8 million for the three months ended September 30, 2016, and consisted primarily of costs billed to us under the Services Agreement of $2.7 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 $0.8 million allocated to us by RSL.

R&D expenses increased by $23.6 million, to $41.9 million, in the six months ended September 30, 2017 compared to the six months ended September 30, 2016, primarily due to increases in expenses for the ongoing LIBERTY 1 and LIBERTY 2, SPIRIT 1 and SPIRIT 2, and HERO trials. R&D expenses for the six months ended September 30, 2017 consisted primarily of CRO and clinical drug supply costs of $33.5 million, personnel expenses of $4.9 million, share-based compensation expense of $1.5 million, $0.2 million of which was allocated to us by RSL, and costs billed to us under the Services Agreements of $0.9 million, including personnel expenses and third-party costs associated with the preparation of our clinical and other research programs. R&D expenses were $18.3 million for the six months ended September 30, 2016, and consisted primarily of in-process R&D 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 5.1 million common shares issued to Takeda and $5.4 million for the estimated fair value of the warrant liability. The remainder consisted of share-based compensation expense of $1.8 million allocated to us by RSL and costs billed to us under the Services Agreement of $3.2 million, including personnel expenses and third-party costs associated with the preparation of our clinical and other research programs.

General and Administrative Expenses

G&A expenses increased by $3.1 million, to $6.1 million, in the three months ended September 30, 2017 compared to the three months ended September 30, 2016, primarily due to an increase in employee salaries and benefits and increases in share-based compensation expense resulting from additional headcount to support the growth of our operations. G&A expenses for the three months ended September 30, 2017 consisted primarily of personnel-related and general overhead expenses of $2.3 million, share-based compensation expense of $2.1 million, including $0.2 million allocated to us by RSI and RSL, legal and professional fees of $1.2 million, and costs of $0.5 million billed to us under the Services Agreements, including personnel expenses, overhead allocations and third-party costs. G&A expenses were $3.0 million for the three months ended September 30, 2016, and consisted primarily of share-based compensation expense of $1.3 million, primarily related to share-based compensation expense allocated to us by RSI and RSL, legal and professional fees of $1.0 million, and costs of $0.3 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 expenses of $0.3 million.

G&A expenses increased by $4.8 million, to $10.3 million, in the six months ended September 30, 2017 compared to the six months ended September 30, 2016, primarily due to an increase in employee salaries and benefits and increases in share-based compensation expense resulting from additional headcount to support the growth of our operations. G&A expenses for the six months ended September 30, 2017 consisted primarily of personnel-related and general overhead expenses of $3.9 million, share-based compensation expense of $3.4 million, including $0.3 million allocated to us by RSI and RSL, legal and professional fees of $1.8 million, and costs of $1.2 million billed to us under the Services Agreements, including personnel expenses, overhead allocations and third-party costs. G&A expenses were $5.5 million for the six months ended September 30, 2016, and consisted primarily of share-based compensation expense of $3.0 million, primarily related to share-based compensation expense allocated by RSI and RSL, legal and professional fees of $1.3 million, and costs of $0.9 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 expenses of $0.3 million.

Changes in the Fair Value of the Warrant Liability

The change in the fair value of the warrant liability was recorded as zero for the three and six months ended September 30, 2017, as the fair value of the warrant liability expired to zero in connection with its expiration on April 30, 2017. For the three and six months ended September 30, 2016, the change in the fair value of the warrant liability was $28.0 million and $29.8 million, respectively, which was primarily due to changes in the assumptions regarding probabilities of successful financing events used to estimate the fair value of the liability, offset by the fair value of warrant exercises.

Liquidity and Capital Resources

Sources of Liquidity

In November 2016, we received net proceeds from our IPO of approximately $200.0 million. In October 2017, we and our subsidiaries, MHL, MSG, MSI, and MSIL, entered into financing commitments with NovaQuest and Hercules under which we secured flexible financing commitments of up to $140.0 million. See “Note 8—Subsequent Events” to our interim unaudited condensed consolidated financial statements contained herein for a further discussion of these agreements. We plan to use the net proceeds from both the NovaQuest and Hercules financings primarily to fund the ongoing Phase 3 development of our lead product candidate, relugolix, for the treatment of heavy menstrual bleeding associated with uterine fibroids, endometriosis-associated pain, and advanced prostate cancer.

Funding Requirements

We recorded net losses of $29.9 million and $34.7 million for the three months ended September 30, 2017 and 2016, respectively, and net losses of $53.2 million and $53.7 million for the six months ended September 30, 2017 and 2016, respectively. As of September 30, 2017, we had $129.3 million of cash available to fund our operations.

We expect to continue to incur significant and increasing operating losses and negative cash flows at least for the next several years. We have not generated any revenue to date and 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 and negative cash flows 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 R&D activities. We anticipate that our capital requirements will increase substantially as we:

- advance our Phase 3 programs of relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids, endometriosis-associated pain, and advanced prostate cancer;
- conduct additional Phase 1 evaluation 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;
- expand our chemistry, manufacturing, and control and other manufacturing related activities;
- seek to identify, acquire, develop, and commercialize additional product candidates;
- integrate acquired technologies into a comprehensive regulatory and product development strategy;
- maintain, expand, and protect our intellectual property portfolio;
- hire scientific, clinical, regulatory, quality, and administrative personnel;
- add operational, accounting, finance, quality, and management information systems;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a medical affairs group with a medical scientific liaison team;
- ultimately establish a sales, marketing, and distribution infrastructure and increase the scale of our external manufacturing capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- service debt obligations and payment of interest associated with the NovaQuest and Hercules financing commitments, and
- operate as a public company.

Our primary use of cash is to fund the development of relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids, endometriosis-associated pain, and advanced prostate cancer. As the competitive environment, particularly for the women's health indications, continues to evolve, the development expenses for these programs are expected to increase. We expect that our existing cash and the financing commitments available to us from NovaQuest and Hercules, will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months. These funds will not be sufficient to enable us to complete all necessary development and commercially launch relugolix. Accordingly, we will need to obtain further funding through other public or private offerings of our capital shares, 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. Because of the numerous risks and uncertainties associated with the development and potential commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays, operating expenditures and capital requirements associated with our current and anticipated product development programs.

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. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our shareholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our shareholders' rights. Our existing agreements with NovaQuest and Hercules involve, and any agreements for future debt or preferred equity financings, if available, may involve, covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

In addition, if we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise 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 six months ended September 30, 2017 and 2016 (in thousands):

	Six Months Ended September 30,	
	2017	2016
Net cash used in operating activities	$ (51,361)	$ (687)
Net cash used in investing activities	$ (157)	$ —
Net cash provided by financing activities	$ 12	$ 760

Operating Activities

For the six months ended September 30, 2017, $51.4 million was used in operating activities. This was primarily attributable to a net loss for the period of $53.2 million, increase of $2.1 million in other assets and decreases of $2.3 million and $2.0 million in due to RSL and RSI and accounts payable, respectively. These amounts were partially offset by $4.9 million share-based compensation and an increase in accrued expenses of $2.6 million.

For the six months ended September 30, 2016, $0.7 million was used in operating activities. The net loss for the period of $53.7 million was partially offset by $13.1 million of non-cash in-process R&D expenses related to the acquisition of the rights to our product candidates, $4.8 million share-based compensation, $29.8 million non-cash changes in the fair value of the warrant liability and $4.0 million allocation of personnel expenses by RSL and RSI associated with the preparation of our clinical and other research programs, the formation of our company and corporate matters, and $1.3 million other expenses.

Investing Activities

For the six months ended September 30, 2017, $0.2 million was used in investing activities, all for the purchase of furniture and equipment.

For the six months ended September 30, 2016, no cash was used in investing activities.

Financing Activities

For the six months ended September 30, 2017, cash provided by financing activities consisted primarily of proceeds from the exercise of stock options.

For the six months ended September 30, 2016, $0.8 million was provided by financing activities, which was primarily the amount of a capital contribution made by RSL.

Contractual Obligations

During the six months ended September 30, 2017, there were no material changes outside of the ordinary course of business to our specified contractual obligations from those disclosed in our Annual Report on Form 10-K for the fiscal year ended March 31, 2017, filed with the SEC on June 14, 2017. Subsequent to September 30, 2017, we entered into the NovaQuest Securities Purchase Agreement, the NovaQuest Equity Purchase Agreement and the Hercules Loan Agreement. See “Note 8—Subsequent Events” to our interim unaudited condensed consolidated financial statements contained herein for a further discussion of these agreements.

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 unaudited condensed consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S GAAP. The preparation of these unaudited 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 R&D and G&A 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 estimating the fair value of our warrant liability which expired in April 2017, R&D accruals, share-based compensation and income taxes have the greatest potential impact on our unaudited 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 audited consolidated financial statements included in our Annual Report on Form 10-K. We believe there have been no material changes to our critical accounting policies and use of estimates as disclosed in our Annual Report on Form 10-K for the fiscal year ended March 31, 2017, filed with the SEC on June 14, 2017.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2016-02, "*Leases* (Topic 842)," 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*." 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. We have adopted this guidance as of April 1, 2017 using a modified retrospective transition method. As a result of the adoption of this standard, we elected to change our policy from estimating forfeitures to recognizing forfeitures when they occur and, as a result, recorded an adjustment of $0.1 million to accumulated deficit with a corresponding offset to additional paid-in-capital as of April 1, 2017. The other amended requirements of ASU No. 2016-09 did not have a material impact on our unaudited condensed consolidated financial statements and related disclosures.

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 September 30, 2017, we had cash of $129.3 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

Under the supervision of our Principal Executive Officer and Principal Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2017, the end of the period covered by this report. The term “disclosure controls and procedures” (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Principal Executive Officer and Principal Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. Based on this evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2017 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.

(c) Inherent Limitations on Effectiveness of Controls

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

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 October 2, 2017, a Consent Order of Dismissal resolving all claims and dismissing with prejudice the previously disclosed litigation involving AbbVie Inc. was signed by all parties and entered by the presiding judge in the Circuit Court of the Nineteenth Judicial Circuit, Lake County, Illinois. The resolution of this matter does not have any material adverse effect on our business, operating results or financial condition. See Part II, Item 1 “Legal Proceedings” of our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2017, filed with the SEC on August 10, 2017, for a prior discussion of this proceeding.

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 unaudited 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 Quarterly Report on Form 10-Q occurs, our business, operating results and financial condition could be seriously harmed and the trading price of our common shares could decline and you could lose all or part of your investment in our common shares. This 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, 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-associated 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 have not generated any product revenue.

Even if we receive regulatory approval for relugolix or MVT-602, we do not know when or if relugolix or MVT-602 will generate product revenue. 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/or MVT-602;
- set an acceptable price for relugolix or MVT-602 and obtain coverage and adequate reimbursement from third-party payors;
- establish sales, marketing, and distribution systems for relugolix or 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 Takeda or other third-party manufacturers and have commercial quantities of relugolix or MVT-602 manufactured at acceptable cost and quality levels;
- attract and retain experienced management and advisory teams;
- 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 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 each product. If we cannot successfully execute any one of the foregoing, our business may not succeed and your investment in our Company 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 unviable. We have never generated any product revenue, and we cannot estimate with precision the extent of our future losses. We do not currently have any products that are available for commercial sale and we may never generate product revenue or achieve profitability. Our net loss was $53.2 million for the six months ended September 30, 2017 and, as of September 30, 2017, we had an accumulated deficit of $138.4 million.

