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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2018

or

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

For the transition period from to

Commission file number 001-37929

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

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

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 ☐

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

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

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

The number of shares outstanding of the Registrant's common shares, $0.000017727 par value per share, on August 3, 2018 , was 68,225,552 .

MYOVANT SCIENCES LTD.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2018

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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*)

	June 30, 2018	March 31, 2018
Assets		
Current assets:		
Cash	$ 143,635	$ 108,624
Prepaid expenses and other current assets	5,702	5,139
Income tax receivable	855	1,000
Total current assets	150,192	114,763
Furniture and equipment, net	1,379	1,273
Other assets	2,777	3,065
Total assets	$ 154,348	$ 119,101
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 5,039	$ 4,578
Interest payable	372	282
Accrued expenses	38,305	30,265
Due to RSL, RSI and RSG	5,207	1,960
Total current liabilities	48,923	37,085
Deferred rent	732	408
Deferred interest payable	407	255
Long-term debt	44,131	43,624
Total liabilities	94,193	81,372
Commitments and contingencies (Note 9)		
Shareholders' equity:		
Common shares, par value $0.000017727 per share, 564,111,242 shares authorized, 64,891,218 and 60,997,856 issued and outstanding common shares at June 30, 2018 and March 31, 2018, respectively	1	1
Additional paid-in capital	350,313	266,178
Accumulated other comprehensive income	449	24
Accumulated deficit	(290,608)	(228,474)
Total shareholders' equity	60,155	37,729
Total liabilities and shareholders' equity	$ 154,348	$ 119,101

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 June 30,	
	2018	**2017**
Operating expenses:		
Research and development [1]	$ 51,341	$ 17,708
General and administrative [2]	8,742	4,182
Total operating expenses	60,083	21,890
Interest expense	1,617	—
Other expense	289	342
Loss before income taxes	(61,989)	(22,232)
Income tax expense	145	1,085
Net loss	$ (62,134)	$ (23,317)
Net loss per common share — basic and diluted	$ (0.98)	$ (0.39)
Weighted average common shares outstanding — basic and diluted	63,310,177	59,247,273

[1] Includes $2,188 and $538 of costs allocated from RSL, RSI, and RSG during the three months ended June 30, 2018 and 2017 , respectively. Also includes share-based compensation expense (see Note 8(D)).

[2] Includes $1,225 and $815 of costs allocated from RSL, RSI, and RSG during the three months ended June 30, 2018 and 2017 , respectively. Also includes share-based compensation expense (see Note 8(D)).

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 June 30,	
	2018	**2017**
Net loss	$ (62,134)	$ (23,317)
Other comprehensive income:		
Foreign currency translation adjustment	425	264
Total other comprehensive income	425	264
Comprehensive loss	$ (61,709)	$ (23,053)

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		Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
Balance at March 31, 2018	60,997,856	$ 1	$ 266,178	$ 24	$ (228,474)	$ 37,729
Issuance of common shares in connection with "at-the-market" equity offering, net of commissions and offering costs of $2.1 million	2,767,129	—	57,315	—	—	57,315
Issuance of common shares in connection with Private Placement with RSL	1,110,015	—	22,500	—	—	22,500
Share-based compensation expense	—	—	4,053	—	—	4,053
Capital contribution — share-based compensation	—	—	191	—	—	191
Foreign currency translation adjustment	—	—	—	425	—	425
Issuance of common shares upon exercise of stock options	16,218	—	76	—	—	76
Net loss	—	—	—	—	(62,134)	(62,134)
Balance at June 30, 2018	64,891,218	$ 1	$ 350,313	$ 449	$ (290,608)	$ 60,155

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)

	Three Months Ended June 30,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (62,134)	$ (23,317)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	4,244	2,201
Depreciation	91	50
Amortization of debt discount and issuance costs	507	—
Foreign currency translation adjustment	425	264
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(563)	(1,961)
Deferred tax assets	—	208
Income tax receivable	145	—
Other assets	288	(3,074)
Accounts payable	389	(143)
Income tax payable	—	826
Interest payable	90	—
Accrued expenses	8,040	(686)
Due to RSL, RSI and RSG	3,247	(1,030)
Deferred rent	324	105
Deferred interest payable	152	—
Net cash used in operating activities	(44,755)	(26,557)
Cash flows from investing activities:		
Purchase of furniture and equipment	(197)	(90)
Net cash used in investing activities	(197)	(90)
Cash flows from financing activities:		
Cash proceeds from issuance of common shares in connection with “at-the-market” equity offering, net of issuance costs paid	57,387	—
Cash proceeds from issuance of common shares in connection with Private Placement with RSL	22,500	—
Cash proceeds from stock option exercises	76	—
Net cash provided by financing activities	79,963	—
Net change in cash	35,011	(26,647)
Cash—beginning of period	108,624	180,838
Cash—end of period	$ 143,635	$ 154,191
Non-cash financing activities:		
Deferred financing costs, unpaid	$ 72	$ —

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 the hormonal preparation used in assisted reproduction. Both relugolix and MVT-602 were licensed to the Company by Takeda Pharmaceuticals International AG, or Takeda, on April 29, 2016.

Since its inception, the Company has devoted substantially all of its efforts to organizing and staffing the Company, raising capital, identifying and in-licensing its product candidates, including acquiring worldwide rights (excluding Japan and certain other Asian countries) to relugolix and worldwide rights to MVT-602, preparing for and advancing the clinical development of its product candidates, and preparing for the potential commercialization of relugolix.

The Company has incurred and expects to continue to incur significant and increasing operating losses and negative cash flows for at least the next several years. To date, the Company has not generated any revenue, and it 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 currently believes its existing cash, together with the remaining financing commitments of $ 92.0 million available to it from NovaQuest Capital Management, or NovaQuest, will be sufficient to fund its operating expenses and capital expenditure requirements through the first quarter of its fiscal year ending March 31, 2020, and to enable it to receive top-line data from the Phase 3 clinical trials for at least one of its women's health clinical programs. This estimate is based on the Company's current assumptions, including assumptions relating to its ability to manage its spend, that might prove to be wrong, and it could use its available capital resources sooner than it currently expects. These funds will not be sufficient to enable the Company to complete all necessary development activities and commercially launch relugolix. Accordingly, the Company will 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 first three fiscal quarters end on June 30, September 30 and December 31. The Company has determined that it has one operating and reporting segment as it allocates resources and assesses financial performance on a consolidated basis.

The accompanying 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 unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2018, filed with the United States Securities and Exchange Commission, or SEC, on June 7, 2018. The unaudited consolidated balance sheet at March 31, 2018 has been derived from the audited consolidated financial statements at that date. 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 months ended June 30, 2018 are not necessarily indicative of the results that may be expected for the fiscal year ending March 31, 2019 , for any other interim period or for any other future year.

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, issued by 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, 2018, filed with the SEC on June 7, 2018.

(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 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 and other expenses 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 controlling shareholder, Roivant Sciences Ltd., or RSL, as well as share-based compensation expenses, research and development, or R&D, expenses, 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 incurred 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. The computation of diluted net loss per common share is based on the weighted-average number of common shares outstanding during the period plus, when their effect is dilutive, incremental shares consisting of shares subject to stock options, restricted share units, restricted share awards, and warrants. In periods in which the Company reports a net loss, all common share equivalents are deemed anti-dilutive such that basic net loss per common share and diluted net loss per common share are equal.

The following potentially dilutive securities have been excluded from the diluted net loss per common share calculations for the three months ended June 30, 2018 and 2017 :

	Three Months Ended June 30,	
	2018	2017
Options	4,779,727	2,406,127
Restricted share awards	1,128,221	1,410,277
Restricted stock units	15,000	—
Warrants	73,710	—
Total	5,996,658	3,816,404

(D) Fair Value Measurements:

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

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

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

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

The Company's financial instruments include cash, accounts payable and long-term debt. Cash and accounts payable are stated at their respective historical carrying amounts, which approximate fair value due to their short-term nature. The carrying value of the Company's long-term debt approximates fair value based on current interest rates for similar types of borrowings and is included in Level 2 of the fair value hierarchy.

(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 February 2018, the FASB issued ASU No. 2018-02, " *Income Statement-Reporting Comprehensive Income* (Topic 220): *Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income* ," or ASU No. 2018-02. ASU No. 2018-02 allows companies to reclassify stranded tax effects resulting from the newly enacted federal corporate income tax rate under the Tax Cuts and Jobs Act, from accumulated other comprehensive (loss) income to retained earnings. ASU No. 2018-02 is effective for fiscal years, and interim periods within those 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 2018, the FASB issued ASU No. 2018-05, " *Income Taxes* (Topic 740): *Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118* ," or ASU No. 2018-05. ASU No. 2018-05 amends certain SEC material in Topic 740 for the income tax accounting implications of the recently issued Tax Cuts and Jobs Act. ASU No. 2018-05 is effective immediately. The Company evaluated the impact of the Act as well as the guidance of Staff Accounting Bulletin No. 118 and incorporated the changes into the determination of a reasonable estimate of its deferred taxes. The Company considers its accounting for the impact of the new law to be provisional and will continue to evaluate the impact this recent tax reform legislation may have on its results of operations, financial position, cash flows and related disclosures.

In June 2018, the FASB issued ASU No. 2018-07, *"Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting,"* or ASU No. 2018-07. ASU No. 2018-07 simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. ASU No. 2018-07 is effective for interim and annual reporting periods beginning after December 15, 2018 and 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.

Note 3—Accrued Expenses

As of June 30, 2018 , and March 31, 2018 , accrued expenses consisted of the following (in thousands):

	June 30, 2018	March 31, 2018
Accrued R&D expenses	$ 35,446	$ 25,988
Accrued compensation-related expenses	1,229	2,792
Accrued professional fees	551	566
Accrued other expenses	1,079	919
Total accrued expenses	$ 38,305	$ 30,265

Note 4—Long-term Debt

(A) NovaQuest Long-term Debt

In October 2017, the Company, its following subsidiaries, Myovant Sciences, Inc., or MSI, Myovant Holdings Limited, or MHL, a private limited company incorporated under the laws of England and Wales, Myovant Sciences GmbH, or MSG, a company with limited liability formed under the laws of Switzerland, and Myovant Sciences Ireland Limited, or MSIL, a company with limited liability formed under the laws of Ireland, as guarantors, 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 the option, at its discretion, to issue up to $60.0 million aggregate principal amount of notes to NovaQuest and concurrent with each purchase of notes, NovaQuest is obligated to purchase up to $20.0 million of the Company's common shares on a pro rata basis, subject to certain terms and conditions, through December 31, 2018 . The equity purchase price for each such purchase 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. The Company has committed that it will issue at least $30.0 million aggregate principal amount of notes through December 31, 2018 , subject to certain terms and conditions, of which $6.0 million aggregate principal amount was issued in October 2017. With this issuance of $6.0 million aggregate principal amount of notes in October 2017, NovaQuest also purchased 138,361 common shares for $2.0 million in accordance with the terms of the NovaQuest Securities Purchase Agreement.

The notes bear interest at a rate of 15% per annum, of which 5% is payable quarterly, and 10% is payable on a deferred basis on the earlier of the Amortization Date (as defined below) and the repayment in full of the notes. 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 , or the Amortization Date, 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 redemption charge. The Company's obligations under the NovaQuest Securities Purchase Agreement are secured by a second-lien security interest in substantially all of the Company's and its subsidiaries' respective assets, other than intellectual property. The NovaQuest Securities Purchase Agreement includes customary affirmative and restrictive covenants and representations and warranties, including a minimum cash covenant that applies commencing on the Amortization Date, and also includes customary events of default. Upon the occurrence of an event of default, a default interest rate of an additional 5% may be applied to the outstanding note balance and NovaQuest may declare all outstanding obligations immediately due and payable and take such other actions 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 Company's discretion through December 31, 2018 , with an option to extend the commitment through December 31, 2019 , subject to certain terms and conditions as set forth in the NovaQuest Equity Purchase Agreement. The Company has committed that it will exercise its option to sell and issue a minimum of $10.0 million of its common shares under the NovaQuest Equity Purchase Agreement through December 31, 2018 , subject to certain terms and conditions. The purchase price for the common shares issued pursuant to 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.

The Company incurred financing costs related to the NovaQuest Securities Purchase Agreement of $1.0 million which are recorded as an offset to long-term debt on the Company's unaudited condensed consolidated balance sheets. These deferred financing costs are being amortized over the term of the debt using the effective interest method, and are included in interest expense in the Company's unaudited condensed consolidated statements of operations. During the three months ended June 30, 2018 , interest expense included $0.1 million of amortized deferred financing costs related to the NovaQuest notes.

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

	June 30, 2018	March 31, 2018
Principal amount	$ 6,000	$ 6,000
Less: unamortized debt issuance costs	(750)	(854)
Loan payables less unamortized debt issuance costs	5,250	5,146
Less: current maturities	—	—
Long-term loan payable, net of current maturities and unamortized debt issuance costs	$ 5,250	$ 5,146

(B) Hercules Long-term Debt

In October 2017, the Company, its following subsidiaries, MSI, MHL, MSG and MSIL as guarantors, 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 in October 2017 and the remaining $15.0 million principal amount was funded in March 2018. The Term Loans bear interest at a variable per annum rate at the greater of (i) the prime rate plus 4.00% and (ii) 8.25% . The interest rate on the Term Loans was 9.00% at June 30, 2018 . Pursuant to the terms of the Hercules Loan Agreement, the Term Loan Maturity Date has been extended from May 1, 2021 to November 1, 2021 as a result of the achievement of a financing milestone during the second quarter of fiscal year 2018. The Company is obligated to make monthly payments of accrued interest until June 1, 2019 , or the Interest-only Period, subject to certain terms and conditions, followed by monthly installments of principal and interest through the maturity date. The Interest-only Period has been extended to December 1, 2019 as a result of the achievement of a financing milestone during the second quarter of fiscal year 2018. The Interest-only Period may be further extended until June 1, 2020 if a certain clinical milestone is met, as specified in the Hercules Loan Agreement. Prepayment of the Term Loan is subject to a prepayment charge. The Company is also obligated to pay an end of term charge of 6.55% of the principal amount of the Term Loans funded under the Hercules Loan Agreement, on the earlier of the maturity date or the date that the Term Loans otherwise become due and payable. The Company's obligations under the Hercules Loan Agreement are secured by a first lien security interest in substantially all of the Company's and its subsidiaries' respective assets, other than intellectual property. The Hercules Loan Agreement includes customary affirmative and restrictive covenants and representations and warranties, including a minimum cash covenant that ceases to apply if the Company achieves certain clinical development and financing milestones as set forth in the Hercules Loan Agreement. The Hercules Loan Agreement also includes customary events of default. Upon the occurrence of an event of default, a default interest rate of an additional 5.00% 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.

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 its common shares equal to 3.00% of the principal amount of the relevant Term Loan funded divided by the exercise price, which is based on the lowest three-day volume-weighted average price for the three consecutive trading days prior to the funding date for such Term Loan. The Warrants may be exercised on a cashless basis, and are immediately exercisable through the seventh anniversary of the applicable funding date. In connection with the first tranche funded under the Hercules Loan Agreement, the Company issued a Warrant to Hercules exercisable for an aggregate of 49,800 of its common shares at an exercise price of $15.06 per common share. Concurrent with the funding of the second tranche, the Company issued a Warrant to Hercules exercisable for an aggregate of 23,910 of its common shares at an exercise price of $18.82 per common share. The Company accounted for the Warrants as equity instruments since they were indexed to the Company's common shares and met the criteria for classification in shareholders' equity (deficit). The relative fair value of the Warrants related to the first and second tranche funding were approximately $0.5 million and $0.3 million , respectively, and were treated as a discount to the Term Loans. This amount is being amortized to interest expense using the effective interest method over the life of the Term Loans. The Company estimated the fair value of the Warrants using the Black-Scholes model based on the following key assumptions:

	Tranche 1	Tranche 2
Exercise price	$15.06	$18.82
Common share price on date of issuance	$14.39	$18.96
Volatility	73.2%	72.3%
Risk-free interest rate	2.15%	2.78%
Expected dividend yield	—%	—%
Contractual term (in years)	7.00 years	7.00 years

The Company issued the first tranche of the Term Loans at a discount of $2.1 million , including the relative fair value of the related Warrant, and incurred financing costs of $1.3 million relating to the Hercules Loan Agreement which are recorded as an offset to long-term debt on the Company's unaudited condensed consolidated balance sheets. The second tranche of the Term Loans was issued at a discount of $1.3 million , including the relative fair value of the related Warrant. The debt discount and deferred financing costs are being amortized over the term of the debt using the effective interest method, and are included in interest expense in the Company's unaudited condensed consolidated statements of operations. During the three months ended June 30, 2018 , interest expense included $0.4 million of amortized debt discount and issuance costs related to the Term Loans.

Outstanding debt obligations are as follows (in thousands):

	June 30, 2018	March 31, 2018
Principal amount	$ 40,000	$ 40,000
End of term charge	2,620	2,620
Less: unamortized debt discount and issuance costs	(3,739)	(4,142)
Loan payables less unamortized debt discount and issuance costs	38,881	38,478
Less: current maturities	—	—
Long-term loan payable, net of current maturities and unamortized debt discount and issuance costs	$ 38,881	$ 38,478

Note 5—Related Party Transactions

(A) Services Agreements:

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 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. Employee compensation expense, inclusive of base salary and fringe benefits, is determined based upon the relative percentage of time utilized on Company matters by the respective employee, which the Company believes is reasonable. All other third-party pass thru costs are billed to the Company at cost. The accompanying unaudited condensed consolidated financial statements include third-party expenses incurred on behalf of the Company that have been paid by RSI and RSL.

In February 2017, the Company and MSI amended and restated the services agreement, effective as of November 11, 2016, to include Myovant Sciences GmbH, or 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 finance and accounting 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 June 30, 2018 and 2017 , the Company incurred expenses (inclusive of third party pass thru costs billed to the Company) of $3.2 million and $1.1 million , respectively, inclusive of the mark-up. These amounts are included in R&D expenses and G&A expenses based upon the nature of the service performed under the Services Agreements.

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

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

In relation to the RSL common share awards and options issued by RSL to RSL, RSI and RSG employees, the Company recorded share-based compensation expense of $0.2 million and $0.2 million , respectively, for the three months ended June 30, 2018 and 2017 . Refer to Note 8 for further details.

Note 6—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 taxes. The Company's effective tax rate for the three months ended June 30, 2018 and 2017 was (0.23)% and (4.88)% , respectively, and is driven by the Company's jurisdictional earnings by location and a valuation allowance that eliminates the Company's global net deferred tax assets.

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

On December 22, 2017, the Tax Cuts and Jobs Act, or the Act, was enacted, which introduced a comprehensive set of tax reform in the United States. The Act revises the U.S. corporate income tax by, among other things, lowering the corporate income tax rate from 35% to 21%, adopting a quasi-territorial income tax system and imposing a one-time transition tax on foreign unremitted earnings, and setting limitations on deductibility of certain costs (e.g., interest expense).

The effects of changes in tax laws are required to be recognized in the period in which the legislation is enacted in accordance with ASC 740, Accounting for Income Taxes. However, due to the complexity and significance of the Act's provisions, the SEC staff issued Staff Accounting Bulletin No. 118, which allows companies to record the tax effects of the Act on a provisional basis based on a reasonable estimate, and then, if necessary, subsequently adjust such amounts during a limited measurement period as more information becomes available. The measurement period ends when a company has obtained, prepared, and analyzed the information necessary to finalize its accounting, but cannot extend beyond one year from enactment.

The Act did not have a material impact on the Company's consolidated financial statements since its global net deferred tax assets are fully offset by a valuation allowance and the Company does not have any off-shore earnings from which to record the mandatory transition tax. However, given the significant complexity of the Act, anticipated guidance from the U.S. Treasury about implementing the Act, and the potential for additional guidance from the SEC or the FASB related to the Act, these estimates may be adjusted during the measurement period. The provisional amounts were based on the Company's present interpretations of the Act and currently available information, including assumptions and expectations about future events, such as its projected financial performance, and are subject to further refinement as additional information becomes available (such as potential new or interpretative guidance issued by the FASB or the Internal Revenue Service and other tax agencies) and further analyses are completed. The Company continues to analyze the changes in certain income tax deductions and gather additional data to compute the full impact on the Company's current and deferred tax assets and liabilities (deferred tax assets and liabilities will be subject to a valuation allowance if adjusted).

Note 7—Shareholders' Equity

(A) Private Placement with RSL

On April 2, 2018 , the Company entered into a share purchase agreement, or the Purchase Agreement, with RSL, its controlling shareholder, pursuant to which the Company agreed to issue and sell to RSL 1,110,015 of its common shares at a purchase price of $20.27 per common share in a private placement, or the Private Placement. In April 2018, the Company received proceeds of $22.5 million from RSL at the closing of the Private Placement.

(B) At-the-Market Equity Offering Program

On April 2, 2018 , the Company entered into a sales agreement, or the Sales Agreement, with Cowen and Company, LLC, or Cowen, to sell its common shares having an aggregate offering price of up to $100.0 million from time to time through an "at-the-market" equity offering program under which Cowen acts as the Company's agent. During the three months ended June 30, 2018 , the Company issued and sold 2,767,129 of its common shares under the Sales Agreement. The common shares were sold at a weighted-average price of $21.47 per common share for aggregate net proceeds to the Company of approximately $57.3 million , after deducting commissions and offering costs payable by the Company. The Company currently has approximately $40.6 million of remaining capacity available under its "at-the-market" equity offering program.

Note 8—Share-Based Compensation

(A) Myovant 2016 Equity Incentive Plan

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 issuance. Pursuant to the "evergreen" provision contained in the 2016 Plan, the number of common shares reserved for issuance under the 2016 Plan automatically increases on April 1 of each year, commencing on (and including) April 1, 2017 and ending on (and including) April 1, 2026, in an amount equal to 4% of the total number of shares of capital stock outstanding on March 31 of the preceding fiscal year, or a lesser number of shares as determined by the Company's board of directors. On April 1, 2018, the number of common shares authorized for issuance increased automatically by 2.4 million shares in accordance with the evergreen provision of the 2016 Plan. At June 30, 2018 , a total of 2.8 million common shares were available for future issuance under the 2016 Plan.

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

(B) Stock Options

A summary of option activity under the Company's 2016 Plan for the three months ended June 30, 2018 is as follows:

	Number of Options
Options outstanding at March 31, 2018	3,549,405
Granted	1,258,340
Exercised	(16,218)
Forfeited	(11,800)
Options outstanding at June 30, 2018	4,779,727
Options vested and expected to vest at June 30, 2018	4,779,727
Options exercisable at June 30, 2018	798,921

(C) Restricted Share Awards and Restricted Stock Units

A summary of restricted share award and restricted stock unit activity under the Company's 2016 Plan for the three months ended June 30, 2018 is as follows:

	Number of Shares
Unvested balance at March 31, 2018	1,213,735
Vested	(70,514)
Unvested balance at June 30, 2018	1,143,221

(D) Share-Based Compensation Expense

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

	Three Months Ended June 30,	
	2018	2017
Share-based compensation expense recognized as:		
R&D expenses	$ 1,561	$ 860
G&A expenses	2,683	1,341
Total	$ 4,244	$ 2,201

Share-based compensation expense is included in R&D and G&A expenses in the accompanying unaudited condensed consolidated statements of operations consistent with the grantee's salary. Share-based compensation expense presented in the table above includes share-based compensation expense allocated to the Company by RSL as described below in Note 8(E).

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

Total unrecognized share-based compensation expense was approximately $47.9 million at June 30, 2018 and is expected to be recognized over a weighted-average period of approximately 3.26 years .

(E) Share-Based Compensation Expense for Related Parties:

(1) Stock Options Granted to RSI Employees:

During the three months ended June 30, 2018 and 2017 , the Company recorded share-based compensation expense related to stock options granted to RSI employees of $14,885 and $0.1 million , respectively. At June 30, 2018 , total unrecognized compensation expense related to stock options granted to RSI employees was $0.1 million , which is expected to be recognized over 2.14 years. This share-based compensation expense is included in R&D and G&A expenses in the accompanying unaudited condensed consolidated statements of operations. During the three months ended June 30, 2018 and 2017 , no options were granted to RSI employees under the 2016 Plan.

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

In relation to the RSL common share awards and RSL options issued by RSL to RSL, RSI and RSG employees, the Company recorded share-based compensation expense of $0.2 million and $0.2 million , respectively, for the three months ended June 30, 2018 and 2017 .

The RSL common share awards and RSL options granted by RSL to RSL, RSI and RSG employees are valued by RSL at fair value on the date of grant and that fair value is recognized as share-based compensation expense over the requisite service period. As RSL is a non-public entity, the RSL common share awards and RSL options are classified as Level 3 by RSL due to their unobservable nature. Significant judgment and estimates were used by RSL to estimate the fair value of these awards and options, as they are not publicly traded. RSL common share awards and RSL options are subject to specified vesting schedules and requirements (a mix of time-based and performance-based events). The fair value is based on various corporate event-based considerations, including targets for RSL's post-IPO market capitalization and future financing events). The fair value of each RSL option is estimated 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 and based upon the relative percentage of time utilized by RSL, RSI and RSG employees on Company matters.

(3) RSL RSUs:

The Company's Principal Executive Officer was granted 66,845 RSL RSUs during the year ended March 31, 2017. These RSUs will vest to the extent certain RSL performance criteria are achieved and certain RSL liquidity conditions are satisfied within specified years of the grant date, provided that the Company's Principal Executive Officer has provided continued service to RSL or its subsidiaries through such date. As of June 30, 2018 , the performance conditions had not been met and were deemed not probable of being met. For the three months ended June 30, 2018 and 2017 , the Company recorded no share-based compensation expense related to these RSL RSUs. At June 30, 2018 , there was $0.9 million of unrecognized compensation expense related to unvested RSL RSUs. The Company will recognize this share-based compensation expense upon achievement of the performance and market conditions through the requisite service period.

Note 9—Commitments and Contingencies

The Company has entered into commitments under its license agreement with Takeda, services agreements with RSI and RSG (See Note 5(A)), and financing agreements with NovaQuest and Hercules (See Note 4). In addition, the Company has entered into services agreements with third parties for pharmaceutical R&D and manufacturing activities and has a lease agreement for office space located in Brisbane, California. 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 its 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.

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

In addition, under the Takeda Commercial Supply Agreement, Takeda has agreed to assist with the transfer of technology and Takeda manufacturing know-how to a second contract manufacturing organization of the Company's subsidiary, Myovant Sciences GmbH. The Company has agreed to reimburse Takeda for all internal costs, and external costs, charges, and expenses, in each case, reasonably incurred by Takeda in connection with any technology transfer services.

The initial term of the Takeda Commercial Supply Agreement began on May 30, 2018 and will continue for five years. At the end of the initial term, the Takeda Commercial Supply Agreement automatically renews for successive one -year terms, unless either party gives notice of termination to the other at least 12 months prior to the end of the then-current term. The Takeda Commercial Supply Agreement may be terminated by either party upon 90 days' notice of an uncured material breach of its terms by the other party, or immediately upon notice to the other party of a party's bankruptcy. Each party will also have the right to terminate the Takeda Commercial Supply Agreement, in whole or in part, for any reason upon 180 days' prior written notice to the other party, provided that any then-open purchase orders, including the initial firm order for relugolix drug substance through December 31, 2019, will remain in effect and be binding on both parties. The Takeda Commercial Supply Agreement, including any then-open purchase order thereunder, will terminate immediately upon the termination of the Takeda Agreement in accordance with its terms.

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

Note 10—Subsequent Event

In July 2018, the Company completed an underwritten public offering of 3,333,334 of its common shares at a public offering price of $22.50 per common share. After deducting the underwriting discounts and commissions and estimated offering costs payable by the Company, the net proceeds to the Company were approximately $70.2 million .

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

The following discussion and analysis of our financial condition, results of operations and cash flows should be read in conjunction with (1) the unaudited 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, 2018 included in our Annual Report on Form 10-K, filed with the United States Securities and Exchange Commission, or the SEC, on June 7, 2018. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "Myovant," the "Company," "we," "us," and "our" refer to Myovant Sciences Ltd. and its wholly-owned 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," "can," "continue," "could," "estimate," "expect," "intend," "likely," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "to be," "will," "would," or the negative or plural of these words, or similar expressions or variations, although not all forward-looking statements contain these words. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those expressed or implied by these forward-looking statements.

The forward-looking statements appearing in a number of places throughout 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 anticipated timing of our clinical trials for relugolix and MVT-602;
- 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 relugolix, MVT-602 and any future product candidates;
- our plans to commercialize relugolix, if approved;
- our ability to launch commercial sales of any approved products, whether alone or in collaboration with others;
- the rate and degree of market acceptance and clinical utility of any approved product candidate;
- our ability to initiate and continue relationships with third-party manufacturers;
- our ability to quickly and efficiently identify and develop product candidates;
- our ability to hire and retain our key scientific or management personnel;
- our ability to obtain, maintain and enforce intellectual property rights for our product candidates;
- the anticipated receipt of the remaining funding available to us under the NovaQuest Securities Purchase Agreement and the NovaQuest Equity Purchase Agreement;
- our estimates regarding our results of operations, financial condition, liquidity, capital requirements, access to capital, prospects, growth and strategies;
- industry trends;
- developments and projections relating to our competitors or our industry; and
- the success of competing drugs that are or may become available.

Such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors known and unknown that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, 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. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Business 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 a part of the hormonal preparation used in assisted reproduction. Both relugolix and MVT-602 were licensed to us by Takeda Pharmaceuticals International AG, or Takeda, on April 29, 2016.

Since our inception, we have devoted substantially all of our efforts to organizing and staffing our company, raising capital, identifying and in-licensing our product candidates, including acquiring worldwide rights (excluding Japan and certain other Asian countries) to relugolix and worldwide rights to MVT-602, preparing for and advancing the clinical development of our product candidates and preparing for the potential commercialization of relugolix.

Financial History

We have incurred, and expect to continue to incur, significant and increasing operating losses and negative cash flows for at least the next several years. To date, we have not generated any revenue, and we do not expect to generate revenue unless and until we successfully complete development and obtain regulatory approval for one of our product candidates. We expect our operating losses, negative cash flows, and operating expenses to increase as we continue the clinical development of, and seek regulatory approval for, our product candidates, and grow our company.

We have funded our operations primarily from the issuance and sale of our common shares and from the financing commitments available to us from NovaQuest Capital Management, or NovaQuest, and Hercules Capital, Inc., or Hercules. Prior to our initial public offering, or IPO, our operations were funded primarily by our controlling shareholder, Roivant Sciences Ltd., or RSL. Through June 30, 2018 , our sources of funding have included:

- In November 2016, we completed our IPO in which we sold 14,500,000 common shares at a price of $15.00 per common share. The net proceeds to us were approximately $200.0 million , after deducting $15.2 million in underwriting discounts and commissions and $2.3 million in offering costs payable by us.
- In October 2017, we and our subsidiaries, entered into financing arrangements with NovaQuest and Hercules under which we obtained financing commitments of up to $140.0 million . As of June 30, 2018 , a total of $92.0 million remained available to us under the NovaQuest Securities Purchase Agreement and the NovaQuest Equity Purchase Agreement and the $40.0 million financing commitment under the Hercules Loan Agreement was fully drawn.
- On April 2, 2018 , we entered into a share purchase agreement, or the Purchase Agreement, with RSL pursuant to which we agreed to issue and sell to RSL 1,110,015 of our common shares at a purchase price of $20.27 per common share in a private placement, or the Private Placement. In April 2018, we received proceeds of $22.5 million from RSL at the closing of the Private Placement.

- On April 2, 2018 , we entered into a Sales Agreement, or the Sales Agreement, with Cowen and Company, LLC, or Cowen, to sell our common shares having an aggregate offering price of up to $100.0 million from time to time through an "at-the-market" equity offering program under which Cowen acts as our agent. During the three months ended June 30, 2018 , we issued and sold 2,767,129 of our common shares under the Sales Agreement. The common shares were sold at a weighted-average-price of $21.47 per common share for aggregate net proceeds to us of approximately $57.3 million , after deducting commissions and offering costs payable by us. We currently have approximately $40.6 million of remaining capacity available under our "at-the-market" equity offering program.

As of June 30, 2018 , and March 31, 2018 , we had an accumulated deficit of $290.6 million and $228.5 million , respectively. We recorded net losses of $62.1 million and $23.3 million for the three months ended June 30, 2018 and 2017 , respectively. As of June 30, 2018 , we had $143.6 million of cash and $92.0 million of financing commitments available to us from NovaQuest.

Subsequent Event

In July 2018, we completed an underwritten public offering of 3,333,334 of our common shares at a public offering price of $22.50 per common share. After deducting the underwriting discounts and commissions and estimated offering costs payable by us, the net proceeds to us were approximately $70.2 million .

Our Product Candidates

Relugolix

We are currently developing relugolix in three target indications: heavy menstrual bleeding associated with uterine fibroids; endometriosis-associated pain; and advanced prostate cancer. Relugolix is an oral, once-daily, small molecule that acts as a GnRH receptor antagonist that binds to and inhibits GnRH receptors in the anterior pituitary gland. Inhibition of GnRH receptors decreases the release of gonadotropins (luteinizing hormone and follicle-stimulating hormone), thereby decreasing the downstream production of estrogen and progesterone by the ovaries in women and testosterone by the testes in men.

As a GnRH receptor antagonist, relugolix has a clinically-validated mechanism of action in each of our three target indications. Lowering estrogen levels decreases heavy menstrual bleeding in women with uterine fibroids and reduces the pelvic pain associated with endometriosis. Decreasing testosterone slows the growth and progression of advanced prostate cancer and is the central objective of treatment in men with advanced prostate cancer or when the disease has recurred following prostatectomy or radiation therapy. Myovant Sciences GmbH, our wholly owned subsidiary, holds global commercial rights to relugolix, excluding Japan, China, Hong Kong, Indonesia, Korea, Malaysia, Philippines, Singapore, Taiwan, Thailand and Vietnam, including the territories and possessions of each of the foregoing. In May 2018, Takeda announced that it had entered into a licensing agreement to grant ASKA Pharmaceutical Co., Ltd. exclusive commercialization rights to relugolix for uterine fibroids and exclusive development and commercialization rights to relugolix for endometriosis, in each indication in Japan.

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

We initiated a Phase 3 clinical program in January 2017, evaluating relugolix in women with heavy menstrual bleeding associated with uterine fibroids. The program consists of two international, replicate pivotal clinical trials, which we refer to as 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. On July 10, 2018, we announced the completion of screening of patients for our LIBERTY 1 trial, and that we expect top-line efficacy and safety data from LIBERTY 1 in the second quarter of calendar year 2019. We also announced that we expect to complete the screening of patients for our LIBERTY 2 trial in the current quarter.