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 anywhere in the world, and they may never receive such approval. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to generate product revenue and achieve profitability is dependent on our ability to complete the development of 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 upon, in part and among other things, the size of the markets in the territories for which we gain regulatory approval, the number of competitors in such markets, the accepted price for relugolix and MVT-602 and whether we own the commercial rights for those territories. If the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of 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 R&D expenses to continue 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 results of operations, 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 through clinical trials. 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 our target women's health indications or for advanced 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 New Drug Applications, or NDAs, or in any foreign country until we receive the requisite approvals from the appropriate authorities in such countries for marketing authorization. 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 authorities;
- the relevant regulatory authorities may require additional clinical trials, which would increase our costs and prolong our development timelines;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or other relevant regulatory authorities for marketing approval;
- the FDA or other relevant regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the Contract Research Organizations, or CROs, that we retain to conduct clinical trials may take actions outside of our control, or otherwise commit errors or breaches of protocols, that materially adversely impact our clinical trials and ability to obtain market approvals;
- the FDA or other relevant regulatory authorities may not find the data from nonclinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of these products outweigh their safety risks;
- the FDA or other relevant regulatory authorities may disagree with our interpretation of data from our nonclinical studies and clinical trials or may require that we conduct additional studies;
- the FDA or other relevant regulatory authorities may not accept data generated in 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 authorities may require development of a risk evaluation and mitigation strategy, or REMS, or its equivalent, as a condition of approval;
- the FDA or other relevant regulatory authorities may find the chemistry, manufacturing and controls data insufficient to support the quality of the product;
- the FDA or other relevant regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; or
- the FDA or other relevant regulatory authorities may change their approval policies or adopt new regulations.

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/or 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 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 before we do, or if 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.

We are conducting our 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 or comparable applications 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.

The terms of the NovaQuest Securities Purchase Agreement and the Hercules Loan Agreement place restrictions on our operating and financial flexibility.

In October 2017, we and our subsidiaries entered into the NovaQuest Securities Purchase Agreement and the Hercules Loan Agreement. Our obligations under the notes issued pursuant to the NovaQuest Securities Purchase Agreement are secured by a second lien security interest in substantially all of our (and our subsidiaries') assets, other than intellectual property, and our obligations under the Hercules Loan Agreement are secured by a first lien security interest in substantially all of our (and our subsidiaries') assets, other than intellectual property.

Each of these agreements includes customary affirmative and restrictive covenants and representations and warranties, including a minimum cash covenant. Under the NovaQuest Securities Purchase Agreement, a minimum cash covenant applies commencing on November 1, 2020 (or November 1, 2021 if extended pursuant to the terms of the NovaQuest Securities Purchase Agreement) and under the Hercules Loan Agreement, a minimum cash covenant applies commencing on December 31, 2017 and ceases to apply if the Company achieves certain clinical development and financial milestones as set forth in the Hercules Loan Agreement. Other restrictive covenants include limitations on additional indebtedness, liens (including a negative pledge on intellectual property and other assets), investments, distributions (including dividends), transfers, mergers or acquisitions, taxes, corporate changes and deposit accounts. Compliance with these covenants may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our shareholders.

Additionally, the NovaQuest Securities Purchase Agreement and the Hercules Loan Agreement each also includes customary events of default, including payment defaults, breaches of covenants following any applicable cure period, cross acceleration to certain debt, certain events relating to bankruptcy or insolvency and certain events relating to United Kingdom or Irish pension plans. Upon the occurrence of an event of default under the NovaQuest Securities Purchase Agreement, a default interest rate of an additional 5.0% will apply to the "Secured Obligations" as defined in the NovaQuest Securities Purchase Agreement, and NovaQuest, as the agent for the holders of the notes, may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the NovaQuest Securities Purchase Agreement. Upon the occurrence of an event of default under the Hercules Loan Agreement, a default interest rate of an additional 5.0% may be applied to the outstanding principal balance, and Hercules may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Hercules Loan Agreement. In addition, upon the occurrence of certain bankruptcy and insolvency events, our obligations under the notes issued pursuant to the NovaQuest Securities Purchase Agreement and our obligations under the Hercules Loan Agreement would automatically become due and payable. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay these outstanding obligations at the time any event of default occurs. In that case, we may be required to delay, limit, reduce or terminate our clinical development efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. NovaQuest and Hercules could also exercise their rights to take possession and dispose of the collateral securing our obligations, which collateral includes all of our (and our subsidiaries') property other than intellectual property. Our business, financial condition and results of operations could be substantially harmed as a result of any of these events.

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 the Takeda Agreement. Under the terms of the Takeda 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 relugolix and MVT-602. Because the length of time and activities associated with successful development of relugolix and MVT-602 are highly uncertain, we are unable to estimate with certainty the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of our planned and ongoing clinical trials for relugolix and MVT-602;
- 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 our products or any future product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale manufacturing activities;

- the cost of establishing sales, marketing and distribution capabilities for our products in regions where we choose to commercialize our products on our own; and
- the initiation, progress, timing and results of our commercialization of our product candidates, if approved for commercial sale.

Based upon our current operating plan, we believe our existing cash and the financing commitments available to us under our agreements with NovaQuest and Hercules will be sufficient for us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. We cannot be certain that additional capital will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back, or discontinue the development or commercialization of our product candidates or potentially discontinue operations. In addition, attempting to secure additional capital may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts. Because of the numerous risks and uncertainties associated with the development and potential commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays, operating expenditures and capital requirements associated with our current and anticipated product development programs.

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. 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 the rights of a common shareholder. Our existing agreements with NovaQuest and Hercules involve, and any agreements for future debt or preferred equity financings, if available, may involve, covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends.

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

We rely on 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 our core intellectual property relating to relugolix and MVT-602 from Takeda. If, for any reason, the Takeda Agreement is terminated or we otherwise lose those rights, it would adversely affect our business. The Takeda Agreement 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 Takeda Agreement, we and a Takeda affiliate have entered into an agreement for the manufacture and supply of clinical trial materials. 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 subsidiaries and we rely on Roivant Sciences, Inc. and Roivant Sciences GmbH to provide various administrative, business development, and other services.

As of September 30, 2017, we had 60 employees. We rely in part on administrative support, business development, and other services provided by RSI and RSG, wholly owned subsidiaries of RSL, pursuant to our Services Agreements with RSI and RSG, as described above and in our Annual Report on Form 10K for the fiscal year ended March 31, 2017, filed with the SEC on June 14, 2017 under Item 1. Business "Our Key Agreements—Services Agreements with Roivant Sciences, Inc. and Roivant Sciences GmbH." Personnel and support staff who provide services to us under these services agreements are not required to do so, 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 for us.

RSI and RSG have limited finance and accounting and other resources. If either RSI or RSG fails to perform its obligations in accordance with the terms of the Services Agreements or to effectively manage our administrative support, certain business development or other services, it could be difficult for us to operate our business and our business could be harmed. In the event of a default under or termination of the Services Agreements, we may be unable to contract with substitute service providers on similar terms, in a timely fashion or at all, and the costs of substituting service providers may be substantial. In addition, a substitute service provider may not be able to provide the same level of service due to lack of pre-existing knowledge or synergies. Any 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.

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

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

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the skills and leadership of our management team and key employees, as well as the key employees of RSI and RSG who provide services to us through the Services Agreements. Our senior management and key employees, as well as those of RSI and RSG, may terminate their positions with us or their employment with RSI or RSG, respectively, at any time. Further, neither RSI nor RSG is required pursuant to the Services Agreements to maintain the employment of any of its key employees on our behalf or to cause those individuals to provide services to us. If we lose one or more members of our senior management team or key employees, or those of RSI or RSG, our ability to successfully implement our business strategy could be seriously harmed. Replacing these individuals may be difficult, cause disruption, and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of, and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate additional key personnel. We do not maintain "key person" insurance for any of our executives or other employees.

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

We expect to hire, either directly, through MSI, MSG or through any other current or future subsidiary of ours, additional employees for our managerial, clinical, scientific and engineering, regulatory, operational, manufacturing, medical affairs, and sales and marketing teams. We may have difficulties 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 across our entities, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our 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, MVT-602 or any potential future product candidate and compete effectively will depend, in part, on our ability to effectively manage any future growth.

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

Our employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers, and other vendors, or those of our affiliates, 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, or those of our affiliates, 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 and cGMP standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; or laws that require the true, complete, and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing, bribery, corruption, antitrust violations, and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our nonclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee or third-party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government agency could allege such fraud or other misconduct, even if none occurred. If our employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers or other vendors, or those of our affiliates, are found to be in violation of any such regulatory standards or requirements, it could have a significant impact on our business and financial results, including the imposition of significant civil, criminal, and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, FDA debarment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements, and oversight if we become subject to a corporate integrity agreement or similar agreement, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

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

- the process by which we identify and decide to acquire product candidates may not be successful;
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance; or
- potential product candidates may not be effective in treating their targeted diseases.

We may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. Further, time and resources spent searching for, identifying, acquiring, and developing potential product candidates may distract management’s attention from our primary business or other development programs. If we are unable to identify and acquire suitable product candidates for clinical development, this would adversely impact our business strategy, our financial position, and share price.

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

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

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

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

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

Our computer systems, as well as those of RSI, RSG and our CROs and other contractors, consultants, and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, cybercriminals, 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, other pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large monetary judgments have been awarded in class action lawsuits where drugs have had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize our 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 uncertain outcomes.

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 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 authorities. 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 or other regulatory authorities may not agree with our proposed endpoints or analysis plans for any clinical trials of relugolix or MVT-602, which may delay the commencement of our planned clinical trials or approval of an NDA or similar application. The clinical trial process is also time-consuming. We estimate that our clinical trials of relugolix and MVT-602 needed for an NDA filing will take at least two years to complete.

Failures can occur at any stage of clinical trials, and we could encounter problems that cause us to abandon or repeat clinical trials. In addition, results from clinical trials may require further evaluation, delaying the next stage of clinical development. For example, promising initial data from our Phase 1 study of MVT-602 require further evaluation prior to initiation of a Phase 2 clinical study. Further, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical studies and initial clinical trials. For example, Takeda’s Phase 2 trial for relugolix in men with advanced prostate cancer, 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 treatment compliance of those patients enrolled into the trial. 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. Likewise, the results of early clinical trials of relugolix and MVT-602 may not be predictive of the results of our planned development programs, and there can be no assurance that the results of studies conducted by collaborators or other third parties will be viewed favorably or are indicative of our own future study results.

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;
- unanticipated impact from changes in or modifications to clinical trial design;
- failure to manufacture sufficient quantities of our product candidates, estradiol and progestin or placebo or failure to obtain sufficient quantities of concomitant medication for use in clinical trials;
- inability to monitor patients adequately during or after treatment;
- inability or unwillingness of medical investigators to follow our clinical and other applicable protocols;
- failure to add a sufficient number of clinical trial sites; or
- clinical sites or others deviating from trial protocol, inappropriately unblinding results, 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, the FDA’s current 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 Investigational New Drug application, or 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, cause a decline in our share price, slow down the approval process, and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition, and results of operations. In addition, many of the factors that cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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

In addition, prior to our acquisition of worldwide rights, excluding Japan and certain other Asian countries, to relugolix and worldwide rights to MVT-602, we had no involvement with or control over the nonclinical or clinical development of either relugolix or MVT-602. We are dependent on Takeda having conducted such R&D in accordance with the applicable protocol, legal, regulatory, and scientific standards, having accurately reported the results of all clinical trials and other research conducted prior to our acquisition of the rights to relugolix and MVT-602, having correctly collected and interpreted the data from these trials and other research, and having supplied us with complete information, data sets, and reports required to adequately demonstrate the results reported through the date of our acquisition of these assets. Problems related to predecessors could result in increased costs and delays in the development of our product candidates, which could adversely affect our ability to generate any future revenue from these product candidates.

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

Takeda is developing relugolix for the treatment of women with uterine fibroid-associated pain and heavy menstrual bleeding in Japan. Takeda recently reported positive top-line results from its two Phase 3 clinical trials in Japan in women with uterine fibroids and is expected to file for approval with Japan's Pharmaceutical and Medical Devices Agency. Favorable announcements by Takeda regarding these trials do not guarantee that the results of our clinical trials will also be favorable as the designs of our Phase 3 clinical trials differ from those of Takeda. Further, if subsequent announcements by Takeda regarding its development of relugolix are unfavorable, it could negatively impact our clinical development plans for relugolix.

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. Likewise, promising results in interim analyses or other preliminary analyses do not ensure that the clinical trial as a whole will be successful. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, even after promising results in earlier nonclinical 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. Enrollment in our clinical trials may be slower than we anticipated, leading to delays in our development timelines. 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 and the proportion of patients screened that meets those criteria, our ability to obtain and maintain patient consents, and the risk that patients enrolled in clinical trials will drop out of the trials before completion. Furthermore, any negative results we or Takeda 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. Similarly, negative results reported by our competitors about their drug candidates may negatively affect patient recruitment in our clinical trials. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop 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 women, 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 our target indications.

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/or 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 for elagolix in women with endometriosis-associated pain and has filed an NDA in September 2017. In October 2017, AbbVie announced that the FDA has granted priority review for elagolix for the management of endometriosis with associated pain, and expects that the Prescription Drug User Fee Act date for the FDA to complete its review will be in the second quarter of 2018. AbbVie has also 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 has commenced 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 Initial Public Offering in January 2017, reported the commencement of 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 of 2017. In January 2017, Allergan and Gedeon Richter announced positive results from the second of two pivotal Phase 3 clinical trials evaluating the efficacy and safety of ulipristal acetate, a selective progesterone receptor modulator, in women with abnormal bleeding due to uterine fibroids. The FDA accepted the filing of their NDA submission for this indication in October 2017. Other GnRH receptor antagonists and selective progesterone receptor modulators are also in development, including vilaprisan, for which Bayer recently initiated a head-to-head study of vilaprisan compared with ulipristal acetate in women with heavy menstrual bleeding due to uterine fibroids and a long-term safety study of vilaprisan compared with standard of care. 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 are 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 or any other jurisdiction until we receive regulatory approval of an NDA from the FDA or similar regulatory authorities outside of the United States.

The time required to obtain approval of an NDA by the FDA 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 ongoing Phase 3 programs, and for approval of MVT-602, we will need to complete an additional Phase 1, 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 approvals requires the submission of extensive nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the safety and efficacy of relugolix 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 therapy (i.e., greater than 6 months) for the treatment of heavy menstrual bleeding associated with uterine fibroids and for the treatment of endometriosis-associated pain, we expect to be required to submit data on a relatively larger patient population followed for at least one year. We expect to rely on third-party CROs and consultants to assist us in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Delays or errors in the submission of applications for marketing approval or issues, including those related to gathering the appropriate data and the inspection process, may ultimately delay or affect our ability to obtain regulatory approval, commercialize our product candidates, and generate product revenue.

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 associated with 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.

Furthermore, concern has been raised by the FDA about a potential increase in the risk of diabetes and certain cardiovascular diseases in men with prostate cancer 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 (or equivalent outside the United States) to impose restrictions on its distribution or other risk management measures;
- we may be required to recall a product;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- 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 of registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or GMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians, recordkeeping, and current Good Clinical Practice, or GCP, requirements for any clinical trials that we conduct post-approval. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or the FDA or other regulatory authorities may require that contraindications, warnings or precautions—including in some cases, a boxed warning—be included in the product labeling. If relugolix or MVT-602 receives marketing approval, the accompanying label may limit the approved use of our product, which could limit sales of the product.

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

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

- restrictions on the manufacture of such products;
- restrictions on the labeling or marketing of such products;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of such products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

The FDA and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of 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.

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

- the efficacy and potential advantages compared to alternative treatments;
- the prevalence and severity of any side effects;
- the content of the approved product label;
- the effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement; 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 currently 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 nontechnical capabilities or make arrangements with third parties to perform these services. To achieve commercial success for any product for which we obtain marketing approval, we will need a sales and marketing organization.

We expect to build a focused sales, distribution, and marketing infrastructure to market our product 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 geographically dispersed sales and marketing teams. Any failure or delay in the development of our internal sales, marketing, and distribution capabilities could delay any product launch, which would adversely impact its commercialization. For example, if 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;
- the inability to negotiate with payors regarding reimbursement for our products; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

If we are unable to build our own sales force or negotiate a collaborative relationship for the commercialization of our product candidates, we may be forced to delay 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 at an earlier stage than otherwise would be ideal and we may be required to relinquish certain 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 outside of the United States, we intend to enter into agreements with third parties to market these products in certain jurisdictions. We expect that we will be subject to additional risks related to international operations or entering into international business relationships, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced or no protection of intellectual property rights;
- unexpected changes in tariffs, trade barriers, and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign reimbursement, pricing, and insurance regimes;
- foreign taxes;
- 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 United States Foreign Corrupt Practices Act, the United Kingdom Bribery Act 2010, and similar antibribery and anticorruption laws in other jurisdictions;

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods, and fires.

We have no prior experience in 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, patient support, charitable organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws regulate the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our products for which we obtain marketing approval. Such laws include, among others:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal false claims laws, including the False Claims Act, which imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or knowingly making or causing to be made, a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; 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 or fraudulent claim for purposes of the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which also impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information on health plans, health care clearing houses, and most providers and their business associates, defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other “transfers of value” made to physicians and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other “transfers of value” to such physician owners (covered manufacturers are required to submit reports to the government by the 90th day of each calendar year); and

- analogous state and foreign laws and regulations, such as state antikickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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 healthcare industry, and impose additional healthcare policy reforms. The law has continued the downward pressure on pharmaceutical pricing, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs. Among the provisions of the Affordable Care Act of importance to our potential product candidates are the following:

- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries under their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs in certain states;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

We cannot predict the full impact of the Affordable Care Act on pharmaceutical companies, as many of the reforms require the promulgation of detailed regulations implementing the statutory provisions, some of which have not yet fully occurred. For example, in January 2016, the Centers for Medicare and Medicaid Services issued a final rule regarding the Medicaid Drug Rebate Program, effective April 1, 2016, that, among other things, revises the manner in which the "average manufacturer price" is to be calculated by manufacturers participating in the program and implements certain amendments to the Medicaid rebate statute created under the Affordable Care Act. Further, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. In January 2017, the President of the United States signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The U.S. House of Representatives passed legislation known as the American Health Care Act of 2017 in May 2017. More recently, the Senate Republicans released and then updated a bill to replace the Affordable Care Act known as the Better Care Reconciliation Act of 2017. The Senate Republicans also introduced legislation to repeal the Affordable Care Act without companion legislation to replace it, and a "skinny" version of the Better Care Reconciliation Act of 2017. Each of these measures was rejected by the full Senate. Congress will likely consider other legislation to replace elements of the Affordable Care Act. We continue to evaluate the effect that the Affordable Care Act and its possible repeal and replacement has on our business.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, the President of the United States signed into law the Budget Control Act of 2011, which, among other things, 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, reduced Medicare payments to several types of providers and increased the statute of limitations period in which the government may recover overpayments to providers from three to five years. Further, there have been several recent United States Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the out-of-pocket cost of prescription drugs, and reform government program reimbursement methodologies for drugs.

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

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

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

Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

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

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

Risks Related to Our Dependence on Third Parties

We do not have our own manufacturing capabilities and will rely on 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 and its affiliates. 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 manufacturing support provided by Takeda under our license agreement with Takeda will be sufficient for us to complete our ongoing Phase 3 programs for relugolix. We expect that the MVT-602 drug substance transferred from Takeda to us under the Takeda Agreement will be sufficient for our near-term development plans, however, additional process development and manufacturing would be required in order for us to complete Phase 3 clinical studies for MVT-602. 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 Takeda or other 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 current GMP requirements for manufacture of drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance, and qualified personnel. If the FDA or comparable foreign regulatory authorities do not approve these facilities for the manufacture of our product candidates or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Further, our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including:

- 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 applicable laws, regulations, and standards, including current GMP and similar foreign standards;
- deficient or improper record-keeping;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell relugolix, a fixed-dose combination product or co-packaging of relugolix and low-dose estradiol and progestin, 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 or other regulatory sanctions related to the manufacture of another company's products;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our products under specified storage conditions and in a timely manner.

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, trademarks, trade secret protections, 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 R&D output before it is too late to obtain patent protection. The patents and patent applications that we own or in-license may fail to result in issued patents with claims that protect 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 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 made a number of significant changes to United States patent laws. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The 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 certain 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 noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering relugolix, MVT-602 or any future product candidate, our competitors might be able to enter the market, which would have an adverse effect on our business.

Third party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate 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 United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization. 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 United States patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

The United States has recently enacted and implemented wide-ranging patent reform legislation. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the United States Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

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 R&D programs that may require us to share trade secrets under the terms of our R&D partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors, and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor’s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors, and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor’s discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

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

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

Risks Related to Our Common Shares

An active trading market for our common shares may not be sustained.

Although our common shares are listed on the NYSE, we cannot assure you that an active trading market for our common shares will continue to develop or be sustained. In addition, as a result of RSL beneficially owning approximately 61.0% of our outstanding common shares, trading in our common shares may be less liquid than the shares of companies with broader public ownership. If an active market for our common shares is not sustained, you may not be able to sell your shares quickly or at the market price. An inactive market may also impair our ability to raise capital to continue to fund operations by selling common shares and may impair our ability to acquire other companies or technologies by using our common shares as consideration.

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

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

- any delay in the commencement, enrollment, and ultimate completion of our clinical trials;
- results of clinical trials of 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;
- short sales of our common shares;
- sales of our common shares by us or our shareholders in the future;
- negative coverage in the media or analyst reports, whether accurate or not;
- issuance of subpoenas or investigative demands, or the public fact of an investigation by a government agency, whether meritorious or not;
- 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.

RSL 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 its board of directors consists of independent directors;
- for an annual performance evaluation of the nominating and corporate governance and compensation committees;
- to 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
- to 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.

RSL 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 September 30, 2017, RSL beneficially owns approximately 61.2% of the voting power of our outstanding common shares and has the ability to substantially influence us through this ownership position. For example, RSL and its shareholders may be able to control elections of directors, issuance of equity, including to our employees under equity incentive plans, amendments of our organizational documents, or approval of any merger, amalgamation, sale of assets or other major corporate transaction. RSL's interests may not always coincide with our corporate interests or the interests of other shareholders, and it may act in a manner with which you may not agree or that may not be in the best interests of our other shareholders. Further, RSL is a privately-held company whose ownership and governance structure is not transparent to our other shareholders. There may be changes to the management or ownership of RSL that could impact RSL's interests in a way that may not coincide with our corporate interests or the interests of other shareholders. So long as RSL continues to own a significant amount of our equity, it will continue to be able to strongly influence or effectively control our decisions.