Takeda's Phase 3 Clinical Development for Uterine Fibroids

In October 2017, Takeda reported positive top-line results from its Phase 3 trial in Japan evaluating the efficacy and safety of relugolix monotherapy compared with leuprorelin for the treatment of heavy menstrual bleeding associated with uterine fibroids. In this trial, approximately 280 patients were randomized 1:1 to receive either 40 mg of relugolix administered orally once daily or leuprorelin acetate administered by injection once every four weeks. Relugolix achieved an 82.2% response rate, meeting the primary endpoint, which was the proportion of patients achieving a pre-defined reduction in menstrual bleeding (Pictorial Blood Loss Assessment Chart, or PBAC, score of <10), and was observed to be statistically non-inferior to leuprorelin alone ($p = 0.0013$). 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. In this trial, 65 patients were randomized 1:1 to receive either 40 mg relugolix or placebo administered orally once daily. Relugolix met the primary endpoint demonstrating a marked improvement in pain in 57.6% of women with uterine fibroids compared to 3.1% of women receiving placebo ($p < 0.0001$). Adverse events in both studies were consistent with the mechanism of action of relugolix and adverse events observed in previous clinical trials. In February 2018, Takeda announced that it had submitted the data from both of these trials to the Ministry of Health, Labour and Welfare in Japan for marketing authorization of relugolix in Japan for the treatment of uterine fibroids. The Phase 3 data from each of these trials will be available to us, and may be used to support our anticipated New Drug Application, or NDA, submission to the U.S. Food and Drug Administration, or FDA. Although we will be solely responsible for obtaining FDA approval for relugolix in the United States, the FDA can accept the results of clinical trials conducted outside the United States that were not conducted under an investigational new drug application in support of an NDA under certain conditions. At a minimum, the trials must have been conducted in accordance with FDA's good clinical practice requirements, and the FDA may also require that the foreign data be applicable to the U.S. population and U.S. medical practice. We cannot provide assurance that the FDA will allow us to use data from Takeda's clinical trials in support of any NDA that we may submit. If it does not, we may be required to perform additional clinical trials.

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

We initiated a Phase 3 clinical program in June 2017, evaluating relugolix in women with endometriosis-associated pain. The program consists of two international replicate pivotal clinical trials, which we refer to as SPIRIT 1 and SPIRIT 2. 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 commercially available 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. We expect to complete enrollment for and anticipate results from the SPIRIT 1 and SPIRIT 2 trials during calendar year 2019.

Our Phase 3 Program for the Treatment of Advanced Prostate Cancer

We initiated a Phase 3 clinical trial in March of 2017, evaluating relugolix in men with advanced prostate cancer, which we refer to as the HERO trial. We believe that the HERO trial, if successful, will be sufficient to support the submission of an NDA based on an End-of-Phase 2 meeting held with the FDA. The European Scientific Advice procedure and an End-of-Phase 2 meeting with the Japanese health authority have also been completed supporting the design of the HERO trial.

The 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 915 men into this trial, with approximately 610 men enrolled into the active treatment arm and 305 men into the leuprolide arm. During the fourth quarter of calendar year 2017, we decreased the expected enrollment from 1,125 to 915 to reflect a change in strategy in China. The decrease in enrollment does not affect the statistical powering of the primary endpoint analysis, which has always been based on the first 915 patients enrolled in the HERO trial. We are in discussions with Takeda regarding the strategy for registration of relugolix for advanced prostate cancer in China. Based on FDA discussions, we believe that we will be required to conduct only one Phase 3 trial with a single relugolix arm to gain approval for relugolix in men with advanced prostate cancer in the United States. Nonetheless, 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. We expect to complete enrollment for the HERO trial during calendar year 2018 and anticipate results from this trial during calendar year 2019.

MVT-602

As part of our license agreement with Takeda, or the Takeda License Agreement, we acquired the worldwide rights to MVT-602, our second product candidate, which has been evaluated in over 150 men. MVT-602 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. In a completed Phase 1 study in healthy female volunteers, a single injection of MVT-602 was observed to cause a dose-dependent luteinizing hormone surge. We initiated a Phase 2a clinical trial in healthy female volunteers to characterize the dose response curve in the controlled ovarian stimulation setting prior to studying MVT-602 in infertile women seeking pregnancy. MVT-602 is being developed as a potential treatment for female infertility in women as part of assisted reproduction, such as in vitro fertilization, or IVF. We believe MVT-602 has the potential to be a safer alternative to human chorionic gonadotropin as a part of assisted reproduction for the treatment of female infertility.

Financial Operations Overview

Revenue

To date, 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 Expenses

Since our inception, our operations have primarily been limited to the in-licensing of the rights to relugolix and MVT-602, the expansion of our team, and the initiation and ongoing activities of our Phase 3 clinical programs. Our research and development, or R&D, expenses include program-specific costs, as well as unallocated costs.

Program-specific costs include:

- direct third-party costs (as well as third-party pass thru costs from Roivant Sciences, Inc., or RSI, and Roivant Sciences GmbH, or RSG), which include expenses incurred under agreements with contract research organizations, or CROs, and contract manufacturing organizations, or CMOs, the cost of consultants who assist with the development of our product candidates on a program-specific basis, investigator grants, sponsored research, manufacturing costs in connection with producing materials for use in conducting nonclinical studies and clinical trials, and other third-party expenses directly attributable to the development of our product candidates.

Unallocated costs include:

- employee-related expenses, such as salaries, share-based compensation, benefits and travel for R&D personnel;
- costs allocated to us for activities performed by RSI and RSG under the Services Agreements and share-based compensation expense allocated to us from RSL;
- depreciation expenses for assets used in R&D activities; and
- other expenses, which include the costs of consultants who assist with R&D activities not specific to a program.

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 clinical trials for relugolix and a Phase 2a study for MVT-602, prepare to seek regulatory approval for our product candidates, expand our employee base and increase personnel-related expenses. 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. In addition, we expect our share-based compensation expense to increase as we continue to increase our number of R&D employees.

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 recruit and 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 commercialization and sale of any of our product candidates. Our R&D activities may be subject to change from time to time as we evaluate our priorities and available resources.

General and Administrative Expenses

General and administrative, or G&A, expenses consist primarily of employee-related expenses, such as salaries, share-based compensation, benefits and travel, legal and accounting fees, general overhead, costs billed to us under the Services Agreements, share-based compensation allocated to us by RSL, and other consulting services.

We anticipate that our G&A expenses will continue to increase in the future to support our ongoing R&D activities and increased 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, among other expenses. Additionally, we anticipate increased costs associated with operating as a public company, including expenses related to maintaining compliance with New York Stock Exchange, or NYSE, rules and United States Securities and Exchange Commission, or SEC, requirements, insurance and investor relations costs. In addition, if relugolix or MVT-602 obtains regulatory approval for marketing, we expect that we would incur expenses associated with building medical affairs, sales and marketing teams and commercialization activities.

Results of Operations

The following table summarizes our results of operations for the three months ended June 30, 2018 and 2017 (in thousands):

	Three Months Ended June 30,	
	2018	2017
Operating expenses:		
Research and development	$ 51,341	$ 17,708
General and administrative	8,742	4,182
Total operating expenses	60,083	21,890
Interest expense	1,617	—
Other expense	289	342
Loss before income taxes	(61,989)	(22,232)
Income tax expense	145	1,085
Net loss	$ (62,134)	$ (23,317)

Research and Development Expenses

For the three months ended June 30, 2018 and 2017 , our R&D expenses consisted of the following (in thousands):

	Three Months Ended June 30,		
	2018	2017	Change
Program-specific costs:			
Relugolix	$ 42,839	$ 14,315	$ 28,524
MVT-602	674	19	655
Unallocated costs:			
Share-based compensation	1,561	860	701
Personnel expense	4,781	1,951	2,830
Services Agreements	457	144	313
Other expense	1,029	419	610
Total R&D expenses	$ 51,341	$ 17,708	$ 33,633

R&D expenses increased by $33.6 million , to $51.3 million , in the three months ended June 30, 2018 compared to $17.7 million in the three months ended June 30, 2017 , primarily due to increases in expenses as a result of the progress of our ongoing Phase 3 clinical trials. R&D expenses in the three months ended June 30, 2018 consisted primarily of CRO, clinical drug supply and other study-related costs of $41.9 million , personnel expenses of $4.8 million , share-based compensation expense of $1.6 million , $0.1 million of which was allocated to us by RSL, and costs billed to us under the Services Agreements of $2.1 million , including unallocated personnel expenses and third-party pass thru costs associated with our ongoing clinical and other research programs.

R&D expenses for the three months ended June 30, 2017 consisted primarily of CRO costs of $12.8 million , share-based compensation expense of $0.9 million , $0.1 million of which was allocated to us by RSL, and costs billed to us under the Services Agreements of $0.4 million , including unallocated personnel expenses and third-party pass thru costs associated with our ongoing clinical and other research programs.

General and Administrative Expenses

G&A expenses increased by $4.6 million , to $8.7 million , in the three months ended June 30, 2018 compared to $4.2 million in the three months ended June 30, 2017 , 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 in the three months ended June 30, 2018 consisted primarily of personnel-related and general overhead expenses of $4.0 million , share-based compensation expense of $2.7 million , including $0.1 million of which was allocated to us by RSL, legal and professional fees of $0.9 million , and costs of $1.1 million billed to us under the Services Agreements, including personnel expenses, overhead allocations and third-party pass thru costs.

G&A expenses for the three months ended June 30, 2017 consisted primarily of personnel-related and general overhead expenses of $1.6 million , share-based compensation expense of $1.3 million , including $0.1 million of which was allocated to us by RSL, costs of $0.7 million billed to us under the Services Agreements, including personnel expenses, overhead allocations and third-party pass thru costs, and legal and professional fees of $0.6 million .

Interest Expense

Interest expense was $1.6 million for the three months ended June 30, 2018 , consisting of interest expense related to the NovaQuest Securities Purchase Agreement and Hercules Loan Agreement as well as the associated non-cash amortization of debt discount and issuance costs.

There was no interest expense for the three months ended June 30, 2017 .

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations primarily from the issuance and sale of our common shares and from the financing commitments available to us from NovaQuest and Hercules. Prior to our IPO, our operations were funded primarily by RSL.

As of June 30, 2018 , we had $143.6 million of cash and $92.0 million of financing commitments available to us from NovaQuest, as compared to $108.6 million of cash and $92.0 million of financing commitments available to us from NovaQuest as of March 31, 2018.

In July 2018, we completed an underwritten public offering of 3,333,334 of our common shares at a public offering price of $22.50 per common share resulting in net proceeds to us of approximately $70.2 million after deducting underwriting discounts and commissions and estimated offering costs payable by us.

We currently have approximately $40.6 million of remaining capacity available under our “at-the-market” equity offering program that we established in April 2018.

Capital Requirements

We recorded net losses of $62.1 million and $23.3 million for the three months ended June 30, 2018 and 2017 , respectively . As of June 30, 2018 , we had an accumulated deficit of $290.6 million .

We have incurred, and expect to continue to incur, significant and increasing operating losses and negative cash flows for at least 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 one of our product candidates. Our operating 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 and G&A 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 a Phase 2a clinical trial in healthy female volunteers to characterize the dose response curve in the controlled ovarian stimulation setting prior to studying MVT-602 in infertile women seeking pregnancy;
- 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 and personnel;
- 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 Securities Purchase Agreement and the Hercules Loan Agreement; and

- operate as a public company.

Our primary use of cash has been and will continue to be 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 clinical development expenses for these programs are expected to increase.

We currently believe that our existing cash, together with the remaining financing commitments of $92.0 million available to us from NovaQuest will be sufficient to fund our operating expenses and capital expenditure requirements through the first quarter of our fiscal year ending March 31, 2020, and to enable us to receive top-line data from the Phase 3 clinical trials for at least one of our women's health clinical programs. This estimate is based on our current assumptions, including assumptions relating to our ability to manage our spend, that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. These funds will not be sufficient to enable us to complete all necessary development activities 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 operations through a combination of cash on hand, the remaining financing commitments available to us from NovaQuest, 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 common shareholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our common 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 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 three months ended June 30, 2018 and 2017 (in thousands):

	Three Months Ended June 30,	
	2018	2017
Net cash used in operating activities	$ (44,755)	$ (26,557)
Net cash used in investing activities	$ (197)	$ (90)
Net cash provided by financing activities	$ 79,963	$ —

Operating Activities

For the three months ended June 30, 2018 , we used $44.8 million in operating activities. This was primarily attributable to a net loss for the period of $62.1 million along with an increase of $0.6 million in prepaid expenses and other current assets. These amounts were partially offset by an increase in accrued expenses of $8.0 million which was primarily due to the progress of our ongoing Phase 3 clinical trials of relugolix, $4.2 million of non-cash share-based compensation expense as a result of an increase in headcount, increase of $3.2 million due to RSL, RSI and RSG and $0.6 million of total depreciation and amortization expense.

For the three months ended June 30, 2017 , $26.6 million was used in operating activities. This was primarily attributable to a net loss for the period of $23.3 million and increases of $3.1 million in other assets and $2.0 million in prepaid expenses and other current assets. These amounts were partially offset by $2.2 million of non-cash share-based compensation expense.

Investing Activities

For the three months ended June 30, 2018 , $0.2 million was used in investing activities, all for the purchase of furniture and equipment.

For the three months ended June 30, 2017 , $0.1 million was used in investing activities, all for the purchase of furniture and equipment.

Financing Activities

For the three months ended June 30, 2018 , $80.0 million was provided by financing activities. This was primarily due to the net proceeds of $57.3 million we received from the sale of 2,767,129 common shares through our "at-the-market" equity offering program that we established in April 2018 and proceeds of $22.5 million we received from the sale of 1,110,015 common shares to RSL in a private placement.

For the three months ended June 30, 2017 , no cash was provided by financing activities.

Contractual Obligations

During the three months ended June 30, 2018 , we entered into a Commercial Manufacturing and Supply Agreement with Takeda, or the Takeda Commercial Supply Agreement. See Note 9, "Commitments and Contingencies" to our unaudited condensed consolidated financial statements contained herein for a further discussion of this agreement.

During the three months ended June 30, 2018 , there were no other material changes outside of the ordinary course of business to the specified contractual obligations set forth in the contractual obligations table included in our Annual Report on Form 10-K for the year ended March 31, 2018 .

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our 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 and disclosures of contingent assets and liabilities as of the dates of the unaudited condensed consolidated financial statements and the reported amounts of expenses incurred 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 expenses, as well as assumptions used to estimate the fair value of common share and option awards. We base our estimates on historical experience and on various other information available to us at the time we make the estimates and judgments 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 inherently 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. Our critical accounting policies are more fully described in "Critical Accounting Policies and Significant Judgments and Estimates" in Part II. Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" 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, 2018 , filed with the SEC on June 7, 2018.

Recent Accounting Pronouncements

For information regarding recently issued accounting pronouncements and the expected impact on our consolidated financial statements, see Note 2, "Summary of Significant Accounting Policies," to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

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. As of June 30, 2018 , we had cash of $143.6 million , consisting of non-interest-bearing deposits denominated in the U.S. dollar and Swiss franc, compared to $108.6 million at March 31, 2018 . We also have certain long-term debt that bears interest at a prime-based variable rate. A hypothetical 10% change in this interest rate would have an approximate $0.4 million impact on our annual interest expense. We do not believe we are currently exposed to any material market risk.

Item 4. Controls and Procedures

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 June 30, 2018 , 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 Securities Exchange Act of 1934, as amended, or 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 June 30, 2018 at the reasonable assurance level.

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(f) and 15d-15(f) of the Exchange Act that occurred during the fiscal quarter ended June 30, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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 Sciences Ltd. have been detected.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 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. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. If any of the events described in the following risk factors and the risks described elsewhere in this 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 no history of commercializing products, which may make it difficult to evaluate our business and prospects.

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, raising capital, identifying and in-licensing our product candidates, including acquiring worldwide rights (excluding Japan and certain other Asian countries) to relugolix and worldwide rights to MVT-602, preparing for and advancing our product candidates into clinical development, conducting global clinical trials, and preparing for the potential commercialization of relugolix. 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 conduct sales and marketing activities necessary for successful product commercialization. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown difficulties in achieving our business objectives. If our product candidates are approved by the U.S. Food and Drug Administration, or FDA, we will need to expand our capabilities to support commercial activities and we may not be successful in adding such capabilities. Consequently, any 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.

We have incurred significant losses since our inception and expect to continue to incur significant and increasing losses for the foreseeable future; and we have not generated any revenue from any commercial products and may never achieve or maintain profitability.

Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or fail to become commercially viable. Since inception, we have focused our efforts on research and development with the goal of achieving regulatory approval and have incurred significant operating losses. Our net loss was $62.1 million and $23.3 million for the three months ended June 30, 2018 and 2017 , respectively, and, as of June 30, 2018, we had an accumulated deficit of $290.6 million .

We expect to continue to incur significant and increasing losses over the next several years as we continue to develop relugolix and MVT-602. Past operating losses, combined with expected future operating losses, have had and will continue to have an adverse effect on our results of operations, financial position and working capital. If we obtain regulatory approval for relugolix or MVT-602, we expect to incur increased sales, marketing and manufacturing expenses. As a result, we expect to continue to incur significant and increasing losses and negative cash flows for the foreseeable future.