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

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

In addition, we are party to certain related party agreements with RSL, RSI, and RSG. These entities and their shareholders, including certain of our directors and employees, may have interests which differ from our interests or those of the minority holders of our common shares. For example, we are party to an option agreement with RSL pursuant to which RSL granted to us 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. It is possible that we could fail to exercise our option with respect to a product candidate under this agreement and that product candidate is then successfully developed and commercialized by RSL or one of its other subsidiaries or affiliates. Any material transaction between us and RSL, RSI, or RSG is subject to our related party transaction policy, which requires prior approval of such transaction by our Audit Committee. To the extent we fail to appropriately deal with any such conflicts of interests, it could negatively impact our reputation and ability to raise additional funds and the willingness of counterparties to do business with us, all of which could have an adverse effect on our business, financial condition, results of operations, and cash flows.

If securities or industry analysts cease to publish research or reports about our business, or publish negative reports about our business, our share price and trading volume could decline.

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

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

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

Future sales of our common shares, or the perception that such sales may occur, could depress our share price, even if our business is doing well.

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

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

We have filed a registration statement on Form S-8 under the Securities Act to register the 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 and result in dilution to the market price of our common shares.

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

As a public company, we have incurred and will continue to incur significant legal, accounting, and other expenses. 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 devote a substantial amount of time to compliance with these requirements. Moreover, changing rules and regulations may increase our legal and financial compliance costs and make some activities more time-consuming and costly. If, notwithstanding our efforts to comply with new or changing laws, regulations, and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. Further, failure to comply with these laws, regulations and standards may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, which could make it more difficult for us to attract and retain qualified members to serve on our board of directors or committees or as members of senior management.

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

We will be required, pursuant to Section 404 of the Sarbanes-Oxley Act (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 Jumpstart Our Business Startups Act of 2012, or the JOBS Act. At such time as we are required to obtain auditor attestation, if we then have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered public accounting firm. We will be required to disclose significant changes made in our internal control procedures on a quarterly basis.

We have begun the costly and challenging process of compiling the system and process documentation necessary to perform the evaluation needed to comply with Section 404. Our process to comply with Section 404 will result in substantial legal, accounting and other compliance expense and significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and finance staff and consultants with appropriate public company experience and technical accounting knowledge, and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404.

During the evaluation and testing process of our internal 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 controls over financial reporting are effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain effective internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common shares could decline, and we could be subject to sanctions or investigations by 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 negatively impact our ability to access 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 $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common shares that are held by non-affiliates exceeds $700.0 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 U.S. judgments obtained in U.S. courts against us based on the civil liability provisions of the U.S. securities laws. It is doubtful whether courts in Bermuda will enforce judgments obtained in other jurisdictions, including the United States, against us or our directors or officers under the securities laws of those jurisdictions or entertain actions in Bermuda against us or our directors or officers under the securities laws of other jurisdictions.

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

We are incorporated under the laws of Bermuda. As a result, our corporate affairs are governed by the Bermuda Companies Act 1981, as amended, or the Companies Act, which differs in some material respects from laws typically applicable to U.S. corporations and shareholders, including the provisions relating to interested directors, amalgamations, mergers and acquisitions, takeovers, shareholder lawsuits, and indemnification of directors. Generally, the duties of directors and officers of a Bermuda company are owed to the company only. Shareholders of Bermuda companies typically do not have rights to take action against directors or officers of the company and may only do so in limited circumstances. Shareholder class actions are not available under Bermuda law. The circumstances in which shareholder derivative actions may be available under Bermuda law are substantially more proscribed and less clear than they would be to shareholders of U.S. corporations. The Bermuda courts, however, would ordinarily be expected to permit a shareholder to commence an action in the name of a company to remedy a wrong to the company where the act complained of is alleged to be beyond the corporate power of the company or illegal, or would result in the violation of the company's memorandum of association or bye-laws. Furthermore, consideration would be given by a Bermuda court to acts that are alleged to constitute a fraud against the minority shareholders or, for instance, where an act requires the approval of a greater percentage of the company's shareholders than those who actually approved it.

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

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

Common shares may be offered or sold in Bermuda only in compliance with the provisions of the Companies Act and the Bermuda Investment Business Act 2003, which regulates the sale of securities in Bermuda. In addition, the Bermuda Monetary Authority must approve all issues and transfers of shares of a Bermuda exempted company. However, the Bermuda Monetary Authority has, pursuant to its statement of June 1, 2005, given its general permission under the Exchange Control Act 1972 and related regulations for the issue and free transfer of our common shares to and among persons who are non-residents of Bermuda for exchange control purposes as long as the shares are listed on an appointed stock exchange, which includes 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. RSL and certain of its affiliates are not 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 income or withholding taxes. We are centrally managed and controlled in the United Kingdom, and under current U.K. tax law, a company which is centrally managed and controlled in the United Kingdom is regarded as resident in the United Kingdom for taxation purposes. We may also become subject to income, withholding or other taxes in certain jurisdictions by reason of our activities and operations, and it is also possible that taxing authorities in any such jurisdictions could assert that we are subject to greater taxation than we currently anticipate. Any such additional tax liability could materially adversely affect our results of operations. For example, Myovant Sciences GmbH is our principal operating company for conducting our business and the entity that holds 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.

RSL, our principal shareholder, is incorporated under the laws of Bermuda. We currently have subsidiaries in the United Kingdom, Switzerland, Ireland, 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, as well as uncertainty as to 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 consolidated tax liability, which could adversely affect our financial condition, results of operations, and cash flows.

Changes in our effective tax rate may reduce our net income in future periods.

Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in Europe (including the United Kingdom), 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 tax rate applicable to dividends received on our common shares by individuals who are U.S. holders, and having interest charges apply to distributions by us and the proceeds of sales of our common shares.

Our status as a PFIC will depend on the composition of our income and the composition and value of our assets (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), which may be 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 at any point prior to our IPO and after our IPO in the taxable year that ended on March 31, 2017. Based on this belief, with respect to the taxable year that ended on March 31, 2017 and foreseeable future taxable years, we believe that we were not a PFIC and presently do not anticipate that we will be a PFIC based upon the expected value of our assets, including any goodwill, and the expected nature and composition of our income and assets. However, our status as a PFIC is a fact-intensive determination made on an annual basis and we cannot provide any assurances regarding our PFIC status for the 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**

None.

(b) **Use of Proceeds**

On November 1, 2016, we closed our IPO, in which we issued and sold 14.5 million 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. We have used the cash proceeds from our IPO as described in the final prospectus filed by us with the SEC on October 27, 2016, and the remaining net cash proceeds are currently deposited with three banking institutions and are 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.

None.

Item 6. Exhibits.

Exhibit Number	Description of Document
3.1	Certificate of Incorporation. (1)
3.2	Memorandum of Association. (2)
3.3	Second Amended and Restated Bye-laws. (3)
10.1+	Employment Agreement, dated as of July 12, 2017, by and between Matthew Lang, JD and Myovant Sciences, Inc.
10.2+	Employment Agreement, dated as of July 24, 2017, by and between Juan Camilo Arjona Ferreira, MD and Myovant Sciences, Inc.
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.

+ Indicates management contract or compensatory plan.

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: November 13, 2017

Exhibit 10.1

MYOVANT SCIENCES, INC.

EMPLOYMENT AGREEMENT

This Employment Agreement (this "***Agreement***") is entered into as of July 12, 2017 by and between Matthew Lang (the "***Executive***") and Myovant Sciences, Inc. (the "***Company***").

RECITALS

A. The Company desires the association and services of the Executive and his skills, abilities, background and knowledge, and is willing to engage the Executive's services on the terms and conditions set forth in this Agreement.

B. The Executive desires to be in the employ of the Company, and is willing to accept such employment on the terms and conditions set forth in this Agreement.

C. This Agreement supersedes any and all prior and contemporaneous oral or written employment agreements or arrangements between the Executive and the Company or any predecessor thereof.

AGREEMENT

In consideration of the foregoing, the parties agree as follows:

1. EMPLOYMENT BY THE COMPANY.

1.1 Position; Duties. Subject to the terms and conditions of this Agreement, the Executive shall hold the position of General Counsel and Corporate Secretary, in which position the Executive shall be an officer of the Company for purposes of Section 16(a)(1) of the Securities Exchange Act of 1934. In this position, the Executive will have the duties and authorities normally associated with a General Counsel and Corporate Secretary of a company. The Executive will report to, and be subject to the direction of, the Company's President and Chief Executive Officer. The Executive shall devote the Executive's full business energies, interest, abilities and productive time to the proper and efficient performance of the Executive's duties under this Agreement; provided, however, that the Executive may devote reasonable periods of time to (a) serving on the board of directors of other corporations subject to the prior approval of the Company's Board of Directors (the "***Board***"), and (b) engaging in charitable or community service activities, so long as none of the foregoing additional activities materially interfere with the Executive's duties under this Agreement.

1.2 Relationship With Parent. It is understood and agreed that the Executive's duties may include providing services to or for the benefit of the Company's affiliates, including, but not limited to, Myovant Sciences Ltd. (the "***Parent***"), provided that the Executive agrees that he will not provide any services from within the United States for the Parent or any affiliate of the Parent that is organized in a jurisdiction outside the United States. In addition, the Executive shall be deemed an officer or executive officer of the Parent, if at all, solely for purposes of the requirements applicable to the Parent as a registrant with the U.S. Securities and Exchange Commission. The Executive will not become an employee of the Parent, and the Executive's activities as an officer or executive officer of the Parent shall be strictly ministerial and shall not involve conducting any of the Parent's business activities from within the United States, including day-to-day management or other operational activities of the Parent.

1.3 Location of Employment. The Executive shall work primarily from the Company's principal base of operations, which is currently in California. The Executive understands that his duties may require periodic business travel.

1.4 Policies and Procedures. The employment relationship between the parties shall be governed by this Agreement and by the policies and practices established by the Company and/or the Board. In the event that the terms of this Agreement differ from or are in conflict with the Company's policies or practices, this Agreement shall govern and control.

1.5 Exclusive Employment; Agreement not to Participate in Company's Competitors. Subject to Sections 1.1 and 1.2 above, except with the prior written consent of the Board, the Executive will not during his employment with the Company undertake or engage in any other employment, occupation or business enterprise. During the Executive's employment, the Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known by the Executive to be adverse or antagonistic to the Company, its business or its prospects, financial or otherwise, or in any company, person or entity that is, directly or indirectly, in competition with the business of the Company. Ownership by the Executive of professionally managed funds over which the Executive does not have control or discretion in investment decisions or an investment representing less than two percent (2%) of the outstanding shares of capital stock of any corporation with one or more classes of its capital stock listed or publicly traded on a national securities exchange or in the over-the-counter market shall not constitute a breach of this Section.

1.6 Start Date. The Executive's employment with the Company is commencing as of the date of this Agreement (the "Start ***Date***").

2. AT-WILL EMPLOYMENT.

The Executive's employment relationship with the Company is, and shall at all times remain, at-will. This means that either the Executive or the Company may terminate the employment relationship at any time, for any reason or for no reason, with or without Cause (as defined below) or advance notice; provided, however, however, the Executive must provide the Company at least sixty (60) days' advance written notice of the Executive's intention to resign from employment (except for a resignation for Good Reason, in which case such procedure shall be governed by the terms set forth in the definition of Good Reason) and the Company shall provide the Executive sixty (60) days' advance written notice in the event of a termination of the Executive's employment by the Company without Cause.

3. COMPENSATION AND BENEFITS.

3.1 Salary. The Company shall pay the Executive a base salary at the annualized rate of $367,000 (the "***Base Salary***"), less payroll deductions and all required withholdings, payable in regular periodic payments in accordance with the Company's normal payroll practices. The Base Salary shall be prorated for any partial year of employment on the basis of a 365-day year. The Base Salary shall be subject to periodic review and may be increased from time to time in the Board's discretion.

3.2 Sign-on Bonus. Within thirty (30) days after the Start Date, the Company shall pay the Executive a sign-on bonus in a lump sum payment of $100,000, together with a tax gross-up payment representing additional compensation in an amount intended to offset, on an after-tax basis, the Executive's income taxes payable in respect of such bonus (collectively, the "***Sign-on Bonus***"). Should the Executive's employment terminate for any reason, voluntarily or involuntarily, prior to the first anniversary of the Start Date, the Executive shall be required to repay the Sign-on Bonus.

3.3 Annual Performance Bonus. Each fiscal year, the Executive will be eligible to earn an annual discretionary cash bonus (the "***Annual Performance Bonus***") with a target equal to 45% of the Executive's Base Salary, based on the Board's assessment of the Executive's individual performance and overall Company performance. In order to earn and receive the Annual Performance Bonus, the Executive must remain employed by the Company through and including the last day of the fiscal year to which the Performance Bonus relates. The Annual Performance Bonus, if any, will be paid no later than thirty (30) days following the end of that fiscal year. The Company's fiscal year currently ends on March 31st. The Annual Performance Bonus payable, if any, shall be prorated for the initial year of employment (on the basis of a 365-day year) or prorated if the Company's review or assessment of the Executive's performance covers a period that is less than a full fiscal year. The determination of whether the Executive has earned a bonus and the amount thereof shall be determined by the Board or a committee thereof in its sole discretion. The Board or a committee thereof reserves the right to modify the bonus criteria from year to year. Within thirty (30) days following a Change of Control (as defined below), the Company shall pay to the Executive a prorated bonus (based on the higher of target or actual achievement of pro rata performance targets for the number of days that have elapsed in such fiscal year as of the Change of Control) and with the bonus amount to be the prorated portion of a full annual bonus based on the number of days that have elapsed in such fiscal year as of the Change of Control.

3.4 Equity.

(a) Subject to the terms of the Parent's 2016 Equity Incentive Plan (the "***Plan***") and approval of the grant by the Parent's board of directors (the "***Parent Board***") or a committee thereof, the Executive will be granted an option to purchase up to 310,000 shares of the Parent's Common Stock (the "***Initial Option***"). The Initial Option shall: (i) have an exercise price equal to the closing price of the Parent's common stock on the New York Stock Exchange on the grant date; (ii) be subject to a four (4)-year vesting period, with 25% of the Initial Option shares vesting on the first anniversary of the grant date and quarterly vesting thereafter, as well as any other terms contained in the grant agreements; and (iii) expire and cease to be exercisable on the ten (10)-year anniversary of the grant date. Under the Company's current grant date policy, option grants are effective on the 15^{th} (or next business day) of the month next following the later of the date of approval of the option grant or the optionee's commencement of employment. The Initial Option will be governed by the Plan and other documents issued in connection with the grant.

(b) In addition, the Executive will be eligible to receive additional discretionary annual equity incentive grants that will vest over a four (4)-year vesting period in amounts commensurate with the Executive's position as General Counsel and Corporate Secretary (the **"*Annual Equity Grants*"**). The Annual Equity Grants will be based upon meeting Company performance metrics to be mutually agreed upon in writing annually.

3.5 Benefits and Insurance. The Executive shall, in accordance with Company policy and the terms of the applicable plan documents, be eligible to participate in benefits under any benefit plan or arrangement that may be in effect from time to time and made available to similarly situated Company executives (including, but not limited to, being named as an officer for purposes of the Company's Directors & Officers insurance policy). In particular, the Executive shall be entitled to vacation each year, in addition to sick leave and observed holidays, in accordance with the policies and practices of the Company. Vacation may be taken at such times and intervals as the Executive shall determine, subject to the business needs of the Company. The Company reserves the right to modify, add or eliminate benefits from time to time.

3.6 Expense Reimbursements. The Company will reimburse the Executive for all reasonable business expenses that the Executive incurs in conducting his duties hereunder, pursuant to the Company's usual expense reimbursement policies. Reimbursement will be made as soon as practicable following receipt from the Executive of reasonable documentation supporting said expenses.

4. PROPRIETARY INFORMATION OBLIGATIONS.

As a condition of employment, the Executive agrees to execute and abide by the Company's Employee Non-Disclosure and Inventions Assignment Agreement ("***NDA***").

5. TERMINATION OF EMPLOYMENT.

5.1 Termination Without Cause Or Resignation For Good Reason.

If the Executive's employment with the Company is terminated without Cause or the Executive resigns for Good Reason, then the Company shall pay the Executive any earned but unpaid Base Salary accrued through the date of termination, at the rates then in effect, less standard deductions and withholdings. In addition, if the Executive furnishes to the Company an executed waiver and release of claims in a form to be provided by the Company, which may include an obligation for the Executive to provide reasonable transition assistance (the "***Release***") that is nonrevocable prior to the Release Date, and if the Executive allows the Release to become effective in accordance with its terms, then the Executive shall receive the following benefits:

(a) The Company shall pay the Executive an amount equal to one times (1x) the sum of (i) the Executive's then current Base Salary (determined prior to any reduction in Base Salary that otherwise constitutes Good Reason, if applicable) and (ii) the Executive's Annual Performance Bonus (as determined under Section 3.3 above, and prior to any reduction in such annual target bonus opportunity that otherwise constitutes Good Reason, if applicable) in respect of the fiscal year in which the termination of employment occurs, at target level. Said amount shall be paid to the Executive in a single lump sum within ten (10) days following the Release Date and will be subject to required withholding;

(b) If the Executive is eligible for and timely elects COBRA continuation coverage, the Company will reimburse COBRA premiums for the first twelve (12) months of COBRA coverage; provided, however, that if the Executive ceases to be eligible for COBRA or becomes eligible to enroll in the group health insurance plan of another employer, the Executive will immediately notify the Company and the Company's obligation to provide the COBRA premium benefits shall immediately cease. Further, notwithstanding the foregoing, if at any time the Company determines, in its sole discretion, that it cannot provide the COBRA premium benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then in lieu of paying COBRA premiums on the Executive's behalf, the Company will pay the Executive on a monthly basis a fully taxable cash payment equal to the COBRA premium for that month, subject to applicable tax withholding. This payment may be, but need not be, used by Executive to pay for COBRA premiums; and

(c) The Executive shall be eligible to become fully vested in 25% of the Executive's then unvested and outstanding equity awards, including the Executive's then remaining unvested portion of the Initial Option and any Annual Equity Grants or other equity grants awarded.

5.2 Other Termination. If the Executive resigns his employment at any time without Good Reason or the Executive's employment is terminated by the Company at any time for Cause or due to death or Disability, the Company shall pay the Executive (or his estate) any Base Salary accrued through the date of such resignation or termination, and (other than upon a termination for Cause) any annual bonus that is due in respect of the prior fiscal year but is unpaid as of the date of termination, at the rates then in effect, less standard deductions and withholdings. In addition, in the event of a termination due to death or Disability, the Executive (or his estate) will be paid an amount equal to the Executive's target bonus amount for the year in which such resignation or termination occurs prorated to the date of such resignation or termination. The Company shall thereafter have no further obligations to the Executive, except as may otherwise be required by law.

5.3 Change of Control. If a Change of Control occurs during the Executive's employment or within three (3) months after the termination of such employment (other than termination by the Company for Cause or due to death or Disability), then the Executive shall become fully vested in 100% of the Executive's then unvested and outstanding equity awards, including the Executive's then remaining unvested portion of the Initial Option, the Annual Equity Grants and other equity grants awarded. In addition, if the Executive's employment with the Company is terminated without Cause or the Executive resigns for Good Reason within three (3) months before or eighteen (18) months after a Change of Control, then the reference to "one times (1x)" in Section 5.1(a) shall be changed to "one and one-half times (1.5x)" and the reference to "twelve (12) months" in Section 5.1(b) shall be changed to "eighteen (18) months."

5.4 Definitions. For purposes of this Agreement, the following terms shall have the following meanings:

(a) ***"Cause"*** shall mean the occurrence of any of the following, the Executive's: (i) conviction of any felony or any crime involving moral turpitude or dishonesty, (ii) participation in a fraud against the Company, (iii) willful and material breach of the Executive's duties and obligations under this Agreement or any other agreement between the Executive and the Company or its affiliates that has not been cured (if curable) within thirty (30) days after receiving written notice from the Board of such breach, (iv) intentional and material damage to the Company's property, or (v) violation of any law, rule or regulation (collectively, "***Law***") relating in any way to the business or activities of the Company or its subsidiaries or affiliates, or other Law that is violated during the course of the Executive's performance of services hereunder that results in the Executive's arrest, censure, or regulatory suspension or disqualification, including, without limitation, the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335(a), or any similar legislation applicable in the United States or in any other country where the Company intends to develop its activities.

(b) ***"Disability"*** shall mean the Executive's inability to perform his duties and responsibilities hereunder, with or without reasonable accommodation, due to any physical or mental illness or incapacity, which condition has continued for a period of 180 days (including weekends and holidays) in any consecutive 365-day period.

(c) ***"Good Reason"*** shall mean the occurrence of any of the following events without the Executive's consent: (i) reduction of the Executive's Base Salary as initially set forth herein or as the same may be increased from time to time; (ii) material reduction in the Executive's authority, duties or responsibilities, as compared to the Executive's authority, duties or responsibilities immediately prior to such reduction, without limiting the foregoing, including a change in the Executive's reporting responsibilities so that he no longer reports directly to the CEO and/or is no longer the Company's General Counsel and Corporate Secretary; (iii) failure or refusal of a successor to the Company to materially assume the Company's obligations under this Agreement in the event of a Change of Control; (iv) once a principal location of employment is selected, a change in the Executive's principal location of employment, resulting in an increase in the Executive's one-way driving distance by more than thirty (30) miles from the Executive's then current principal residence on file with the Company; or (v) the failure to timely grant the Initial Option, as described above; provided, however, any resignation by the Executive shall only be deemed for Good Reason pursuant to this definition if: (1) the Executive gives the Company written notice of the Executive's intent to terminate for Good Reason within ninety (90) days following the first occurrence of the condition(s) that he believes constitute(s) Good Reason, which notice shall describe such condition(s); (2) the Company fails to remedy such condition(s) within thirty (30) days following receipt of the written notice (the "***Cure Period***"); and (3) the Executive voluntarily terminates his employment within thirty (30) days following the end of the Cure Period.

(d) A ***"Change of Control***" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) A merger or consolidation in which the Company is a constituent party (or a subsidiary of the Company is a constituent party and the Company issues shares of its capital stock pursuant to such merger or consolidation), other than a merger or consolidation in which the voting securities of the Company outstanding immediately prior to such merger or consolidation continue to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the combined voting power of the voting securities of the surviving entity outstanding immediately after such merger or consolidation; or

(ii) Any transaction or series of related transactions in which more than fifty percent (50%) of the Company's voting power is transferred, other than the sale by the Company of stock in transactions the primary purpose of which is to raise capital for the Company's operations and activities; or

(iii) A sale, lease, exclusive license or other disposition of all or substantially all of the assets of the Company.

Notwithstanding the foregoing definition, the term Change of Control will not include (x) a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company or Parent, or (y) a liquidation or dissolution ancillary to or in connection with an assignment for the benefit of creditors, a bankruptcy proceeding, appointment of receiver or similar proceeding or transaction.