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 have never generated any product revenue. 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. Even if we successfully obtain regulatory approvals 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. For example, ORILISSA™, an oral GnRH receptor antagonist for the management of moderate to severe pain associated with endometriosis, was recently approved by the FDA. The launch and commercialization of such competing drug may limit the revenue from relugolix. 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 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 are a clinical-stage biopharmaceutical company with no products approved for commercial sale. We have invested and expect to continue to invest a substantial portion of our efforts and expenditures in the development and advancement of our product candidates, relugolix and MVT-602. Our business and our ability to generate revenue depends heavily on the successful clinical development, regulatory approval and commercialization of these product candidates, which may never occur. We currently generate no revenues from sales of any product. We may never receive regulatory approval for any indication for relugolix or MVT-602 and may never be able to develop or commercialize a marketable product. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of products are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and other countries. We are not permitted to market relugolix or MVT-602 in the U.S. until we receive approval of New Drug Applications, or NDAs, or in any foreign country until we receive the requisite approvals from the appropriate regulatory authorities in such countries.

Obtaining approval of an NDA or similar 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. See the Risk Factor titled "The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, and inherently unpredictable, and even if we obtain approval for a product candidate in one country or jurisdiction, we may never obtain approval for or commercialize it in any other jurisdiction which would limit our ability to realize our full market potential." We have not submitted an NDA to the FDA, or any comparable application to any other regulatory authority.

Even if we receive regulatory approval for relugolix or MVT-602, our ability to generate revenues from relugolix or MVT-602 will depend on our ability to:

- set an acceptable price for relugolix or MVT-602 and obtain coverage and adequate reimbursement for third-party payors;
- establish effective sales, marketing, and distribution systems in jurisdictions around the world for relugolix (excluding Japan and certain other Asian countries) or MVT-602;
- initiate and continue relationships with Takeda and/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;
- establish the safety and efficacy of relugolix and MVT-602 in comparison to competing products; and
- maintain, expand, and protect our intellectual property portfolio

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

If we are unable to formulate a fixed-dose combination version of relugolix with low-dose estradiol and progestin for women ' s health indications, its potential commercial opportunity and competitive advantage could be limited.

GnRH antagonists, like relugolix, may cause reversible loss of bone mineral density due to the hypoestrogenic state induced by GnRH antagonists that may limit duration of use. This risk, and a related risk of hot flush, may be mitigated by the co-administration of low-dose estradiol and progestin as hormonal add-back therapy. A key part of our relugolix clinical development strategy is to formulate a fixed-dose combination of relugolix with low-dose estradiol and progestin add-back therapy to facilitate patient convenience and compliance. If we are unsuccessful in our attempts to formulate a fixed-dose combination in time for the initial application for market authorization, we expect to seek approval for relugolix tablets co-packaged with commercially available low-dose estradiol and progestin. This would potentially decrease our advantages relative to our competition by requiring patients to take two pills once daily instead of one pill once daily until the fixed-dose combination could be developed. 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 co-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 could 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' respective 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 until such time as Myovant achieves both the clinical development and financing 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 outstanding obligations under 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 obligations under the Hercules Loan Agreement, 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' respective assets 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 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, upon further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance; 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 common share price.

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 License Agreement, pursuant to which we are obligated to cover substantial development costs of relugolix and MVT-602 and make royalty payments in connection with the net sales of resulting products, if any.

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 capital we will require for development and any approved marketing and commercialization activities. Under the terms of the NovaQuest Securities Purchase Agreement and the NovaQuest Equity Purchase Agreement, failure of relugolix clinical trials would negatively impact our ability to obtain the remaining financing currently available to us. 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.

We currently believe that our existing cash, together with the remaining financing commitments of $92.0 million available to us from NovaQuest will be sufficient to fund our operating expenses and capital expenditure requirements through the first quarter of our fiscal year ending March 31, 2020, and to enable us to receive top-line data from the Phase 3 clinical trials for at least one of our women's health clinical programs. This estimate is based on our current assumptions, including assumptions relating to our ability to manage our spend, that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. These funds will not be sufficient for us to compete all necessary development activities and commercially launch relugolix. 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 equity securities may cause dilution to existing shareholders, raising additional funds through debt financings may involve restrictive covenants, and raising funds through collaboration and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

Until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, strategic alliances, and license and development agreements or other collaborations. To the extent that we raise additional capital by issuing equity securities, our existing shareholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that 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.

In addition, 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 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 and commercial trial material to support development of relugolix and MVT-602. 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 License Agreement is terminated or we otherwise lose the rights thereunder, it would adversely affect our business. The Takeda License Agreement imposes on us obligations relating to exclusivity, territorial restrictions, 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.

In June 2016, we and one of Takeda's affiliates, Takeda Pharmaceutical Company Limited, or Takeda Limited, entered into an agreement for the manufacture and supply of relugolix. Under this agreement, Takeda Limited will supply us, and we will obtain from Takeda Limited, all of our requirements for relugolix drug substance and drug product to be used under our development plans for all indications. Takeda Limited is also assisting us with a technical transfer of the manufacturing process for relugolix to us and our designee and we are paying the expenses related to such transfer. On May 30, 2018, we entered into a Commercial Manufacturing and Supply Agreement with Takeda, or the Takeda Commercial Supply Agreement, pursuant to which Takeda will manufacture and supply us with relugolix drug substance to support the commercial launch of relugolix, if marketing authorization is granted. Takeda has also agreed to assist with the transfer of technology and manufacturing know-how to a second contract manufacturing organization of our subsidiary, Myovant Sciences GmbH. We will pay the expenses related to such transfer. If Takeda fails to fulfill its obligations to manufacture and supply clinical and/or commercial quantities of relugolix to us or fails to enable the transfer of the manufacturing process for relugolix to us or our designee, our development plans and commercialization of relugolix, if approved, could be significantly delayed or otherwise adversely affected.

We currently have a limited number of employees and we rely on Roivant Sciences, Inc. and Roivant Sciences GmbH to provide various services for us.

As of June 30, 2018, we had 104 employees. To operate our business, we rely in part on services provided by Roivant Sciences, Inc., or RSI, and Roivant Sciences GmbH, or RSG, wholly owned subsidiaries of Roivant Sciences Ltd., or RSL, pursuant to the Services Agreements we have with these entities. Personnel and support staff who provide services to us under these Services Agreements are not required to treat management and administration of our business as their primary responsibility or act exclusively for us, and we do not expect them to do so. Under the Services Agreements, RSI and RSG have the discretion to determine who, among their employees, will perform services for us. RSI and RSG have limited financing 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 services provided to us, the operations of our business may be adversely affected.

In addition, we expect that the level of support we receive from RSI and RSG will decrease in the near term as RSL seeks to decrease and decentralize the amount of services it provides to its affiliated companies, including Myovant. As a result, we will be required to replace many of these services with our own internally developed teams or substitute third-party service providers. We primarily intend to develop these capabilities internally, and may incur increased costs as we hire and train additional personnel. If we are unable to develop these capabilities or we fail to do so in a timely and effective manner, the operations of our business would be adversely affected.

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

We expect to hire additional employees for our managerial team and other teams supporting G&A commercial, operations and many other functions. Many of the other pharmaceutical companies we currently 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 of career advancement. Some of these opportunities may be more appealing to high-quality candidates and consultants than what we have to offer. Due to these reasons, we may not be able to attract or retain qualified personnel.

In addition, our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the skills and leadership of our management team and key employees. Our senior management and key employees may terminate their positions with us at any time. In addition, we do not maintain "key person" insurance for any of our executives or other employees. If we lose one or more members of our senior management team or key employees, our ability to successfully implement our business strategies could be 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. 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, our ability to commercialize relugolix or MVT-602 if we obtain regulatory approvals, and our ability to implement our business strategies.

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

We expect to expand our organization and hire additional employees. Our management is expected to have increasing responsibilities to identify, recruit, maintain, motivate, and integrate additional employees, consultants and contractors which may divert a disproportionate amount of its attention away from our day-to-day activities. The expected growth may also require significant capital expenditures and divert financial resources from other projects. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate or grow revenue could be adversely affected, and we may not be able to implement our business strategy. As a result, our future financial performance and our ability to commercialize relugolix, MVT-602 or any potential future product candidate may be adversely affected.

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, illegal activity, or other misconduct. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA or other regulatory bodies, including those laws that require the reporting of true, complete, and accurate information to such regulatory bodies; manufacturing and cGMP standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; or laws and regulations that require the true, complete, and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing, bribery, corruption, antitrust violations, and other abusive practices. See the Risk Factors titled "Our current and future relationships with investigators, healthcare professionals, consultants, third-party payors, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties," "International expansion of our business exposes us to business, legal, regulatory, political, operational, financial, economic, and other risks associated with conducting business outside of the U.S.," and "If we obtain approval to market any products outside of the U.S., a variety of risks associated with international operations could materially adversely affect our business." 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. We have a Code of Business Conduct and Ethics and other corporate compliance policies, but it is not always possible to identify and deter employee or third-party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. 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, suspension or delay in our clinical trials, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, FDA debarment, contractual damages, reputational harm, diminished profits and future earnings, 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.

International expansion of our business exposes us to business, legal, regulatory, political, operational, financial, economic, and other risks associated with conducting business outside of the U.S.

Part of our business strategy involves international expansion, including establishing and maintaining operations outside of the U.S. and establishing and maintaining relationships with health care providers, payors, government officials, distributors and manufacturers globally. Conducting business internationally involves a number of risks, including:

- multiple conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, anti-bribery and anti-corruption laws, regulatory requirements and other governmental approvals, permits and licenses;
- possible failure by us or our distributors to obtain appropriate licenses or regulatory approvals for the sale or use of our product candidates, if approved, in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing multiple payor-reimbursement 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;
- business interruptions resulting from geopolitical actions, economic instability, or natural disasters, including, but not limited to, wars and terrorism, political unrest, outbreak of disease, earthquakes, boycotts, curtailment of trade, and other business restrictions;

- failure to comply with foreign laws, regulations, standards and regulatory guidance governing the collection, use, disclosure, retention, security and transfer of personal data, including the European Union General Data Privacy Regulation, or GDPR, which introduces strict requirements for processing personal data of individuals within the European Union; 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.

Also, see the Risk Factor titled "International expansion of our business exposes us to business, legal, regulatory, political, operational, financial, economic, and other risks associated with conducting business outside of the U.S." 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 internal computer systems, as well as those of RSI and RSG, and our third-party collaborators, consultants or contractors, may fail or suffer cybersecurity breaches and data leakage, which could result in a material disruption of our business and operations.

Our computer systems, as well as those of RSI, RSG and our Contract Research Organizations, or CROs, contract manufacturing organizations, or CMOs, and other contractors, consultants, and law and accounting firms, may sustain damage or data leakage from computer viruses, unauthorized access, data breaches, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war, and telecommunication and electrical failures. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems or infrastructure, by our workforce, others with authorized access to our information systems or unauthorized persons could cause interruptions in our operations and 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 clinical 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.

The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our or our third-party providers' systems, portable media or storage devises. We could also experience a business interruption, theft of confidential information or reputational damage from industrial espionage attacks, malware or other cyber-attacks, which may compromise our information system infrastructure or lead to data leakage, either internally or at our third-party providers. While we have invested in the protection of data and information technology, there can be no assurance that our efforts will prevent services interruptions or security breaches.

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

We are subject to federal and state laws and regulations requiring that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, state security breach notification laws, state health information privacy laws and federal and state consumer protection laws impose requirements regarding the collection, use, and storage of personal information.

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

Use of social media platforms presents new risks.

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

The failure to successfully implement an enterprise resource planning system could adversely impact our business and results of operations.

We intend to implement a company-wide enterprise resource planning, or ERP, system to upgrade certain existing business, operational, and financial processes, upon which we rely. ERP implementations are complex and time-consuming projects that require transformations of business and finance processes in order to reap the benefits of the ERP system; any such transformation involves risk inherent in the conversion to a new computer system, including loss of information and potential disruption to normal operations. Additionally, if the ERP system is not effectively implemented as planned, or the system does not operate as intended, the effectiveness of our internal controls over financial reporting could be adversely affected or our ability to assess those controls adequately could be delayed. Significant delays in documenting, reviewing and testing our internal control over financial reporting could cause us to fail to comply with our U.S. Securities and Exchange Commission, or SEC, reporting obligations related to our management's assessment of our internal control over financial reporting. In addition, if we experience interruptions in service or operational difficulties and are unable to effectively manage our business during or following the implementation of the ERP system, our business and results of operations could be harmed.

Potential product liability lawsuits against us could cause us to incur substantial liabilities and could impact ongoing and planned clinical trials as well as 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 regulatory or governmental agencies, consumers, health care providers, other pharmaceutical companies or others taking or otherwise coming into contact with our products. On occasion, large monetary judgments have been awarded in class action lawsuits where drugs have had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend related litigation;

- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize our products or any future product candidates;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased demand for our products or any future product candidate, if approved for commercial sale; and
- loss of revenue.

The product liability and clinical trial insurance we currently carry, and any additional product liability and clinical trial 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 common share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization of any product candidates we develop.

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 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 analysis plans for any clinical trials of relugolix or MVT-602, which may delay the approval of an NDA or similar application. The clinical trial process is also time-consuming.

Failures can occur at any stage of clinical trials, and we could encounter problems that cause us to abandon or repeat clinical trials. In addition, results from clinical trials may require further evaluation, delaying the next stage of clinical development or submission of an NDA. Further, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical studies and initial clinical trials. 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, statistical 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 or the discontinuation of advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Likewise, the results of 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;
- lack of effectiveness during clinical trials;
- identification of dosing issues;
- inability to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- slower than expected rates of patient recruitment and enrollment or failure to recruit suitable patients to participate in a trial;
- failure to open a sufficient number of clinical trial sites;
- unanticipated impact from changes in or modifications to clinical trial design;
- inability or unwillingness of clinical investigators or study participants to follow our clinical and other applicable protocols;
- premature discontinuation of study participants from clinical trials or missing data;
- failure to manufacture or release sufficient quantities of relugolix, MVT-602, estradiol, progestin or placebo or failure to obtain sufficient quantities of concomitant medication, that in each case meet our quality standards, for use in clinical trials;
- inability to monitor patients adequately during or after treatment; or
- inappropriate unblinding of study results.

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, or Good Manufacturing Practice, or GMP, 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 or 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 common 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 research and development in accordance with the applicable protocols, 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.

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 efficacy 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.

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 reported positive top-line results from its two Phase 3 clinical trials in Japan in women with uterine fibroids and announced that it had submitted the data from both of these trials to the Ministry of Health, Labour and Welfare in Japan for marketing authorization of relugolix in Japan for the treatment of uterine fibroids. 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.

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

We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials on our current timelines, or at all, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our clinical 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, enroll, 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, enrollment, or retention in our clinical trials. Also, marketing authorization of competitors in the same class of product candidates may impair our ability to recruit, enroll, or retain patients into our clinical trials, delaying or potentially preventing us from completing 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.

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. For example, ORILISSA ™ , an oral GnRH receptor antagonist, was recently approved by the FDA for the management of moderate to severe pain associated with endometriosis and is expected to be launched by AbbVie in August 2018. 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 developing and commercializing 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. Many of our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a smaller number of our competitors. Competition may reduce the number and types of patients available to us to participate in clinical trials, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors.

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

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 in safety and efficacy 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 U.S. and by similar regulatory authorities outside the U.S. 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 Takeda, nor any future collaborator is permitted to market any of our product candidates in the U.S. or any other jurisdiction until we receive regulatory approval of an NDA from the FDA or similar regulatory authorities outside of the U.S.

The time required to obtain approval of an NDA by the FDA or similar regulatory authorities outside of the U.S. is unpredictable but typically takes many years following the commencement of clinical 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 for relugolix, and for approval of MVT-602, we will need to complete 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 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. On May 18, 2018, the European Medicines Agency Pharmacovigilance Risk Assessment Committee, or PRAC, completed its review of Esmya (ulipristal acetate) following reports of serious liver injury. The PRAC concluded that Esmya may have contributed to the development of some cases of serious liver injury. The PRAC has recommended that Esmya must not be used in women with known liver problems and should be used for more than one treatment course only in women who are not eligible for surgery. Liver function testing should be performed at the start of each treatment course and once a month and for two to four weeks after stopping treatment for the first two treatment courses. Although a different class of drugs, the review of post-marketing events of liver toxicity for Esmya by the PRAC, may lead to increased scrutiny regarding liver function for GnRH antagonists.

If any of our product candidates are approved and then cause serious or unexpected side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or require a Risk Evaluation and Mitigation Strategy, or a REMS (or equivalent outside the U.S.) to impose restrictions on its distribution or other risk management measures;
- we may be required to recall a product;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- 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 repeat a nonclinical study or clinical trial or terminate a program, even if other studies or trials related to the program are ongoing or have been successfully completed;
- we could be sued and held liable for harm caused to patients;
- we could elect to discontinue the sale of our product;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing 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 our full market potential.

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

Even if we obtain regulatory approval for 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 cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of drug product samples to physicians, recordkeeping, and current GCP requirements for any clinical trials that we conduct post-approval. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval 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 U.S., and other comparable regulations in foreign jurisdictions, relating to the promotion of prescription drugs may lead to enforcement actions and investigations by the FDA, Department of Justice, State Attorney Generals and other foreign regulatory agencies alleging violations of U.S. federal and state health care fraud and abuse laws, as well as state consumer protection laws and comparable laws in foreign jurisdictions.

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

- 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;
- requirement of a REMS (or equivalent outside the U.S.);
- 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 U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or to the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

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 payor 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 these product candidates to obtain market acceptance would harm our business and could require us to seek additional financing.

If we are unable to establish sales, 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 are currently building our sales and marketing infrastructure; however, we currently do not have an established 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 U.S., 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 access to 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 even if we are 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 market any products outside of the U.S., a variety of risks associated with international operations could materially adversely affect our business.

If either relugolix or MVT-602 is approved for marketing outside of the U.S., 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 U.S.;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, the United Kingdom Bribery Act 2010, or similar antibribery and anticorruption laws in other jurisdictions as well as various regulations pertaining to data privacy, such as the GDPR;
- 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.

Also, see the Risk Factor titled "International expansion of our business exposes us to business, legal, regulatory, political, operational, financial, economic, and other risks associated with conducting business outside of the U.S." We have no prior experience in these countries, 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, healthcare professionals, consultants, third-party payors, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient support, 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 and civil monetary penalties laws, including the False Claims Act, which among other things, 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;
- a number of federal, state and foreign laws, regulations, guidance and standards that impose requirements regarding the protection of health or other personal data that are applicable to or affect our operations;
- 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 90 th day of each calendar year); and
- analogous state and foreign laws and regulations, such as state anti-kickback 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, as well as state and local laws that require the registration of pharmaceutical sales representatives; 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 U.S. and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of relugolix 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 the U.S. 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, or ACA, 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.

The financial impact of the ACA over the next few years will depend on a number of factors including, but not limited to, the policies reflected in implementing regulations and guidance and changes in sales volumes for products affected by the new system of rebates, discounts and fees.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the current administration to repeal or replace certain aspects of the ACA. Since January 2017, the President has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. The tax legislation enacted on December 22, 2017 entitled "an Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018," or the Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment on certain individuals who fail to maintain qualifying health coverage. Additionally, on January 22, 2018, the President signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain fees mandated under the ACA. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to increase the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans. Moreover, in July 2018, CMS announced that it has suspended further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program pending the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment.

In addition, other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. These changes included aggregate 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 remain in effect through 2027 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period in which the government may recover overpayments to providers from three to five years.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. Additionally, on May 11, 2018, President Trump laid out his administration's "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" to reduce the cost of prescription drugs while preserving innovation and cures. Although some of these and other proposals will require authorization through additional legislation to become effective, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

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.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program.

Legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance, or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

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 U.S., 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 U.S. and in some foreign jurisdictions that could affect our ability to sell any future drugs profitably. These legislative and regulatory changes may negatively impact the reimbursement for any future drugs, if approved.

Risks Related to Our Dependence on Third Parties

We do not have our own manufacturing capabilities and will rely on 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 do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. While relugolix and MVT-602 were being developed by Takeda, they were also being manufactured by Takeda and third-party contract manufacturing organizations. 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 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 terms of the Takeda License 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 2 and 3 clinical studies for MVT-602. The drug substance transferred from Takeda may not meet our quality standards and may be disqualified from use in our planned clinical programs. Third-party vendors may be difficult to identify for MVT-602 process and formulation development and manufacturing due to special capabilities required and they may not be able to meet our quality standards. Further, we are 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.

Both relugolix and MVT-602 are potent hormonal therapies and therefore require specialized manufacturing facilities. Depending on actual commercial demand, additional third-party manufacturing facilities will have to be established to meet the demand through technology transfer, process validation and regulatory approval before product manufactured at the new facilities can be marketed. Any delay in the technology transfer and process validation could limit adequate supply to meet our commercial demand.

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 Takeda and 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 cGMP requirements for manufacture of drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance, and qualified personnel. If the FDA or comparable foreign regulatory authorities do not approve these facilities for the manufacture of our product candidates or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Further, our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including:

- delay or inability to develop 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 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.

Manufacturing problems, including at our third-party manufacturers and corporate partners, could cause inventory shortages and delay product shipments and regulatory approvals, which may adversely affect our business operations.

In order to sustain our business, we must be able to produce sufficient quantities of our product candidates to satisfy our clinical trial needs and any approved products to satisfy demand. Our product candidates and products, if approved, are a result of complex manufacturing processes. The manufacturing process for pharmaceutical products is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations.

Our product candidates are currently manufactured by third-party manufacturers or corporate partners and we expect that any future product candidates as well as any products, if approved, will be manufactured by third-party manufacturers or corporate partners. We depend on these third parties to perform manufacturing activities effectively and on a timely basis.

Our third party manufacturers and corporate partners are independent entities who are subject to their own unique operational and financial risks which are out of our control. If we or any of these third-party manufacturers or corporate partners fail to perform as required, this could cause delays in our clinical trials and applications for regulatory approval, as well as meet demand for any approved products. We utilize a limited number of third-party manufacturers and corporate partners and may not be able to locate additional or replacement facilities on a reasonable basis, or at all.

Pharmaceutical manufacturing operations are subject to routine inspections by regulatory agencies. If we or our third-party manufacturers and corporate partners are unable to remedy any deficiencies cited by FDA in its inspections, our ability to deliver product candidates to clinical trial sites on a timely basis, the timing of any potential regulatory approvals of products in development, and our ability to deliver commercial product for any approved products, could be negatively impacted. To the extent that any of these risks materialize, our business and financial results may be adversely affected.

We may not be able to obtain materials or supplies necessary to conduct clinical trials or to manufacture and sell any of our product candidates, if approved.

We need access to certain supplies and products to conduct our clinical trials and to manufacture commercial inventories of our product candidates, if approved. If we are unable to purchase sufficient quantities of these materials or find suitable alternate materials in a timely manner, our development efforts for our product candidates may be delayed or our ability to manufacture commercial products would be limited.

Suppliers of key components and materials must be named in the new drug application or marketing authorization application filed with the FDA, European Medicines Agency, or other regulatory authority for any product candidate for which we are seeking marketing approval, and significant delays can occur if the qualification of a new supplier is required. Even after a manufacturer is qualified by the regulatory authority, the manufacturer must continue to expend time, money, and effort in the area of production and quality control to ensure full compliance with GMP. Manufacturers are subject to regular, periodic inspections by the regulatory authorities following initial approval. If, as a result of these inspections, a regulatory authority determines that the equipment, facilities, laboratories or processes do not comply with applicable regulations and conditions of product approval, the regulatory authority may suspend the manufacturing operations. If the manufacturing operations of any single suppliers for any of our products are suspended, we may be unable to generate sufficient quantities of commercial or clinical supplies of product to meet demand, which could harm our business. In addition, if delivery of material from our suppliers were interrupted for any reason, we may be unable to ship commercial products that may be approved for marketing or supply our products in development for clinical trials. In addition, some of our products and the materials that we utilize in our operations are made only at one facility, which we may not be able to replace in a timely manner and on commercially reasonable terms, or at all. Problems with any of the single suppliers we depend on, including in the event of a disaster, including an earthquake, equipment failure, or other difficulty, may negatively impact our development and commercialization efforts.

If we were to encounter any of these difficulties, our ability to provide our products, if approved, and product candidates to patients would be jeopardized.

We are reliant on third parties to conduct, 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 for the execution of nonclinical studies. We control only certain aspects of our CROs' activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with current GLP and GCP regulations and guidelines enforced by the FDA and are also required by the competent authorities of the member states of the European Economic Area and comparable foreign regulatory authorities to comply with the International Council for Harmonization guidelines for any of our product candidates that are in nonclinical and clinical development, respectively. The regulatory authorities enforce GCP regulations through periodic inspections of 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.

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

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

Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, trademarks, trade secret protection, and confidentiality agreements to protect the intellectual property related to our drug development programs and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries with respect to relugolix, MVT-602, and any future product candidates. We seek to protect our proprietary position by filing patent applications in the U.S. and abroad related to our development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

The patents and patent applications that we own or in-license may fail to result in issued patents with claims that protect relugolix, MVT-602 or any future product candidate in the U.S. or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. Even if patents do successfully issue and even if such patents cover relugolix, MVT-602 or any future product candidate, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates or companion diagnostic that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for relugolix, MVT-602 or any future product candidate, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize future drugs. Any such outcome could have a materially adverse effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been and will continue to be the subject of litigation and new legislation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. For example, many countries restrict the patentability of methods of treatment of the human body. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result of these and other factors, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection.

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

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent term can be adjusted to recapture a portion of delay by the USPTO in examining the patent application (patent term adjustment) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension), or both. The scope of patent protection may also be limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates.

We have licensed certain intellectual property rights covering our current product candidates from Takeda. If, for any reason, the Takeda License Agreement is terminated or we otherwise lose those rights, it could adversely affect our business. The Takeda License Agreement imposes, and any future collaboration agreements or license agreements we enter into are likely to impose various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture, and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

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

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

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the U.S., involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation, and administrative law proceedings, inter partes review, and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization. We have conducted searches for information in support of patent protection and otherwise evaluate 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.

Also, there may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe.

In addition, third parties may obtain patent rights in the future and claim that use of our technologies infringes upon rights. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

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

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

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the U.S., in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common shares.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

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

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

Filing, prosecuting, and defending patents covering relugolix, MVT-602, and any future product candidate throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the U.S. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we expect to rely on third parties to manufacture relugolix, 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 New York Stock Exchange, or NYSE, we cannot assure you that an active trading market for our common shares will continue to be sustained. In addition, as a result of a large proportion of our common shares being held by passive investors (for example, RSL beneficially owning approximately 56.2% of our outstanding common shares as of August 3, 2018), trading in our common shares may be less liquid than the shares of companies with broader public active institutional investor ownership. If an active market for our common shares is not sustained, your ability to trade our shares may be limited. 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;
- actual or anticipated 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 U.S. 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;
- variations in our financial results or the financial results of companies that are perceived to be similar to us;
- changes in estimates of financial results or investment recommendations by securities analysts;
- significant lawsuits, including patent or shareholder litigation, and disputes or other developments relating to our proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- short sales of our common shares;
- sales of a substantial number of our common shares in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares;
- sales or purchases of our common shares by our executive officers;

- issuance of additional shares of our common shares, or the perception that such issuances may occur, including through our "at-the-market" offering program;
- 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 liquidity of our common shares;
- investors' general perception of our company and our business;
- general political, economic, industry, and market conditions;
- effects of natural or man-made catastrophic events; 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 biotechnology and 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. 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 August 3, 2018 , RSL beneficially owns approximately 56.2% 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 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 covers us downgrades their investment recommendation on 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 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, including through our "at-the-market" equity offering program could depress our common 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 and through our "at-the market" equity offering program, 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 plan. In addition, we have filed an amended registration statement on Form S-3 under the Securities Act to register the offer and sale of up to an aggregate of $300.0 million of our securities, as well as the resale of up to 49,800 common shares held by Hercules, and in July 2018 sold 3,333,334 common shares under this registration statement. Sales of these common shares or the issuance of such securities may have an adverse effect on the trading price of our common shares. In addition, in the future we may issue additional 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.

In April 2018, we entered into an "at-the-market" sales agreement with Cowen and Company, LLC, or Cowen pursuant to which we may sell from time to time, common shares having an aggregate offering price of up to $100.0 million through Cowen, acting as our agent. Whether we choose to affect future sales under the "at-the-market" equity offering program will depend on a number of factors, including, among others, market conditions and the trading price of our common shares relative to other sources of capital. The issuance from time to time of common shares through our "at-the-market" equity offering program or in any other equity offering, or the perception that such sales may occur, could have the effect of depressing the market price of our common shares.

We have incurred and will continue to incur 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 accounting 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.

If we are unable to develop and maintain proper and effective internal control over financial reporting and disclosure controls and procedures, investor confidence in our company and, as a result, the value of our common shares, may be adversely affected.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting as of the end of each fiscal year. 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.

In addition, effective disclosure controls and procedures enable us to make timely and accurate disclosure of financial and non-financial information that we are required to disclose. If our disclosure controls and procedures are ineffective in the future, we may be unable to report our financial results or make other disclosures accurately on a timely basis, which could cause our reported financial results or other disclosures to be materially misstated and result in the loss of investor confidence and cause the market price of our common shares to decline.

We are an emerging growth company, and 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 30 th , 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 U.S., against us or our directors or officers under the securities laws of those jurisdictions or entertain actions in Bermuda against us or our directors or officers under the securities laws of other jurisdictions.

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

We are incorporated under the laws of Bermuda. As a result, our corporate affairs are governed by the Bermuda Companies Act 1981, as amended, 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 U.S., particularly the State of Delaware. Therefore, our shareholders may have more difficulty protecting their interests than would shareholders of a corporation incorporated in a jurisdiction within the U.S.

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

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

Our bye-laws enable our board of directors to issue preference shares, which may discourage a change of control.

Our bye-laws contain provisions that enable our board of directors to determine the powers, preferences, and rights of our preference shares and to issue the preference shares without shareholder approval.

This could discourage, delay or prevent a transaction involving a change in control of our company and may prevent our shareholders from receiving the benefit from any premium to the market price of our common shares offered by a bidder in a takeover context. Even in the absence of a takeover attempt, the existence of this provision may adversely affect the prevailing market price of our common shares if it is viewed as discouraging takeover attempts in the future.

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) could 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 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.

We and RSL, our principal shareholder, are incorporated under the laws of Bermuda. We currently have subsidiaries in the United Kingdom, Switzerland, Ireland, and the U.S. If we succeed in growing our business, we expect to conduct increased operations through our subsidiaries in various countries and tax jurisdictions, in part through intercompany service agreements between us, RSL, our controlling shareholder, and our subsidiaries. In that case, our corporate structure and intercompany transactions, including the manner in which we develop and use our intellectual property, will be organized so that we can achieve our business objectives in a tax-efficient manner and in compliance with applicable transfer pricing rules and regulations. If two or more affiliated companies are located in different countries or tax jurisdictions, the tax laws and regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arm's length and that appropriate documentation be maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable 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. If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arm's length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, potentially resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations, and cash flows.

In addition, tax laws are dynamic and subject to change as new laws are passed and new interpretations of the law are issued or applied. For example, the Tax Act was enacted in the United States, which introduced a comprehensive set of tax reforms. We continue to assess the impact of such tax reform legislation on our business and may determine that changes to our structure, practice or tax positions are necessary in light of the Tax Act. Certain impacts of this legislation have been taken into account, including the reduction of the U.S. corporate income tax rate from the previous 35 percent to 21 percent. The Tax Act in conjunction with the tax laws of other jurisdictions in which we operate, however, may require consideration of changes to our structure and the manner in which we conduct our business. Such changes may nevertheless be ineffective in avoiding an increase in our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

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

Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in Europe (including the United Kingdom and Switzerland), the U.S., Bermuda, and other jurisdictions, as well as being affected by certain changes currently proposed by the Organization for Economic Co-operation and Development and their action plan on Base Erosion and Profit Shifting. Such changes may become more likely as a result of recent economic trends in the jurisdictions in which we operate, particularly if such trends continue. If such a situation was to arise, it could adversely impact our tax position and our effective tax rate. Failure to manage the risks associated with such changes, or misinterpretation of the laws providing such changes, could result in costly audits, interest, penalties, and reputational damage, which could adversely affect our business, results of our operations, and our financial condition.

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

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

A non-U.S. corporation is considered a CFC if more than 50 percent of (1) the total combined voting power of all classes of stock of such corporation entitled to vote, or (2) the total value of the stock of such corporation, is owned, or is considered as owned by applying certain constructive ownership rules, by United States shareholders (U.S. persons who own stock representing 10% or more of the vote or, for taxable years of non-U.S. corporations beginning after December 31, 2017, and for taxable years of shareholders with or within which such taxable years of non-U.S. corporations end, 10% or more of the value) on any day during the taxable year of such non-U.S. corporation. Certain United States shareholders of a CFC generally are required to include currently in gross income such shareholders' share of the CFC's "Subpart F income", a portion of the CFC's earnings to the extent the CFC holds certain U.S. property, and a portion of the CFC's "global intangible low-taxed income" (as defined under Section 951A of the Code). Such United States shareholders are subject to current U.S. federal income tax with respect to such items, even if the CFC has not made an actual distribution to such shareholders. "Subpart F income" includes, among other things, certain passive income (such as income from dividends, interests, royalties, rents and annuities or gain from the sale of property that produces such types of income) and certain sales and services income arising in connection with transactions between the CFC and a person related to the CFC. "Global intangible low-taxed income" may include most of the remainder of a CFC's income over a deemed return on its tangible assets.

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

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. Additionally, a look-through rule generally applies with respect to 25% or more owned subsidiaries. If we are characterized as a PFIC, U.S. holders of our common shares may suffer adverse tax consequences, including having gains realized on the sale of our common shares treated as ordinary income rather than capital gain, the loss of the preferential tax rate applicable to dividends received on our common shares by individuals who are U.S. holders, and having interest charges apply to distributions by us and the proceeds of sales of our common shares.

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets from time to time. The 50% passive asset test described above is generally based on the fair market value of each asset, with the value of goodwill and going concern value determined in large part by reference to the market value of our common shares, which may be volatile. Our status may also depend, in part, on how quickly we utilize the cash proceeds from our IPO and subsequent financings in our business. With respect to the taxable year that ended on March 31, 2018, 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 our current taxable year ending March 31, 2019, we expect to implement 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

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds from Initial Public Offering

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

No offering expenses or proceeds 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.

We have used all of the net proceeds from our IPO primarily to fund the nonclinical and clinical development of relugolix and MVT-602, to expand our internal research and development capabilities, and for general corporate purposes.