5.5 ***"Release Date"*** shall mean the date that is fifty-five (55) days following the date of the Executive's termination.

5.6 **Effect of Termination**. The Executive agrees that should his employment be terminated for any reason, he shall be deemed to have resigned from any and all positions with the Company and the Parent, including, but not limited to, any position he may hold on the Board or the Parent Board.

5.7 Section 409A Compliance.

(a) It is intended that any benefits under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Internal Revenue Code of 1986, as amended ("***Section 409A***"), provided under Treasury Regulations Sections 1.409A-1(b)(4), and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulations Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement (whether severance payments, if any, or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. A termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits upon or following a termination of employment unless such termination is also a "***separation from service***" within the meaning of Section 409A and, for purposes of any such provision of this Agreement, references to a "***resignation,***" "***termination,***" "***termination of employment***" or like terms shall mean separation from service. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by the Company at the time of a separation from service to be a "***specified employee***" for purposes of Section 409A(a)(2)(B)(i), and if any payments or benefits that the Executive becomes entitled to under this Agreement on account of such separation from service are deemed to be "***deferred compensation***," then to the extent delayed commencement of any portion of such payments or benefits is required in order to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided prior to the earliest of (i) the expiration of the six-month period measured from the date of separation from service, (ii) the date of Executive's death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such period, all payments deferred pursuant to this paragraph shall be paid in a lump sum, and any remaining payments due shall be paid as otherwise provided herein. No interest shall be due on any amounts so deferred.

(b) With regard to any provision herein that provides for reimbursement of costs and expenses or in-kind benefits, except as permitted by Section 409A, (i) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit, (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year, and (iii) such payments shall be made on or before the last day of the Executive's taxable year following the taxable year in which the expense was incurred. The Company makes no representation or warranty and shall have no liability to the Executive or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Code Section 409A but do not satisfy an exemption from, or the conditions of, Code Section 409A.

5.8 Section 280G.

(a) If any payment or benefit (including payments and benefits pursuant to this Agreement) that the Executive would receive in connection with a Change of Control or other transaction (the "***Transaction***") from the Company or otherwise ("***Transaction Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the "***Code***"), and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then the Company shall cause to be determined, before any amounts of the Transaction Payment are paid to the Executive, which of the following two alternative forms of payment would result in the Executive's receipt, on an after-tax basis, of the greater amount of the Transaction Payment notwithstanding that all or some portion of the Transaction Payment may be subject to the Excise Tax: (1) payment in full of the entire amount of the Transaction Payment (a "***Full Payment***"), or (2) payment of only a part of the Transaction Payment so that the Executive receives the largest payment possible without the imposition of the Excise Tax (a "***Reduced Payment***"). For purposes of determining whether to make a Full Payment or a Reduced Payment, the Company shall cause to be taken into account the value of all applicable federal, state and local income and employment taxes and the Excise Tax (all computed at the highest applicable marginal rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction of such state and local taxes). If a Reduced Payment is made, (x) the Executive shall have no rights to any additional payments and/or benefits constituting the Transaction Payment, and (y) reduction in payments and/or benefits shall occur in the manner that results in the greatest economic benefit to the Executive as determined in this paragraph. If more than one method of reduction will result in the same economic benefit, the portions of the Transaction Payment shall be reduced pro rata.

(b) Notwithstanding the foregoing, in the event that no stock of the Company is readily tradeable on an established securities market or otherwise (within the meaning of Section 280G of the Code) at the time of the Change of Control of the Company, the Company shall cause a vote of shareholders to be held to approve the portion of the Transaction Payments that equals or exceeds three times (3x) the Executive's "***base amount***" (within the meaning of Section 280G of the Code) (the "***Excess Parachute Payments***") in accordance with Treas. Reg. §1.280G-1, and the Executive shall cooperate with such vote of shareholders, including the execution of any required documentation subjecting the Executive's entitlement to all Excess Parachute Payments to such shareholder vote. In the event that the Company does not cause a vote of shareholder to be held to approve all Excess Parachute Payments, the provisions set forth in Section 5.8(a) of this Agreement shall apply.

(c) Unless the Executive and the Company otherwise agree in writing, any determination required under this section shall be made in writing by the Company's independent public accountants (the "***Accountants***"), whose determination shall be conclusive and binding upon the Executive and the Company for all purposes. For purposes of making the calculations required by this section, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Accountants shall provide detailed supporting calculations to the Company and the Executive as requested by the Company or the Executive. The Executive and the Company shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this section. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this section.

6. ARBITRATION.

Except as otherwise set forth below in connection with equitable remedies, any dispute, claim or controversy arising out of or relating to this Agreement or the Executive's employment with the Company (collectively, "***Disputes***"), including, without limitation, any dispute, claim or controversy concerning the validity, enforceability, breach or termination of this Agreement, if not resolved by the parties, shall be finally settled by arbitration in accordance with the then-prevailing Employment Arbitration Rules and Procedures of JAMS, as modified herein ("***Rules***"). The requirement to arbitrate covers all Disputes (other than disputes which by statute are not arbitrable) including, but not limited to, claims, demands or actions under the Age Discrimination in Employment Act (including Older Workers Benefit Protection Act); Americans with Disabilities Act; Civil Rights Act of 1866; Civil Rights Act of 1991; Employee Retirement Income Security Act of 1974; Equal Pay Act; Family and Medical Leave Act of 1993; Title VII of the Civil Rights Act of 1964; Fair Labor Standards Act; Fair Employment and Housing Act; any other provision of the California Labor, Government or Civil Code; IWC Wage Orders; and any other law, ordinance or regulation regarding discrimination or harassment or any terms or conditions of employment. There shall be one arbitrator who shall be jointly selected by the parties. If the parties have not jointly agreed upon an arbitrator within twenty (20) calendar days of respondent's receipt of claimant's notice of intention to arbitrate, either party may request JAMS to furnish the parties with a list of names from which the parties shall jointly select an arbitrator. If the parties have not agreed upon an arbitrator within ten (10) calendar days of the transmittal date of such list, then each party shall have an additional five (5) calendar days in which to strike any names objected to, number the remaining names in order of preference, and return the list to JAMS, which shall then select an arbitrator in accordance with the Rules. The place of arbitration shall be San Francisco, California. By agreeing to arbitration, the parties hereto do not intend to deprive any court of its jurisdiction to issue a pre-arbitral injunction, including, without limitation, with respect to the NDA. The arbitration shall be governed by the Federal Arbitration Act, 9 U.S.C. §§ 1-16. Judgment upon the award of the arbitrator may be entered in any court of competent jurisdiction. Discovery shall be permitted in the arbitration as provided by Section 1283.05 of the California Code of Civil Procedure. The Company shall pay all administrative fees of JAMS in excess of $435 (a typical filing fee in court) and the arbitrator's fees and expenses. Each party shall bear its or his own costs and expenses (including attorney's fees) in any such arbitration and the arbitrator shall have no power to award costs and attorney's fees except as provided by statute or by separate written agreement between the parties. In the event any portion of this arbitration provision is found unenforceable by a court of competent jurisdiction, such portion shall become null and void leaving the remainder of this arbitration provision in full force and effect. The parties agree that all information regarding the arbitration, including any settlement thereof, shall not be disclosed by the parties hereto, except as otherwise required by applicable law.

7. GENERAL PROVISIONS.

7.1 Representations and Warranties. The Executive represents and warrants that the Executive is not restricted or prohibited, contractually or otherwise, from entering into and performing each of the terms and covenants contained in this Agreement, and that the Executive's execution and performance of this Agreement will not violate or breach any other agreements between the Executive and any other person or entity. In addition, the Executive represents and warrants that the Executive is not debarred and has not received notice of any action or threat with respect to debarment under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335(a) or any similar legislation applicable in the United States or in any other country where the Company intends to develop its activities. The Executive understands and agrees that this Agreement is contingent on the Executive's submission of satisfactory proof of identity and legal authorization to work in the United States, as well as verification of auditor independence.

7.2 Advertising Waiver. The Executive agrees to permit the Company, and persons or other organizations authorized by the Company, to use, publish and distribute advertising or sales promotional literature concerning the products and/or services of the Company in which the Executive's name and/or pictures of the Executive appear. The Executive hereby waives and releases any claim or right the Executive may otherwise have arising out of such use, publication or distribution.

7.3 Miscellaneous. This Agreement, along with the NDA and any applicable equity awards that have been granted, constitutes the complete, final and exclusive embodiment of the entire agreement between the Executive and the Company with regard to its subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. This Agreement may not be modified or amended except in a writing signed by both the Executive and a duly authorized officer or member of the Board. This Agreement will bind the heirs, personal representatives, successors and assigns of both the Executive and the Company, and inure to the benefit of both the Executive and the Company, and to his and its heirs, successors and assigns. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Agreement and the provision in question will be modified so as to be rendered enforceable. This Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the State of California as applied to contracts made and to be performed entirely within California. Any ambiguity in this Agreement shall not be construed against either party as the drafter. Any waiver of a breach of this Agreement shall be in writing and shall not be deemed to be a waiver of any successive breach. This Agreement may be executed in counterparts and facsimile signatures will suffice as original signatures.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first written above.

MYOVANT SCIENCES, INC.
By: /s/ Lynn Seely
Name: Lynn Seely, MD
Title: President and Chief Executive Officer

Accepted and Agreed:
/s/ Matthew Lang
Matthew Lang

Exhibit 10.2

MYOVANT SCIENCES, INC.

EMPLOYMENT AGREEMENT

This Employment Agreement (this "***Agreement***") is entered into as of July 24, 2017 by and between Juan Camilo Arjona Ferreira, M.D. (the "***Executive***"), and Myovant Sciences, Inc. (the "***Company***").

RECITALS

A. The Company desires the association and services of the Executive and his skills, abilities, background and knowledge, and is willing to engage the Executive's services on the terms and conditions set forth in this Agreement.

B. The Executive desires to be in the employ of the Company, and is willing to accept such employment on the terms and conditions set forth in this Agreement.

C. This Agreement supersedes any and all prior and contemporaneous oral or written employment agreements or arrangements between the Executive and the Company or any predecessor thereof.

AGREEMENT

In consideration of the foregoing, the parties agree as follows:

1. EMPLOYMENT BY THE COMPANY.

1.1 Position; Duties. Subject to the terms and conditions of this Agreement, the Executive shall hold the position of Chief Medical Officer. In this position, the Executive will have the duties and authorities normally associated with a Chief Medical Officer of a company. The Executive will report to, and be subject to the direction of, the Company's President and Chief Executive Officer. The Executive shall devote the Executive's full business energies, interest, abilities and productive time to the proper and efficient performance of the Executive's duties under this Agreement; provided, however, that the Executive may devote reasonable periods of time to (a) serving on the board of directors of other corporations subject to the prior approval of the Company's Board of Directors (the "***Board***"), and (b) engaging in charitable or community service activities, so long as none of the foregoing additional activities materially interfere with the Executive's duties under this Agreement.

1.2 Relationship With Parent. It is understood and agreed that the Executive's duties may include providing services to or for the benefit of the Company's affiliates, including, but not limited to, Myovant Sciences Ltd. (the "***Parent***"), provided that the Executive agrees that he will not provide any services from within the United States for the Parent or any affiliate of the Parent that is organized in a jurisdiction outside the United States. In addition, the Executive shall be deemed an officer or executive officer of the Parent, if at all, solely for purposes of the requirements applicable to the Parent as a registrant with the U.S. Securities and Exchange Commission. The Executive will not become an employee of the Parent, and the Executive's activities as an officer or executive officer of the Parent shall be strictly ministerial and shall not involve conducting any of the Parent's business activities from within the United States, including day-to-day management or other operational activities of the Parent.