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	Schedule / Form	File No.	Exhibit No.	Filing Date
3.1	Certificate of Incorporation.	S-1	333-213891	3.1	09/30/2016
3.2	Memorandum of Association.	S-1	333-213891	3.2	09/30/2016
3.3	Third Amended and Restated Bye-laws.	8-K	001-37929	3.1	02/09/2018
10.1	Sales Agreement, dated as of April 2, 2018, between Myovant Sciences Ltd. and Cowen and Company, LLC.	8-K	001-37929	1.1	04/03/2018
10.2	Share Purchase Agreement, dated as of April 2, 2018, between Myovant Sciences Ltd. and Roivant Sciences Ltd.	8-K	001-37929	99.1	04/03/2018
10.3†	Waiver and Amendment to the Securities Purchase Agreement, dated as of March 28, 2018, by and among the Registrant, Myovant Holdings Limited, Myovant Sciences GmbH, Myovant Sciences Ireland Limited, Myovant Sciences, Inc., the Purchasers (as defined therein) and NovaQuest Pharma Opportunities Fund IV, L.P.				
10.4†	Second Waiver and Amendment to the Securities Purchase Agreement, dated as of March 30, 2018, , dated October 16, 2017, by and among the Registrant, Myovant Holdings Limited, Myovant Sciences GmbH, Myovant Sciences Ireland Limited, Myovant Sciences, Inc., the Purchasers (as defined therein) and NovaQuest Pharma Opportunities Fund IV, L.P.				
10.5†*	Commercial Manufacturing & Supply Agreement, effective as of May 30, 2018, by and between Myovant Sciences GmbH and Takeda Pharmaceutical Company Limited.				
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				

†Filed herewith.
*Confidential treatment has been requested for portions omitted from this exhibit (indicated by asterisks) and those portions have been separately filed with the SEC.
** These certifications are being furnished solely to accompany this 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 Exchange Act, 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.

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: August 7, 2018

Exhibit 10.3

Execution Version

WAIVER AND
AMENDMENT TO SECURITIES PURCHASE AGREEMENT

This Waiver and Amendment to Securities Purchase Agreement (the " ***Waiver and Amendment*** ") is entered into as of the 28 th day of March 2018, by and among Myovant Sciences Ltd., an exempted company incorporated and organized under the laws of Bermuda (" ***Issuer*** "), Myovant Holdings Limited, a company incorporated in England and Wales with registered number 10317663 (" ***Myovant England*** "), Myovant Sciences GmbH, a limited liability company (*Gesellschaft mit beschränkter Haftung*) incorporated and organized under the laws of Switzerland (" ***Myovant Switzerland*** "), Myovant Sciences Ireland Limited, a private company limited by shares organized under the laws of Ireland with registered number 601541 (" ***Myovant Ireland*** "), Myovant Sciences, Inc., a Delaware corporation (" ***Myovant Delaware*** " and, together with Myovant England, Myovant Switzerland and Myovant Ireland, each a " ***Guarantor*** ", and together with Issuer, collectively, the " ***Note Parties*** "), the several banks and other financial institutions or entities from time to time parties to the Purchase Agreement (as defined below) (each referred to as a " ***Purchaser*** " and collectively referred to as " ***Purchasers*** "), and NOVAQUEST PHARMA OPPORTUNITIES FUND IV, L.P., a Cayman Islands exempted limited partnership, in its capacity as administrative agent and collateral agent for itself and Purchasers (in such capacity, the " ***Agent*** ").

W I T N E S S E T H

WHEREAS, the Note Parties, Agent and Purchasers have entered into that certain Securities Purchase Agreement dated as of October 16, 2017 (as the same may be amended, restated, supplemented or otherwise modified from time to time, the " ***Purchase Agreement*** "), pursuant to which Purchasers have agreed to purchase certain Notes from Issuer in accordance with the terms thereof; and

WHEREAS, clause (ii) of Section 2.01(b) of the Purchase Agreement states that "no Purchase Request shall be delivered and no Note shall be issued for a nominal principal amount of less than $1,000,000" (the " ***Minimum Issuance Amount*** "); and

WHEREAS, on October 30, 2017, Issuer issued to NovaQuest Pharma Opportunities Fund IV (Parallel), L.P. a Note with a nominal principal amount of $523,364.82 (the " ***Relevant Note*** "); and

WHEREAS, Section 11.03(b) of the Purchase Agreement provides that the Note Parties, the Agent and the Required Purchasers may, by written consent, (i) waive certain requirements of the Purchase Agreement and (ii) amend the Purchase Agreement; and

WHEREAS, the Note Parties, the Agent and the Required Purchasers desire to waive the Minimum Issuance Amount as applied to the Relevant Note; and

WHEREAS, the Note Parties, the Agent and the Required Purchasers' desire to amend the Purchase Agreement pursuant to this Waiver and Amendment to modify the minimum amount of any Purchase Request and the minimum denomination in which any Note may be issued; and

WHEREAS, the undersigned constitute all of the Note Parties, the Agent and the Required Purchasers.

NOW, THEREFORE, in consideration of the premises and of the mutual covenants, conditions and agreements set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows.

1. Defined Terms . Capitalized terms used herein (including in the preamble and recitals above) but not otherwise defined herein shall have the respective meanings ascribed to such terms in the Purchase Agreement.

2. Waiver . Subject to the terms and conditions of this Waiver and Amendment, Agent and the Required Purchasers hereby waive the Minimum Issuance Amount with regard to the Relevant Note. The foregoing waiver is a limited, one-time waiver and, except as expressly set forth herein, shall not be deemed to: (a) constitute a waiver of any other provision or Event of Default under the Purchase Agreement or any other Note Document, whether now existing or hereafter arising, (b) constitute a waiver of any right or remedy of Agent or any Purchaser under the Purchase Agreement or any other Note Document, or (c) establish a custom or course of dealing or conduct between Agent and Purchasers, on the one hand, and any Note Party on the other hand with respect to the waiver of any other provision under the Purchase Agreement or any other Note Document. The foregoing waiver shall not be deemed to constitute a consent of any other act, omission or any breach of the Purchase Agreement or any of the other Note Documents.

3. Amendment to Purchase Agreement . Subject to the satisfaction of the conditions precedent set forth herein, Section 2.01(b) of the Purchase Agreement is hereby deleted in its entirety and the following language is hereby substituted therefor:

> " **Purchase Request** . To request a Purchase, prior to the Note Purchase Commitment Termination Date, Issuer shall complete, sign and deliver a Purchase Request at least fifteen (15) Business Days before the requested Purchase Date to Agent. Each Purchaser shall purchase Notes in the manner requested by the Purchase Request; provided that (i) each of the conditions precedent to the issuance and sale of such Notes is satisfied as of the requested Purchase Date; (ii) no Purchase Request shall be delivered for an aggregate principal amount of less than $1,150,000; and (iii) no single Note shall be issued in a denomination of less than $100,000."

4. Conditions . The effectiveness of this Waiver and Amendment is subject to the satisfaction of the following conditions precedent:

(a) the execution and delivery of this Waiver and Amendment by the Note Parties, Agent and Required Purchasers, together with such other documents and instruments reasonably requested by Agent; and

(b) no Event of Default shall have occurred and be continuing.

5. No Modification . Except as expressly stated herein, the Agent and Purchasers reserve all rights, privileges and remedies under the Note Documents. Except as amended or consented to hereby, the Purchase Agreement and other Note Documents remain unmodified and in full force and effect. All references in the Note Documents to the Purchase Agreement shall be deemed to be references to the Purchase Agreement as amended hereby.

6. Successors and Assigns . The provisions of this Waiver and Amendment shall inure to the benefit of and be binding on each Note Party and its permitted assigns (if any), except that no Note Party shall assign its obligations hereunder or under any of the other Note Documents without Agent's express prior written consent, and any such attempted assignment shall be void and of no effect.

7. Governing Law . This Waiver and Amendment shall be governed by and construed under the laws of the State of New York, excluding conflict of laws principles that would cause the application of laws of any other jurisdiction.

8. Reaffirmation of Obligations . Each Note Party (a) acknowledges and consents to all of the terms and conditions of this Waiver and Amendment, (b) affirms all of its obligations under the Note Documents and (c) agrees that this Waiver and Amendment does not operate to reduce or discharge such Note Party's obligations under the Note Documents.

9. Reaffirmation of Security Interests . Each Note Party (a) affirms that each of the Liens granted in or pursuant to the Note Documents are valid and subsisting and (b) agrees that this Waiver and Amendment shall in no manner impair or otherwise adversely affect any of the Liens granted in or pursuant to the Note Documents.

10. Counterparts . This Waiver and Amendment may be executed in any number of counterparts, and by different parties hereto in separate counterparts, each of which when so delivered shall be deemed an original, but all of which counterparts shall constitute but one and the same instrument.

[Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have executed this Waiver and Amendment to Securities Purchase Agreement as of the day and year first above written.

ISSUER:

MYOVANT SCIENCES LTD.

Signature:	/s/ Frank Karbe
Print Name:	Frank Karbe
Title:	Principal Accounting Officer

GUARANTORS:

MYOVANT HOLDINGS LIMITED

Signature:	/s/ Evia Mary Soussi
Print Name:	Evia Mary Soussi
Title:	Director

in the presence of:

Witness Signature	/s/ Jason Reader
Print Name:	Jason Reader
Witness Address	First Floor, Templeback, 10 Templeback, Bristol, BS1 6F2

MYOVANT SCIENCES GMBH

Signature:	/s/ Marianne Romeo Dinsmore
Print Name:	Marianne Romeo Dinsmore
Title:	Director

SIGNED

for and on behalf of

MYOVANT SCIENCES IRELAND LIMITED

by its lawfully appointed attorney

David Pierce

Print name of Attorney

in the presence of:

/s/ Lonan Durand

Witness signature

/s/ David Pierce

Signature of Attorney

Lonan Durand

Print Name

3 Oaktree Lawn Carpenterstown Park, Castleknock D15

Print Address

Financial Controller

Witness Occupation

MYOVANT SCIENCES INC.

Signature:	/s/ Frank Karbe
Print Name:	Frank Karbe
Title:	CFO

[Signature Page to Waiver and Amendment to Securities Purchase Agreement]

AGENT:

NOVAQUEST PHARMA OPPORTUNITIES FUND IV, L.P.

By: NQ POF IV GP, L.P., its general partner

By: NQ POF IV GP, LTD, its general partner

Signature:	/s/ John L. Bradley, Jr.
Print Name:	John L. Bradley, Jr.
Title:	Director

PURCHASERS:

NOVAQUEST PHARMA OPPORTUNITIES FUND IV, L.P.

By: NQ POF IV GP, L.P., its general partner

By: NQ POF IV GP, LTD, its general partner

Signature:	/s/ John L. Bradley, Jr.
Print Name:	John L. Bradley, Jr.
Title:	Director

NOVAQUEST PHARMA OPPORTUNITIES FUND IV (PARALLEL), L.P.

By: NQ POF IV GP, L.P., its general partner

By: NQ POF IV GP, LTD, its general partner

Signature:	/s/ John L. Bradley, Jr.
Print Name:	John L. Bradley, Jr.
Title:	Director

Exhibit 10.4

SECOND WAIVER AND
AMENDMENT TO SECURITIES PURCHASE AGREEMENT

This Second Waiver and Amendment to Securities Purchase Agreement (the " ***Waiver and Amendment*** ") is entered into as of the 30th day of March 2018, by and among Myovant Sciences Ltd., an exempted company incorporated and organized under the laws of Bermuda (" ***Issuer*** "), Myovant Holdings Limited, a company incorporated in England and Wales with registered number 10317663 (" ***Myovant England*** "), Myovant Sciences GmbH, a limited liability company (*Gesellschaft mit beschränkter Haftung*) incorporated and organized under the laws of Switzerland (" ***Myovant Switzerland*** "), Myovant Sciences Ireland Limited, a private company limited by shares organized under the laws of Ireland with registered number 601541 (" ***Myovant Ireland*** "), Myovant Sciences, Inc., a Delaware corporation (" ***Myovant Delaware*** " and, together with Myovant England, Myovant Switzerland and Myovant Ireland, each a " ***Guarantor*** ", and together with Issuer, collectively, the " ***Note Parties*** "), the several banks and other financial institutions or entities from time to time parties to the Purchase Agreement (as defined below) (each referred to as a " ***Purchaser*** " and collectively referred to as " ***Purchasers*** "), and NOVAQUEST PHARMA OPPORTUNITIES FUND IV, L.P., a Cayman Islands exempted limited partnership, in its capacity as administrative agent and collateral agent for itself and Purchasers (in such capacity, the " ***Agent*** ").

W I T N E S S E T H

WHEREAS, the Note Parties, Agent and Purchasers have entered into that certain Securities Purchase Agreement dated as of October 16, 2017 (as the same may be amended, restated, supplemented or otherwise modified from time to time, the " ***Purchase Agreement*** "), pursuant to which Purchasers have agreed to purchase certain Notes from Issuer in accordance with the terms thereof; and

WHEREAS, clause (iii) of Section 2.01(f) of the Purchase Agreement states that "to the extent that the Notes have not been listed and admitted to trading on the BSX (or another recognized stock exchange within the meaning of Section 1005 Income Tax Act 2007) prior to the first scheduled interest payment date, the payment of any amount of interest which would have been due and payable on such date shall be deferred until the next Business Day after the second scheduled interest payment date (the "Initial Payment Extension Provision"); and

WHEREAS, on March 22, 2018, Issuer submitted its listing application to the BSX in full, but does not expect the listing to be admitted until up to fifteen days after the second scheduled interest payment date; and

WHEREAS, Section 11.03(b) of the Purchase Agreement provides that the Note Parties, the Agent and the Required Purchasers may, by written consent, (i) waive certain requirements of the Purchase Agreement and (ii) amend the Purchase Agreement; and

WHEREAS, the Note Parties, the Agent and the Required Purchasers desire to waive the Initial Payment Extension Provision and amend Section 2.01(f) (iii) to extend such provision by fifteen days; and

WHEREAS, the Note Parties, the Agent and the Required Purchasers desire to amend the Purchase Agreement pursuant to this Waiver and Amendment to modify the first date on which the payment of interest on the Notes must be paid; and

WHEREAS, the undersigned constitute all of the Note Parties, the Agent and the Required Purchasers.

NOW, THEREFORE, in consideration of the premises and of the mutual covenants, conditions and agreements set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows.

1. Defined Terms. Capitalized terms used herein (including in the preamble and recitals above) but not otherwise defined herein shall have the respective meanings ascribed to such terms in the Purchase Agreement.

2. Waiver. Subject to the terms and conditions of this Waiver and Amendment, Agent and the Required Purchasers hereby waive the Initial Payment Extension Provision to the extent the payment of any amount of interest would be due and payable on the next Business Day after the second scheduled interest payment date. The foregoing waiver is a limited, one-time waiver and, except as expressly set forth herein, shall not be deemed to: (a) constitute a waiver of any other provision or Event of Default under the Purchase Agreement or any other Note Document, whether now existing or hereafter arising, (b) constitute a waiver of any right or remedy of Agent or any Purchaser under the Purchase Agreement or any other Note Document, or (c) establish a custom or course of dealing or conduct between Agent and Purchasers, on the one hand, and any Note Party on the other hand with respect to the waiver of any other provision under the Purchase Agreement or any other Note Document. The foregoing waiver shall not be deemed to constitute a consent of any other act, omission or any breach of the Purchase Agreement or any of the other Note Documents.

3. Amendment to Purchase Agreement. Subject to the satisfaction of the conditions precedent set forth herein, Section 2.01(f)(iii) of the Purchase Agreement is hereby deleted in its entirety and the following language is hereby substituted therefor:

"(iii) is fifteen days after the second scheduled interest payment date."

4. Conditions. The effectiveness of this Waiver and Amendment is subject to the satisfaction of the following conditions precedent:

(a) the execution and delivery of this Waiver and Amendment by the Note Parties, Agent and Required Purchasers, together with such other documents and instruments reasonably requested by Agent; and

(b) no Event of Default shall have occurred and be continuing.

5. No Modification. Except as expressly stated herein, the Agent and Purchasers reserve all rights, privileges and remedies under the Note Documents. Except as amended or consented to hereby, the Purchase Agreement and other Note Documents remain unmodified and in full force and effect. All references in the Note Documents to the Purchase Agreement shall be deemed to be references to the Purchase Agreement as amended hereby.

6. Successors and Assigns. The provisions of this Waiver and Amendment shall inure to the benefit of and be binding on each Note Party and its permitted assigns (if any), except that no Note Party shall assign its obligations hereunder or under any of the other Note Documents without Agent's express prior written consent, and any such attempted assignment shall be void and of no effect.

7. Governing Law. This Waiver and Amendment shall be governed by and construed under the laws of the State of New York, excluding conflict of laws principles that would cause the application of laws of any other jurisdiction.

8. Reaffirmation of Obligations. Each Note Party (a) acknowledges and consents to all of the terms and conditions of this Waiver and Amendment, (b) affirms all of its obligations under the Note Documents and (c) agrees that this Waiver and Amendment does not operate to reduce or discharge such Note Party's obligations under the Note Documents.

9. Reaffirmation of Security Interests . Each Note Party (a) affirms that each of the Liens granted in or pursuant to the Note Documents are valid and subsisting and (b) agrees that this Waiver and Amendment shall in no manner impair or otherwise adversely affect any of the Liens granted in or pursuant to the Note Documents.

10. Counterparts . This Waiver and Amendment may be executed in any number of counterparts, and by different parties hereto in separate counterparts, each of which when so delivered shall be deemed an original, but all of which counterparts shall constitute but one and the same instrument.

[Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have executed this Waiver and Amendment to Securities Purchase Agreement as of the day and year first above written.

ISSUER:

MYOVANT SCIENCES LTD.