1.3 Location of Employment. The Executive shall work primarily from the Company's principal base of operations, which is currently in California. The Executive understands that his duties may require periodic business travel.

1.4 Policies and Procedures. The employment relationship between the parties shall be governed by this Agreement and by the policies and practices established by the Company and/or the Board. In the event that the terms of this Agreement differ from or are in conflict with the Company's policies or practices, this Agreement shall govern and control.

1.5 Exclusive Employment; Agreement not to Participate in Company's Competitors. Subject to Sections 1.1 and 1.2 above, except with the prior written consent of the Board, the Executive will not during his employment with the Company undertake or engage in any other employment, occupation or business enterprise. During the Executive's employment, the Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known by the Executive to be adverse or antagonistic to the Company, its business or its prospects, financial or otherwise, or in any company, person or entity that is, directly or indirectly, in competition with the business of the Company. Ownership by the Executive of professionally managed funds over which the Executive does not have control or discretion in investment decisions or an investment representing less than two percent (2%) of the outstanding shares of capital stock of any corporation with one or more classes of its capital stock listed or publicly traded on a national securities exchange or in the over-the-counter market shall not constitute a breach of this Section.

1.6 Start Date. The Executive's employment with the Company is commencing as of the date of this Agreement (the "***Start Date***").

2. AT-WILL EMPLOYMENT.

The Executive's employment relationship with the Company is, and shall at all times remain, at-will. This means that either the Executive or the Company may terminate the employment relationship at any time, for any reason or for no reason, with or without Cause (as defined below) or advance notice; provided, however, however, the Executive must provide the Company at least three (3) months' advance written notice of the Executive's intention to resign from employment (except for a resignation for Good Reason, in which case such procedure shall be governed by the terms set forth in the definition of Good Reason) and the Company shall provide the Executive three (3) months' advance written notice in the event of a termination of the Executive's employment by the Company without Cause.

3. COMPENSATION AND BENEFITS.

3.1 Salary. The Company shall pay the Executive a base salary at the annualized rate of $408,000 (the "***Base Salary***"), less payroll deductions and all required withholdings, payable in regular periodic payments in accordance with the Company's normal payroll practices. The Base Salary shall be prorated for any partial year of employment on the basis of a 365-day year. The Base Salary shall be subject to periodic review and may be increased from time to time in the Board's discretion.

3.2 Sign-on Advance. The Company shall pay the Executive a sign-on advance in two lump sum payments totaling $100,000, together with a tax gross-up payment representing additional compensation in an amount intended to offset, on an after-tax basis, the Executive's income taxes payable in respect of such advance (collectively, the "***Sign-on Advance***"). The first payment of $50,000 will be paid within thirty (30) days after the Start Date, and the second payment of $50,000 will be paid six months after the Start Date. Should the Executive's employment terminate for any reason, voluntarily or involuntarily, prior to the first anniversary of the Start Date, the Executive shall be required to repay the Sign-on Advance.

3.3 Annual Performance Bonus. Each fiscal year, the Executive will be eligible to earn an annual discretionary cash bonus (the "***Annual Performance Bonus***") with a target equal to 45% of the Executive's Base Salary, based on the Board's assessment of the Executive's individual performance and overall Company performance. In order to earn and receive the Annual Performance Bonus, the Executive must remain employed by the Company through and including the last day of the fiscal year to which the Performance Bonus relates. The Annual Performance Bonus, if any, will be paid no later than thirty (30) days following the end of that fiscal year. The Company's fiscal year currently ends on March 31st. The Annual Performance Bonus payable, if any, shall be prorated for the initial year of employment (on the basis of a 365-day year) or prorated if the Company's review or assessment of the Executive's performance covers a period that is less than a full fiscal year. The determination of whether the Executive has earned a bonus and the amount thereof shall be determined by the Board or a committee thereof in its sole discretion. The Board or a committee thereof reserves the right to modify the bonus criteria from year to year.

3.4 Equity.

(a) Subject to the terms of the Parent's 2016 Equity Incentive Plan (the "***Plan***") and approval of the grant by the Parent's board of directors (the "***Parent Board***") or a committee thereof, the Executive will be granted an option to purchase up to 260,000 shares of the Parent's common stock (the "***Initial Option***"). The Initial Option shall: (i) have an exercise price equal to the closing price of the Parent's common stock on the New York Stock Exchange on the grant date; (ii) be subject to a four (4)-year vesting period, with 25% of the Initial Option shares vesting on the first anniversary of the grant date and quarterly vesting thereafter, as well as any other terms contained in the grant agreements; and (iii) expire and cease to be exercisable on the ten (10)-year anniversary of the grant date. Under the Company's current grant date policy, option grants are effective on the 15th (or next business day) of the month next following the later of the date of approval of the option grant or the optionee's commencement of employment. The Initial Option will be governed by the Plan and other documents issued in connection with the grant.

(b) Subject and subsequent to the approval of the Board, the Executive will be granted 10,000 restricted stock units (the "***Initial RSUs***") of the Parent to be issued under the Plan. The Initial RSUs shall be subject to a 4-year vesting period, with 25% of the Initial RSUs vesting after approximately one year and approximately quarterly vesting thereafter, as well as any other terms contained in the grant agreement.

(c) In addition, the Executive will be eligible to receive additional discretionary annual equity incentive grants that will vest over a four (4)-year vesting period in amounts commensurate with the Executive's position as Chief Medical Officer (the **"*Annual Equity Grants*"**). The Annual Equity Grants will be based upon meeting Company performance metrics to be mutually agreed upon in writing annually.

3.5 Benefits and Insurance. The Executive shall, in accordance with Company policy and the terms of the applicable plan documents, be eligible to participate in benefits under any benefit plan or arrangement that may be in effect from time to time and made available to similarly situated Company executives (including, but not limited to, being named as an officer for purposes of the Company's Directors & Officers insurance policy). In particular, the Executive shall be entitled to vacation each year, in addition to sick leave and observed holidays, in accordance with the policies and practices of the Company. Vacation may be taken at such times and intervals as the Executive shall determine, subject to the business needs of the Company. The Company reserves the right to modify, add or eliminate benefits from time to time.

3.6 Expense Reimbursements. The Company will reimburse the Executive for all reasonable business expenses that the Executive incurs in conducting his duties hereunder, pursuant to the Company's usual expense reimbursement policies. Reimbursement will be made as soon as practicable following receipt from the Executive of reasonable documentation supporting said expenses.

3.7 Relocation. Within twelve (12) months after the Start Date, the Executive will be eligible to receive a relocation package to assist in his relocation to the Company's California office location. This relocation package will include transportation of the Executive and his family to San Francisco, as well as transportation of the Executive's household goods and up to two (2) automobiles. The relocation package will also include one (1) house-hunting trip for the Executive and his spouse. In addition, the Executive will be eligible to receive up to three months of temporary housing.

4. PROPRIETARY INFORMATION OBLIGATIONS.

As a condition of employment, the Executive agrees to execute and abide by the Company's Employee Non-Disclosure and Inventions Assignment Agreement ("***NDA***").

5. TERMINATION OF EMPLOYMENT.

5.1 Termination Without Cause Or Resignation For Good Reason.

If the Executive's employment with the Company is terminated without Cause or the Executive resigns for Good Reason, then the Company shall pay the Executive any earned but unpaid Base Salary accrued through the date of termination, at the rates then in effect, less standard deductions and withholdings. In addition, if the Executive furnishes to the Company an executed waiver and release of claims in a form to be provided by the Company, which may include an obligation for the Executive to provide reasonable transition assistance (the "***Release***") that is nonrevocable prior to the Release Date, and if the Executive allows the Release to become effective in accordance with its terms, then the Executive shall receive the following benefits:

(a) The Company shall pay the Executive an amount equal to one times (1x) the sum of (i) the Executive's then current Base Salary and (ii) the Executive's Annual Performance Bonus in respect of the fiscal year in which the termination of employment occurs, at target level. Said amount shall be paid to the Executive in a single lump sum within ten (10) days following the Release Date and will be subject to required withholding;

(b) If the Executive is eligible for and timely elects COBRA continuation coverage, the Company will reimburse COBRA premiums for the first twelve (12) months of COBRA coverage; provided, however, that if the Executive ceases to be eligible for COBRA or becomes eligible to enroll in the group health insurance plan of another employer, the Executive will immediately notify the Company and the Company's obligation to provide the COBRA premium benefits shall immediately cease. Further, notwithstanding the foregoing, if at any time the Company determines, in its sole discretion, that it cannot provide the COBRA premium benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then in lieu of paying COBRA premiums on the Executive's behalf, the Company will pay the Executive on a monthly basis a fully taxable cash payment equal to the COBRA premium for that month, subject to applicable tax withholding. This payment may be, but need not be, used by Executive to pay for COBRA premiums; and

(c) The Executive shall be eligible to become fully vested in 25% of the Executive's then unvested and outstanding equity awards, including the Executive's then remaining unvested portion of the Initial Option, the Initial RSUs and any Annual Equity Grants or other equity grants awarded. However, if the termination without Cause or resignation for Good Reason occurs on or before the eighteen (18)-month anniversary of a Change of Control (but not before a Change of Control), then the Executive shall be eligible to become fully vested in 100% of the Executive's then unvested and outstanding equity awards, including the Executive's then remaining unvested portion of the Initial Option, the Initial RSUs and any Annual Equity Grants or other equity grants awarded.

5.2 Other Termination. If the Executive resigns his employment at any time without Good Reason or the Executive's employment is terminated by the Company at any time for Cause or due to death or Disability, the Company shall pay the Executive (or his estate) any Base Salary accrued through the date of such resignation or termination, at the rates then in effect, less standard deductions and withholdings. In addition, in the event of a termination due to death or Disability, the Executive (or his estate) will be paid an amount equal to the Executive's target Performance Bonus amount for the fiscal year in which such resignation or termination occurs prorated to the date of such resignation or termination. The Company shall thereafter have no further obligations to the Executive, except as may otherwise be required by law.

5.3 Definitions. For purposes of this Agreement, the following terms shall have the following meanings:

(a) ***"Cause"*** shall mean the occurrence of any of the following, the Executive's: (i) conviction of any felony or any crime involving moral turpitude or dishonesty, (ii) participation in a fraud against the Company, (iii) willful and material breach of the Executive's duties and obligations under this Agreement or any other agreement between the Executive and the Company or its affiliates that has not been cured (if curable) within thirty (30) days after receiving written notice from the Board of such breach, (iv) intentional and material damage to the Company's property, or (v) violation of any law, rule or regulation (collectively, "***Law***") relating in any way to the business or activities of the Company or its subsidiaries or affiliates, or other Law that is violated during the course of the Executive's performance of services hereunder that results in the Executive's arrest, censure, or regulatory suspension or disqualification, including, without limitation, the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335(a), or any similar legislation applicable in the United States or in any other country where the Company intends to develop its activities.

(b) ***"Disability"*** shall mean the Executive's inability to perform his duties and responsibilities hereunder, with or without reasonable accommodation, due to any physical or mental illness or incapacity, which condition has continued for a period of 180 days (including weekends and holidays) in any consecutive 365-day period.