Signature:	/s/ Frank Karbe
Print Name:	Frank Karbe
Title:	Principal Accounting Officer

GUARANTORS:

MYOVANT HOLDINGS LIMITED

Signature:	/s/ Evia Mary Soussi
Print Name:	Evia Mary Soussi
Title:	Director

in the presence of:

Witness Signature	/s/ Jason Reader
Print Name:	Jason Reader
Witness Address	First Floor, Templeback, 10 Templeback, Bristol, BS1 6F2

MYOVANT SCIENCES GMBH

Signature:	/s/ Marianne Romeo Dinsmore
Print Name:	Marianne Romeo Dinsmore
Title:	Director

SIGNED

for and on behalf of

MYOVANT SCIENCES IRELAND LIMITED

by its lawfully appointed attorney

David Pierce

Print name of Attorney

in the presence of:

/s/ Lonan Durand

Witness signature

/s/ David Pierce

Signature of Attorney

Lonan Durand

Print Name

3 Oaktree Lawn Carpenterstown Park, Castleknock D15

Print Address

Financial Controller

Witness Occupation

MYOVANT SCIENCES INC.

Signature:	/s/ Frank Karbe
Print Name:	Frank Karbe
Title:	CFO

[Signature Page to Waiver and Amendment to Securities Purchase Agreement]

AGENT:

NOVAQUEST PHARMA OPPORTUNITIES FUND IV, L.P.

By: NQ POF IV GP, L.P., its general partner

By: NQ POF IV GP, LTD, its general partner

Signature:	/s/ Ronald J. Wooten
Print Name:	Ronald J. Wooten
Title:	Director

PURCHASERS:

NOVAQUEST PHARMA OPPORTUNITIES FUND IV, L.P.

By: NQ POF IV GP, L.P., its general partner

By: NQ POF IV GP, LTD, its general partner

Signature:	/s/ Ronald J. Wooten
Print Name:	Ronald J. Wooten
Title:	Director

NOVAQUEST PHARMA OPPORTUNITIES FUND IV (PARALLEL), L.P.

By: NQ POF IV GP, L.P., its general partner

By: NQ POF IV GP, LTD, its general partner

Signature:	/s/ Ronald J. Wooten
Print Name:	Ronald J. Wooten
Title:	Director

Exhibit 10.5
EXECUTION COPY

COMMERCIAL MANUFACTURING & SUPPLY AGREEMENT

BY AND BETWEEN

TAKEDA PHARMACEUTICAL COMPANY LIMITED

AND

MYOVANT SCIENCES GMBH

DATE: MAY 30, 2018

[***] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

COMMERCIAL MANUFACTURING & SUPPLY AGREEMENT

This Commercial Manufacturing & Supply Agreement (the " **Agreement** ") is made effective as of May 30, 2018 (the " **Effective Date** ") by and between **Takeda Pharmaceutical Company Limited** , a company having its principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan (" **Takeda** ") and **Myovant Sciences GmbH** , a company having its principal place of business at Viaduktstrasse 8, 4051 Basel, Switzerland (" **Myovant** "). Myovant and Takeda are sometimes referred to herein individually as a " **Party** " and collectively as the " **Parties** ."

RECITALS

WHEREAS, Takeda's Affiliate, Takeda Pharmaceuticals International AG (" **TPIZ** ") and Myovant Parent (as defined below), Myovant Sciences Ltd. (f/k/a Roivant Endocrinology Ltd.) (" **Myovant Ltd.** "), are parties to that certain License Agreement dated April 29, 2016 (" **License Agreement** ") pursuant to which TPIZ granted to Myovant Ltd. a license in the Licensee Territory and the Takeda Territory (as defined in the License Agreement) under certain patents, patent applications, know-how and other proprietary information for the further Development and Commercialization of the TAK-385 Licensed Products in accordance with the terms and conditions set forth in the License Agreement;

WHEREAS , the Parties entered into that certain Letter of Intent (the " **Letter of Intent** ") as of March 9, 2018 regarding the procurement by Myovant of the Drug Substance (as defined herein), as manufactured by Takeda at the [***] (as defined herein) and supplied to Myovant; and

WHEREAS , in accordance with the License Agreement and the terms and conditions set out below, Takeda, on behalf of TPIZ, now agrees to provide certain quantities of Drug Substance and Myovant agrees to receive from Takeda certain quantities of Drug Substance in order to Commercialize the TAK-385 Licensed Product, as further described below.

NOW, THEREFORE, and in consideration of the mutual covenants contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

ARTICLE 1
DEFINITIONS

The following capitalized terms used in this Agreement shall have the meanings specified below; and all other capitalized terms used but not otherwise defined in this Agreement shall have their respective meanings set forth in the License Agreement, provided that solely with respect to such terms in the License Agreement, (i) all references to "Licensee" and "Takeda" in such other capitalized terms shall be deemed to refer to Myovant and Takeda hereunder (respectively) and all references to "Affiliate" in any such capitalized terms shall refer to "Affiliate" as defined below, (ii) all references to a "Party" and the "Parties" in any such capitalized terms shall be deemed to refer to a Party and the Parties hereunder (respectively), (iii) all references to the "Effective Date" and the "Agreement" in any such capitalized terms shall be deemed to refer to the Effective Date hereunder and this Agreement (respectively), (iv) all references to the "Term" in any such capitalized terms shall be deemed to refer to the Term hereunder. For convenience, a glossary of such capitalized terms from the License Agreement that are used herein, as excerpted and redacted for the purposes hereof, is attached hereto as Exhibit D ; provided, however, that if there is any inadvertent conflict between the terms on such Exhibit D and the same terms in the License Agreement, the terms in the License Agreement shall control unless the context duly requires otherwise.

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

[***] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

1.2 " **Batch Documentation** " means the documentation provided to Myovant or the Qualified Designee (as defined below) at the time of delivery of Drug Substance, as agreed upon by the Parties in the Quality Agreement or as required by Applicable Laws.

1.3 " **Detectable Defect** " shall have the meaning set forth in Section 9.1 hereof.

1.4 " **Drug Product** " means a final, packaged or unpackaged pharmaceutical product for use solely for administration to humans consisting of any TAK-385 Licensed Product. For clarity, such pharmaceutical product under the Takeda Clinical Manufacturing and Supply Agreement shall not be included herein.

1.5 " **Drug Substance** " means the active pharmaceutical ingredient for the chemical compound coded by Takeda as TAK-385, the structure of which is set forth on Schedule 1.138 of the License Agreement, with the Specifications (as defined below), and is Manufactured pursuant to Section 7.1 hereof. For clarity, such pharmaceutical ingredient under the Takeda Clinical Manufacturing and Supply Agreement shall not be included herein.

1.6 " **Excluded Affiliate** " means (a) any Myovant Parent Affiliate (as defined below) or (b) any direct or indirect subsidiary of a Myovant Parent Affiliate, other than any Myovant Parent (as defined below), that (i) is controlled (as defined in Section 1.1 hereof) by such Myovant Parent Affiliate but is not controlled by Myovant or any Myovant Parent and (ii) is established for the development and commercialization of compounds and products other than the Licensed Compounds and Licensed Products.

1.7 " **Firm Order** " is defined in Section 6.1.2(b) hereof.

1.8 " **Firm Order Period** " is defined in Section 6.1.2(b) hereof.

1.9 **"Fiscal Year"** or **"FY"** means a twelve (12) month period ending on March 31 st in a given Calendar Year of the Term; *provided, however,* that (a) the first Fiscal Year of the Term shall begin on the Effective Date and end on March 31 st , 2019; and, (b) the last Fiscal Year of the Term shall end upon the expiration or termination of this Agreement.

1.10 " **FTE Rate** " is defined in Schedule 4.2.3 hereto.

1.11 "[***]" means the Manufacturing facility of Drug Substance operated by Takeda and located in [***].

1.12 " **Initial Firm Order** " is defined in Section 6.1.2(a) hereof.

1.13 " **Initial Firm Order Period** " is defined in Section 6.1.2(a) hereof.

1.14 " **JPY** " means Japanese Yen.

1.15 " **Myovant Parent** " means any Person of which Myovant is a wholly owned subsidiary. For clarity, as of the Effective Date, the Myovant Parent is Myovant Sciences Ltd.

1.16 " **Myovant Parent Affiliate** " means any Person that controls (as defined in Section 1.1 hereof) the Myovant Parent, including, as of the Effective Date, Roivant Sciences Ltd.

1.17 "[***]" means that certain compound or substance as further described in Schedule 1.17 hereto including its specifications.

1.18 " **Permits** " means any licenses, permits, registrations, certifications or other approvals from a Governmental Authority as needed for the Manufacturing of Drug Substance at the [***] hereunder.

1.19 " **Project Work Order** " shall have the meaning set forth in Section 12.1 hereof.

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1.20 " **Qualified Designee** " means any Sublicensee or Subcontractor, including a contract manufacturing organization duly engaged by Myovant to Manufacture the Drug Substance for Myovant (" **CMO** ").

1.21 " **Quality Agreement** " means the Quality Assurance Agreement between the Parties for the supply of Drug Substance under this Agreement to be entered into in accordance with Section 7.5 hereof.

1.22 " **Quality Release** " means certification by Takeda's quality control department that Drug Substance Manufactured by or on behalf of Takeda complies with the Quality Agreement and Takeda's quality release specifications as confirmed by release testing.

1.23 " **Specifications** " means the specifications for the design, composition, Manufacture, packaging, and/or quality control of the Drug Substance, as set forth in Exhibit A attached hereto, which may be duly amended from time-to-time.

1.24 " **Subcontractor** " means, with respect to a Party, any consultant, subcontractor, distributor, co-promotion partner, or other vendor engaged by such Party to conduct its obligations under this Agreement, the Quality Agreement and/or the License Agreement.

1.25 " **Technical Support Services** " shall have the meaning set forth in Section 12.1 hereof.

ARTICLE 2
DRUG SUBSTANCE SUPPLY; GOVERNANCE

2.1 Purchase and Supply. Subject to the terms and conditions set forth in this Agreement, the License Agreement and the Quality Agreement, Takeda shall supply to Myovant, and Myovant shall obtain from Takeda, certain quantities of Drug Substance under this Agreement. Except as otherwise provided in the License Agreement: (a) Myovant shall, and shall ensure that its Affiliates and Qualified Designees, use the Drug Substance only in the Field in the Licensee Territory, and (b) Myovant shall not, and shall not permit its Affiliates and Qualified Designees to, use the Drug Substance directly or indirectly (i) in the Takeda Territory, or (ii) in a manner that is reasonably likely to directly or indirectly enable a Third Party to use the Drug Substance in contravention of subsection (i) above. For clarity, Myovant may at its sole cost and responsibility, use, sell or otherwise transfer to any Third Party the Drug Substance supplied hereunder, or any Drug Product that incorporates such Drug Substance, as necessary to duly satisfy the applicable requirements of Myovant, its Affiliates and Qualified Designees in connection with the performance of Manufacture, Development or Commercialization of Drug Product in the Field in the Licensee Territory as authorized under the License Agreement.

2.2 Governance.

2.2.1 Role of the JRC . The JRC shall oversee all activities under this Agreement, including under the Quality Agreement. For purposes of such oversight, each Party may designate appropriate ad hoc personnel, including from quality and regulatory functions, to attend meetings of the JRC in a non-voting capacity and in accordance with Section 2.3.1 of the License Agreement.

2.3 Joint Manufacturing Working Group.

2.3.1 Establishment; Responsibilities. The Parties have established, under the License Agreement, a joint manufacturing working group (the " **Joint Manufacturing Working Group** " or " **JMWG** "), which shall have, with respect to this Agreement, the responsibilities set forth in this Section 2.3. For clarity, Section 4.1 of the License Agreement and the "Transition Plan" described therein shall remain in full force and effect for Licensed Compounds including the Drug Substance under this Agreement; *provided, however* , that the disclaimers set forth in Section 4.2.2 (Takeda Materials Disclaimer) of the License Agreement will not negate any express warranties made by Takeda in this Agreement. The JMWG shall be responsible for overseeing, reviewing and coordinating activities related to the supply of Drug Substance under this Agreement and operational decisions with respect thereto, including as follows:

(a) The implementation of activities under the Drug Substance Transition Plan (as defined below);

(b) The creation of the Gain-sharing Report and implementation of changes described therein, as set forth in Section 7.3 (Continuous Improvement) hereof.

For clarity, the JMWG shall have no authority to amend or waive compliance with any provision of this Agreement.

2.3.2 JMWG Membership. Promptly after the Effective Date, each Party will designate at least one (1) representative for the JMWG and provide the other Party with written notice of such representative; provided that (a) a Party may designate additional representatives to the extent such Party reasonably determines that the matters coming before the JMWG require additional subject matter expertise and (b) each Party will at all times have equal numbers of representatives on the JMWG. Either Party may designate substitutes for its JMWG representative(s) if one (1) or more of such Party's designated representatives is unable to be present at a meeting. From time to time during the Term, each Party may replace its JMWG representative(s) by written notice to the other Party specifying the prior representative and their replacement.

2.3.3 Meetings; Expenses. Unless otherwise agreed by the JMWG, the JMWG will meet [***] until the First Commercial Sale of the first Drug Product. After such First Commercial Sale of the first Drug Product and during the remainder of the Term, unless otherwise agreed by the JMWG, the JMWG will meet [***]. Additional meetings of the JMWG may be held with the consent of each Party (such consent not to be unreasonably withheld, conditioned, or delayed). In the case of any dispute referred to the JMWG, such meeting will be held within [***] Business Days following referral to the JMWG, or as soon as reasonably possible. The JMWG may meet either (a) in person at either Party's facilities or at such locations as the Parties may otherwise agree or (b) by teleconference or videoconference. Additional non-members of the JMWG having relevant experience may from time to time be invited to participate in a JMWG meeting. Non-member employees of a Party or its Affiliates will only be allowed to attend if: (i) the other Party's representatives have consented to the attendance (such consent not to be unreasonably withheld, conditioned, or delayed); and (ii) such non-employee participant is subject to written confidentiality and non-use obligations substantially similar as those set forth in this Agreement. Each Party will be responsible for all of its own expenses incurred in connection with participating in any such JMWG meetings, including all travel and all expenses associated therewith. The Parties will share equally any Third Party expenses reasonably incurred in connection with an off-site JMWG meeting (*e.g.* , fees for a meeting room out of the Parties' facilities).

2.3.4 JMWG Decisions. The JMWG will use good faith efforts to reach unanimous agreement with respect to all matters within the JMWG's authority in accordance with Section 2.3.1 hereof. Should the JMWG not be able to reach agreement with respect to any such matter, then such matter shall be referred to the JRC. For clarity, any member of the JMWG shall, after the conclusion of such good faith efforts, have the authority to refer to the JRC any matter properly before the JMWG for which no agreement has been reached after such good faith efforts.

2.3.5 Contact Persons. Each Party will appoint a person who will oversee contact between the Parties for all matters relating to this Agreement (each, a " **Contact Person** "), which person may be replaced at any time upon written notice to the other Party. Each Contact Person will work together to manage and facilitate the communication between the Parties under this Agreement. The Contact Persons will not have decision-making authority with respect to any matter under this Agreement.

ARTICLE 3
PRICE

3.1 Price . Myovant shall pay Takeda for the price for Drug Substance as follows in Section 3.1.1 and Section 3.1.2 hereof:

3.1.1 [***] . Without prejudice to Section 6.1.2 hereof, and in addition to any fees and costs reasonably accrued to or incurred by Takeda in accordance with Section 6.1.4(b) hereof, Myovant shall pay Takeda an amount of the price intended to [***] and used to Manufacture the Drug Substance for Myovant under this Agreement for its Commercialization of Drug Product under the License Agreement, as follows:

(a) **[***]** . For the Drug Substance to be delivered to Myovant, its Affiliates or their Qualified Designees during the Term on or before [***] i.e., such Drug Substance under the Letter of Intent, Myovant shall pay Takeda a fixed amount of [***] of Drug Substance for such [***] used to Manufacture such Drug Substance as set forth in Schedule 3.1 hereto.

(b) **[***]** . For the Drug Substance to be delivered to Myovant, its Affiliates or their Qualified Designees [***] Myovant shall pay Takeda a fixed amount of [***] of Drug Substance for such [***] used to Manufacture such Drug Substance as set forth in Schedule 3.1 hereto.

(c) **[***]** . For the Drug Substance to be delivered to Myovant, its Affiliates or their Qualified Designees during the Term on or after [***] Myovant shall pay Takeda that certain amount intended to [***] *provided, however,* that: (i) Takeda shall use its commercially reasonable efforts to [***] (ii) [***] shall not be [***] under substantially similar terms and conditions, [***] and (iii) [***] in the Manufacture of Drug Substance under this Agreement.

(d) **[***]** . With respect to all Drug Substance delivered under this Agreement, the amounts that Myovant is obligated to pay under this Section 3.1.1 for such Drug Substance are based solely on [***].

3.1.2 Drug Substance Manufacturing by Takeda . In consideration for all other Manufacturing activities performed and materials [***] used by Takeda or its Affiliates in the Manufacture of Drug Substance under this Agreement, including [***] Myovant shall pay Takeda an amount of the price for Drug Substance to be delivered to Myovant, its Affiliates or their Qualified Designees under this Agreement pursuant to the corresponding Purchase Order in accordance with Section 6.1.3 hereof, which shall be subject to the applicable Firm Order in accordance with Section 6.1.2 hereof, as follows:

(a) **[***]** . For the Drug Substance to be delivered to Myovant, its Affiliates or their Qualified Designees during the Term on or before [***] i.e., such Drug Substance under the Letter of Intent, an amount of [***] of such Drug Substance as set forth in Schedule 3.1 hereto.