(c) ***"Good Reason"*** shall mean the occurrence of any of the following events without the Executive's consent: (i) reduction of the Executive's Base Salary as initially set forth herein or as the same may be increased from time to time; (ii) material reduction in the Executive's authority, duties or responsibilities, as compared to the Executive's authority, duties or responsibilities immediately prior to such reduction; (iii) failure or refusal of a successor to the Company to materially assume the Company's obligations under this Agreement in the event of a Change of Control; (iv) once a principal location of employment is selected, a change in the Executive's principal location of employment, resulting in an increase in the Executive's one-way driving distance by more than thirty (30) miles from the Executive's then current principal residence on file with the Company; or (v) the failure to timely grant the Initial Option or the Initial RSUs, as described above; provided, however, any resignation by the Executive shall only be deemed for Good Reason pursuant to this definition if: (1) the Executive gives the Company written notice of the Executive's intent to terminate for Good Reason within ninety (90) days following the first occurrence of the condition(s) that he believes constitute(s) Good Reason, which notice shall describe such condition(s); (2) the Company fails to remedy such condition(s) within thirty (30) days following receipt of the written notice (the "***Cure Period***"); and (3) the Executive voluntarily terminates his employment within thirty (30) days following the end of the Cure Period.

(d) A **"*Change of Control*"** means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) A merger or consolidation in which the Company is a constituent party (or a subsidiary of the Company is a constituent party and the Company issues shares of its capital stock pursuant to such merger or consolidation), other than a merger or consolidation in which the voting securities of the Company outstanding immediately prior to such merger or consolidation continue to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the combined voting power of the voting securities of the surviving entity outstanding immediately after such merger or consolidation; or

(ii) Any transaction or series of related transactions in which more than fifty percent (50%) of the Company's voting power is transferred, other than the sale by the Company of stock in transactions the primary purpose of which is to raise capital for the Company's operations and activities; or

(iii) A sale, lease, exclusive license or other disposition of all or substantially all of the assets of the Company.

Notwithstanding the foregoing definition, the term Change of Control will not include (x) a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company or Parent, or (y) a liquidation or dissolution ancillary to or in connection with an assignment for the benefit of creditors, a bankruptcy proceeding, appointment of receiver or similar proceeding or transaction.

5.4 ***"Release Date"*** shall mean the date that is fifty-five (55) days following the date of the Executive's termination.

5.5 **Effect of Termination**. The Executive agrees that should his employment be terminated for any reason, he shall be deemed to have resigned from any and all positions with the Company and the Parent, including, but not limited to, any position he may hold on the Board or the Parent Board.

5.6 Section 409A Compliance.

(a) It is intended that any benefits under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Internal Revenue Code of 1986, as amended ("***Section 409A***"), provided under Treasury Regulations Sections 1.409A-1(b)(4), and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulations Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement (whether severance payments, if any, or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. A termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits upon or following a termination of employment unless such termination is also a "***separation from service***" within the meaning of Section 409A and, for purposes of any such provision of this Agreement, references to a "***resignation,***" "***termination,***" "***termination of employment***" or like terms shall mean separation from service. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by the Company at the time of a separation from service to be a "***specified employee***" for purposes of Section 409A(a)(2)(B)(i), and if any payments or benefits that the Executive becomes entitled to under this Agreement on account of such separation from service are deemed to be "***deferred compensation***," then to the extent delayed commencement of any portion of such payments or benefits is required in order to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided prior to the earliest of (i) the expiration of the six-month period measured from the date of separation from service, (ii) the date of Executive's death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such period, all payments deferred pursuant to this paragraph shall be paid in a lump sum, and any remaining payments due shall be paid as otherwise provided herein. No interest shall be due on any amounts so deferred.

(b) With regard to any provision herein that provides for reimbursement of costs and expenses or in-kind benefits, except as permitted by Section 409A, (i) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit, (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year, and (iii) such payments shall be made on or before the last day of the Executive's taxable year following the taxable year in which the expense was incurred. The Company makes no representation or warranty and shall have no liability to the Executive or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Code Section 409A but do not satisfy an exemption from, or the conditions of, Code Section 409A.

5.7 Section 280G.

(a) If any payment or benefit (including payments and benefits pursuant to this Agreement) that the Executive would receive in connection with a Change of Control or other transaction (the "***Transaction***") from the Company or otherwise ("***Transaction Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the "***Code***"), and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then the Company shall cause to be determined, before any amounts of the Transaction Payment are paid to the Executive, which of the following two alternative forms of payment would result in the Executive's receipt, on an after-tax basis, of the greater amount of the Transaction Payment notwithstanding that all or some portion of the Transaction Payment may be subject to the Excise Tax: (1) payment in full of the entire amount of the Transaction Payment (a "***Full Payment***"), or (2) payment of only a part of the Transaction Payment so that the Executive receives the largest payment possible without the imposition of the Excise Tax (a "***Reduced Payment***"). For purposes of determining whether to make a Full Payment or a Reduced Payment, the Company shall cause to be taken into account the value of all applicable federal, state and local income and employment taxes and the Excise Tax (all computed at the highest applicable marginal rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction of such state and local taxes). If a Reduced Payment is made, (x) the Executive shall have no rights to any additional payments and/or benefits constituting the Transaction Payment, and (y) reduction in payments and/or benefits shall occur in the manner that results in the greatest economic benefit to the Executive as determined in this paragraph. If more than one method of reduction will result in the same economic benefit, the portions of the Transaction Payment shall be reduced pro rata.

(b) Notwithstanding the foregoing, in the event that no stock of the Company is readily tradeable on an established securities market or otherwise (within the meaning of Section 280G of the Code) at the time of the Change of Control of the Company, the Company shall cause a vote of shareholders to be held to approve the portion of the Transaction Payments that equals or exceeds three times (3x) the Executive's "***base amount***" (within the meaning of Section 280G of the Code) (the "***Excess Parachute Payments***") in accordance with Treas. Reg. §1.280G-1, and the Executive shall cooperate with such vote of shareholders, including the execution of any required documentation subjecting the Executive's entitlement to all Excess Parachute Payments to such shareholder vote. In the event that the Company does not cause a vote of shareholder to be held to approve all Excess Parachute Payments, the provisions set forth in Section 5.7(a) of this Agreement shall apply.

(c) Unless the Executive and the Company otherwise agree in writing, any determination required under this section shall be made in writing by the Company's independent public accountants (the "***Accountants***"), whose determination shall be conclusive and binding upon the Executive and the Company for all purposes. For purposes of making the calculations required by this section, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Accountants shall provide detailed supporting calculations to the Company and the Executive as requested by the Company or the Executive. The Executive and the Company shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this section. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this section.

6. ARBITRATION.

Except as otherwise set forth below in connection with equitable remedies, any dispute, claim or controversy arising out of or relating to this Agreement or the Executive's employment with the Company (collectively, "***Disputes***"), including, without limitation, any dispute, claim or controversy concerning the validity, enforceability, breach or termination of this Agreement, if not resolved by the parties, shall be finally settled by arbitration in accordance with the then-prevailing Employment Arbitration Rules and Procedures of JAMS, as modified herein ("***Rules***"). The requirement to arbitrate covers all Disputes (other than disputes which by statute are not arbitrable) including, but not limited to, claims, demands or actions under the Age Discrimination in Employment Act (including Older Workers Benefit Protection Act); Americans with Disabilities Act; Civil Rights Act of 1866; Civil Rights Act of 1991; Employee Retirement Income Security Act of 1974; Equal Pay Act; Family and Medical Leave Act of 1993; Title VII of the Civil Rights Act of 1964; Fair Labor Standards Act; Fair Employment and Housing Act; any other provision of the California Labor, Government or Civil Code; IWC Wage Orders; and any other law, ordinance or regulation regarding discrimination or harassment or any terms or conditions of employment. There shall be one arbitrator who shall be jointly selected by the parties. If the parties have not jointly agreed upon an arbitrator within twenty (20) calendar days of respondent's receipt of claimant's notice of intention to arbitrate, either party may request JAMS to furnish the parties with a list of names from which the parties shall jointly select an arbitrator. If the parties have not agreed upon an arbitrator within ten (10) calendar days of the transmittal date of such list, then each party shall have an additional five (5) calendar days in which to strike any names objected to, number the remaining names in order of preference, and return the list to JAMS, which shall then select an arbitrator in accordance with the Rules. The place of arbitration shall be San Francisco, California. By agreeing to arbitration, the parties hereto do not intend to deprive any court of its jurisdiction to issue a pre-arbitral injunction, including, without limitation, with respect to the NDA. The arbitration shall be governed by the Federal Arbitration Act, 9 U.S.C. §§ 1-16. Judgment upon the award of the arbitrator may be entered in any court of competent jurisdiction. Discovery shall be permitted in the arbitration as provided by Section 1283.05 of the California Code of Civil Procedure. The Company shall pay all administrative fees of JAMS in excess of $435 (a typical filing fee in court) and the arbitrator's fees and expenses. Each party shall bear its or his own costs and expenses (including attorney's fees) in any such arbitration and the arbitrator shall have no power to award costs and attorney's fees except as provided by statute or by separate written agreement between the parties. In the event any portion of this arbitration provision is found unenforceable by a court of competent jurisdiction, such portion shall become null and void leaving the remainder of this arbitration provision in full force and effect. The parties agree that all information regarding the arbitration, including any settlement thereof, shall not be disclosed by the parties hereto, except as otherwise required by applicable law.

7. GENERAL PROVISIONS.

7.1 Representations and Warranties. The Executive represents and warrants that the Executive is not restricted or prohibited, contractually or otherwise, from entering into and performing each of the terms and covenants contained in this Agreement, and that the Executive's execution and performance of this Agreement will not violate or breach any other agreements between the Executive and any other person or entity. In addition, the Executive represents and warrants that the Executive is not debarred and has not received notice of any action or threat with respect to debarment under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335(a) or any similar legislation applicable in the United States or in any other country where the Company intends to develop its activities. The Executive understands and agrees that this Agreement is contingent on the Executive's submission of satisfactory proof of identity and legal authorization to work in the United States, as well as verification of auditor independence.

7.2 Advertising Waiver. The Executive agrees to permit the Company, and persons or other organizations authorized by the Company, to use, publish and distribute advertising or sales promotional literature concerning the products and/or services of the Company in which the Executive's name and/or pictures of the Executive appear. The Executive hereby waives and releases any claim or right the Executive may otherwise have arising out of such use, publication or distribution.

7.3 Miscellaneous. This Agreement, along with the NDA and any applicable equity awards that have been granted, constitutes the complete, final and exclusive embodiment of the entire agreement between the Executive and the Company with regard to its subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. This Agreement may not be modified or amended except in a writing signed by both the Executive and a duly authorized officer or member of the Board. This Agreement will bind the heirs, personal representatives, successors and assigns of both the Executive and the Company, and inure to the benefit of both the Executive and the Company, and to his and its heirs, successors and assigns. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Agreement and the provision in question will be modified so as to be rendered enforceable. This Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the State of California as applied to contracts made and to be performed entirely within California. Any ambiguity in this Agreement shall not be construed against either party as the drafter. Any waiver of a breach of this Agreement shall be in writing and shall not be deemed to be a waiver of any successive breach. This Agreement may be executed in counterparts and facsimile signatures will suffice as original signatures.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first written above.

MYOVANT SCIENCES, INC.

By: /s/ Lynn Seely
Lynn Seely, M.D.
President and Chief Executive Officer

Accepted and Agreed:
/s/ Juan Camilo Arjona Ferreira
Juan Camilo Arjona Ferreira, M.D.

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: November 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: November 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 September 30, 2017 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: November 13, 2017	By:	/s/ Lynn Seely
		Lynn Seely
		Principal Executive Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the SEC or its staff upon request.

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 September 30, 2017 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: November 13, 2017

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

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the SEC or its staff upon request.