(b) **[***]** . For the Drug Substance to be delivered to Myovant, its Affiliates or their Qualified Designees during the Term between [***] Myovant shall pay Takeda a fixed amount of [***] of such Drug Substance as set forth in Schedule 3.1 hereto.

(c) **[***]** . **and Thereafter** : For the Drug Substance to be delivered to Myovant, its Affiliates or the Qualified Designee during the Term on or after [***], that certain amount of the price per kilogram of such Drug Substance; *provided, however,* that: (i) Takeda shall use its commercially reasonable efforts to [***] and, (ii) on or before [***], the Parties will review such price and renegotiate in good faith an increase or decrease therein as reasonably needed. For clarity, there shall be no change to the price under this Section 3.1.2(c) except pursuant to a mutual written amendment or a substitution of Schedule 3.1 hereto, in each case in accordance with Section 19.13 hereof.

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3.2 Invoicing. Takeda shall submit to Myovant an invoice for the Drug Substance upon delivery thereof to Myovant hereunder. In addition, Takeda shall send each such invoice to: [***]. Each invoice shall be accompanied by the following information: an applicable Purchase Order number(s), [***] for each of the foregoing in accordance with Section 3.1 hereof, and [***] in each case, in accordance with this Agreement. Without limiting the generality of the foregoing, each invoice so submitted to Myovant shall be accompanied by [***], and any other payment information or documentation with respect to the [***] as reasonably needed, available, and permitted to do so. Myovant shall pay such invoices in accordance with Article 13 hereof.

3.3 Currency; Exchange Rate. The prices as referred to in Sections 3.1.1(a) and 3.1.2(a) hereof; and those in Sections 3.1.1(b) and 3.1.2(b) hereof, are set given the prevailing [***] exchange rate [***] announced by [***] on: [***] and thereafter, on [***] (or, in the case of bank holiday, the first regular business day thereof) [***]. Except as otherwise agreed on by the Parties in writing, any impact on such prices due to the currency fluctuation of more than [***] from the applicable Base Exchange Rate, as measured at the time payment is due under this Agreement, shall be [***] borne and duly settled by both Parties.

ARTICLE 4
TECHNOLOGY TRANSFER

4.1 General. For the purposes of technology transfer process described in Section 4.2 of the License Agreement with respect to Drug Substance, this ARTICLE 4 sets forth the rights and duties of the Parties to provide technology transfer services with respect to the Manufacture of Drug Substance. For clarity, Section 4.2 of the License Agreement shall remain in full force and effect.

4.2 Technology Transfer.

4.2.1 Transition Plan . In accordance with the transition plan attached hereto as Exhibit B (the " **Drug Substance Transition Plan** "), as may be amended or modified by the Parties from time to time upon mutual written agreement, Takeda shall use reasonable efforts to make available to Myovant's initial CMO all Takeda Know-How [***] that is reasonably necessary or useful to enable the Manufacture of Drug Substance up until the successful completion of the applicable process validation protocol for such CMO to Myovant's reasonable satisfaction (the **"Transition Completion"**), including without limitation all Inventions and other improvements to the Manufacture of Drug Substance discovered or developed in connection with this Agreement, by or on behalf of Myovant (the " **Takeda Manufacturing Know-How** "), by providing copies or samples of relevant documentation, materials, and other embodiments of such Takeda Manufacturing Know-How, including data within reports, notebooks, and electronic files. Takeda shall perform the tasks and deliver each deliverable pursuant to the Drug Substance Transition Plan. If the Parties disagree on the occurrence of Transition Completion, then either Party may refer such disagreement to the JRC for a final determination that shall be binding on both Parties in accordance with the terms of License Agreement as applicable. Except as otherwise expressly specified in the Drug Substance Transition Plan, Takeda shall be permitted to make such Takeda Manufacturing Know-How available in such form as Takeda determines in its sole reasonable discretion, including, if Takeda so elects, in the form such Takeda Manufacturing Know-How is maintained by Takeda. If reasonably requested by Myovant or such Qualified Designee, Takeda may translate any Takeda Manufacturing Know-How into English as part of the Transition Services to be performed by Takeda in accordance with Section 4.2.3 hereof. For clarity, Takeda shall be only required to perform the activities set forth in the Drug Substance Transition Plan with respect to Myovant or such Qualified Designee. If Myovant wishes to transfer the Takeda Know-How to any other Qualified Designee, then Myovant (and its initial Qualified Designee) shall be solely responsible for such technology transfer thereto; *provided, however,* that if Myovant reasonably requests Takeda's assistance, Takeda may provide such assistance as far as reasonably needed and available to Takeda. In any event, all the technology transfer services conducted by Takeda hereunder shall be at Myovant's sole cost and expense.

4.2.2 Takeda Materials . Any materials, including [***] provided by Takeda in connection with the transfer of the Takeda Manufacturing Know-How hereunder (the " **Takeda Materials** ") shall remain the sole property of Takeda. Subject to the foregoing and any other obligations as applicable hereunder and the License Agreement, Myovant may, in connection with transferring the Takeda Manufacturing Know-How to any Qualified Designee, transfer Takeda Materials thereto; *provided, however* , that Myovant shall (a) itself retain legal control of all such Takeda Materials, including, but not limited to, the right to require any Qualified Designee to return all such Takeda Materials to Myovant at Myovant's request, (b) use such Takeda Materials only in the fulfillment of obligations or exercise of rights under this Agreement, including, but not limited to, to transfer the Takeda Manufacturing Know-How to Qualified Designees, (c) not use such Takeda Materials or deliver the same to, or for the benefit of, any Third Party (other than Qualified Designees), without Takeda's prior written consent, and (d) not use such Takeda Materials in research or testing involving human subjects except as expressly provided under this Agreement or the License Agreement.

4.2.3 Transition Services. Takeda shall perform certain services to facilitate the technology transfer described in Section 4.2.1 hereof in accordance with the Drug Substance Transition Plan (the " **Transition Services** "). Myovant shall reimburse Takeda as described on Schedule 4.2.3 hereto for all internal costs, and external costs, charges, and expenses, in each case, reasonably incurred by Takeda in connection with any Transition Services requested by Myovant and agreed to by Takeda, including, but not limited to, those so incurred heretofore. For clarity, the FTE Rate set forth in such Schedule shall be applicable only under this Agreement, and shall not be construed to amend any terms of the FTE and FTE Rate in the License Agreement whatsoever and howsoever. Myovant shall be responsible for any Third Party expenses incurred by either Party in connection with the Transition Services. Takeda shall invoice Myovant for any reimbursement for any Transition Services to which it is entitled under this Section 4.2.3 [***], and Myovant shall pay all invoices submitted by Takeda within [***] of the date of receipt of the invoice. Myovant stipulates that such cooperation shall not require Takeda to conduct any research or Development activities.

4.2.4 Additional Transition Services . With respect to any Transition Services outside the scope of the Drug Substance Transition Plan, at the reasonable written request of Myovant, Takeda shall negotiate in good-faith, and may (in any event, shall not be obligated, but will not unreasonably refuse, to) provide such additional Transition Services, as reasonably needed and available, in order to support transfer of Manufacturing technology and additional Takeda Materials, including without limitation by providing documentation, information and other materials reasonably available and necessary for the Manufacture of Drug Substance or taking any action(s) reasonably available and necessary to comply with any request or demand of any Regulatory Authority, to Myovant or the Qualified Designees (" **Additional Transition Services** "). For clarity, Takeda shall not be obligated (but will not unreasonably refuse) to conduct hereunder any experiments and studies whatsoever for the data and information on the Drug Substance not available to Takeda then. Myovant shall reimburse Takeda for such Additional Transition Services under the same terms as provided in Section 4.2.3 hereof. At the reasonable written request of Myovant for any Additional Transition Services for the transfer of documentation, information and other materials reasonably available and necessary for the Manufacture of Drug Product, further, the Parties shall negotiate in good-faith, and may (as for Takeda, in any event, shall not be obligated to) enter into a subsequent transition plan therefor (the " **Drug Product Transition Plan** "). The Drug Product Transition Plan so entered shall set forth the timelines, obligations, deliverables and other duties of each Party with respect to the transfer of Takeda Materials reasonably available and necessary for the Manufacture of Drug Product. In any event, Takeda shall not be required to conduct any of the Additional Transition Services hereunder for [***].

4.2.5 Improvements to Manufacturing Technology. Subject to the applicable terms and conditions of the License Agreement, among others, those in its Article 10 (Intellectual Property Matters) and Sections 13.1 (Term) and 13.13 (Survival), during the Term and thereafter, each Party shall promptly disclose to the other Party in writing any [***] relating to the Manufacture of Drug Substance, including pursuant to Section 7.3 hereof (such [***], the " **Manufacturing Improvements** "), including with each such notice a detailed technical description and a summary of the potential costs and benefits of such Manufacturing Improvements. Promptly upon receipt of such notice, the Parties shall in good faith discuss whether such Manufacturing Improvement(s) should be implemented by the disclosing Party and, upon the other Party's request, a process to transfer such Manufacturing Improvement(s) to such other Party at the cost and expense of such other Party in accordance with Section 4.2.3 hereof (in the case of a transfer from Myovant to Takeda, such provisions shall apply *mutatis mutandis*). For clarity, Takeda may in its sole reasonable discretion, implement any of such Manufacturing Improvements as needed to conduct the Manufacture of TAK-385 Licensed Compound and/or TAK-385 Licensed Product for the Development and Commercialization thereof in Takeda Territory, subject to the terms and conditions of change control as applicable to the Drug Substance under the Quality Agreement.

ARTICLE 5
REGULATORY ACTIVITIES AND RESPONSIBILITIES

5.1 General Obligations of Takeda. Takeda shall, or shall cause its Affiliates or Third Parties on its behalf to, (a) perform its obligations under this Agreement in compliance with all Applicable Laws, including all GMPs, and in accordance with the Quality Agreement, (b) undertake all regulatory activity with respect to the Manufacture of the Drug Substance hereunder, including components thereof, such as the [***], in accordance with the License Agreement (among others, its Sections 6.1 (Regulatory Materials and Regulatory Approvals), 6.2 (Regulatory Cooperation), 7.1 (Commercialization Responsibilities) and 7.2 (Commercialization Diligence Obligations), given its Section 5.2 (Development Diligence Obligations)) and as otherwise required by Applicable Laws or Regulatory Authorities. Subject to any other terms of this Agreement as applicable, including those in Section 7.2 (Modifications) hereof, Takeda shall be responsible for obtaining and maintaining all Permits and fees required by any Regulatory Authority with respect to any Takeda Manufacturing facility where any aspect of the Drug Substance is Manufactured hereunder.

5.2 General Obligations of Myovant. Other than Takeda's responsible Permits and fees related to Takeda's Manufacturing facilities pursuant to Section 5.1 hereof, Myovant shall obtain and maintain at its expense during the Term all permits as well as all Regulatory Approvals required for Myovant to use the Drug Substance in accordance with the License Agreement and fulfill its obligations under this Agreement and the Quality Agreement. Myovant shall, and shall ensure that its Affiliates, Sublicensees and Subcontractors: (a) comply with the requirements and restrictions of any permits and other Applicable Laws applicable to the use of the Drug Substance in accordance with the License Agreement; (b) use the Drug Substance in compliance with Applicable Laws; and (c) comply with Myovant's obligations under this Agreement.

5.3 Communication with Regulatory Authorities. Notwithstanding anything to the contrary in the License Agreement, including but not limited to Article 6 therein, or the Quality Agreement, Takeda shall promptly notify Myovant following receipt by Takeda of any regulatory inquiry or communication, or the occurrence of any inspection, regarding the Manufacture of Drug Substance in compliance with GMP. If Takeda or its Affiliate(s) or Subcontractor(s) receive notice of an inspection or an inspection visit by any Governmental Authority that directly involves Drug Substance or is likely to materially impact Takeda's ability to supply Drug Substance to Myovant hereunder, Takeda shall give Myovant prompt written notification thereof (but in no event later than [***] after Takeda receives such notice) and Takeda shall provide Myovant with copies of applicable documentation with respect thereto, and Myovant shall have a reasonable opportunity to review and comment on Takeda's proposed response; *provided, however,* that Myovant's opportunity to review and comment shall not be extended so as to cause any response of Takeda to be later than is required by such Governmental Authority. Unless prohibited by Applicable Law, Takeda shall allow a representative of Myovant to be present at and observe any inspection by any Governmental Authority concerning Drug Substance. All other communications with Regulatory Authorities, including without limitations any regulatory audits, shall be governed by the License Agreement and Quality Agreement.

[***] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

ARTICLE 6
FORECASTING AND ORDERING

6.1 Forecasts and Purchase Orders.

6.1.1 Forecasts. Not later than [***] of the Effective Date of this Agreement, Myovant shall submit to Takeda, Myovant's forecast for its desired quantities of the Drug Substance to be delivered to Myovant on a Calendar Quarter-by-Calendar Quarter basis for the first proceeding [***] full Calendar Quarters of the Term (the " **Initial Rolling Forecast** "). No later than the [***] Business Day of each Calendar Quarter during the remainder of the Term, Myovant shall provide to Takeda a rolling forecast for the then proceeding [***] Calendar Quarters (the Initial Rolling Forecast and each such subsequent forecast, a " **Rolling Forecast** "). Myovant shall submit each Rolling Forecast to the addressee of contact for Takeda listed in Schedule 6.1.1 hereto, which addressee Takeda may change by providing a written notice to Myovant from time to time during the Term. The Rolling Forecast shall set forth the desired quantity of Drug Substance in full lot increments or decrements.

6.1.2 Binding Quantities.

(a) **Initial Firm Order.** Myovant shall order and hereby orders, and Takeda shall supply to Myovant, the Drug Substance set forth on Schedule 6.1.2(a) (the " **Initial Firm Order** "), which sets forth the quantities of Drug Substance to be delivered through the [***] (such period, the " **Initial Firm Order Period** "). Notwithstanding anything in this Agreement to the contrary, Takeda hereby irrevocably accepts the Initial Binding Order.

(b) **Subsequent Firm Orders.** After the Initial Firm Order Period, the first [***] of each Rolling Forecast for Drug Substance submitted by Myovant (the Initial Firm Order Period and each such subsequent period, as applicable, a " **Firm Order Period** ") shall be, unless Takeda otherwise notifies Myovant not later than [***] Business Days after Takeda's actual receipt thereof, binding upon Myovant and Takeda, and shall constitute a firm order (the Initial Firm Order and each such subsequent firm order, a " **Firm Order** "). For clarity, the Rolling Forecast issued in accordance with Section 6.1.1 on the [***]. The remainder of each Rolling Forecast that is not within the Firm Order Period shall be non-binding upon Myovant and Takeda, and may be changed by Myovant thereafter, subject to Takeda's rights and remedies available hereunder, among others, those pursuant to Sections 6.1.2 through 6.1.4 (both inclusive) hereof.

(c) Notwithstanding anything to the contrary in this Agreement other than Section 18.3 (Consequences of Termination) hereof, as for the Initial Firm Order or any Firm Order, if Myovant makes reductions with respect to the Initial Firm Order Period or any Firm Order Period in any subsequent Rolling Forecast or otherwise and fails to accordingly order and purchase such Drug Substance for any reason whatsoever, then, subject to Section 17.2 hereof, Myovant shall [***] reasonably accrued to or incurred by Takeda arising out of or in connection with such change or failure and pursuant to Section 6.1.4 hereof (and without prejudice to those for the experiment, return and otherwise disposal thereof); *provided, however,* that Takeda makes its commercially reasonable efforts to [***].

6.1.3 Purchase Orders.

(a) **Issuance and Acceptance.** In addition to its submission of a Rolling Forecast, Myovant shall submit to Takeda, a purchase order for Drug Substance (a " **Purchase Order** ") in the quantity set forth in the Initial Firm Order and any subsequent Firm Order. Each Purchase Order shall specify (i) the quantity of Drug Substance and (ii) the desired delivery date and location, on the basis of [***], in each case in accordance with the Initial Firm Order or such Firm Order (as applicable), no later than [***] before the desired delivery date of Drug Substance. Such Purchase Order shall be accepted by Takeda unless, excluding with respect to Purchase Orders for the Initial Binding Order, Takeda otherwise notifies Myovant not later than [***] Business Days after Takeda's actual receipt thereof. For clarity, Takeda shall accept all Purchase Orders that correspond to the Initial Firm Order. To the extent of any conflict between a Purchase Order and this Agreement, this Agreement shall control.

(b) **Deviations from the Firm Order.** If the quantity set forth in a given Purchase Order exceeds the quantity set forth in the corresponding Firm Order, Takeda shall use its reasonable efforts to satisfy the amount contained in such Purchase Order; *provided, however,* that Takeda shall not be required to Manufacture and supply the quantity set forth in such Purchase Order that exceeds the quantity set forth in the corresponding Firm Order. For the avoidance of doubt, such reasonable efforts shall not require Takeda [***]. For clarity, further, Myovant cannot issue a Purchase Order that is less than the quantity set forth in the corresponding Firm Order for Drug Substance.

6.1.4 [***].

(a) **Reimbursement by Myovant** . The Parties acknowledge that: (a) Takeda will order [***] from Third Parties based on the quantities and delivery dates specified in each Rolling Forecast for delivery of Drug Substance under this Agreement unless Takeda otherwise notifies Myovant not later than [***] Business Days after Takeda's actual receipt thereof; and (b) the sum that Myovant is obligated to pay Takeda for Drug Substance in accordance with Section 3.1.1 hereof is based on the costs of [***] in the Manufacture of such Drug Substance under this Agreement. Therefore, if (i) in any Rolling Forecast, Myovant reduces the quantity of Drug Substance forecast during the first [***] Calendar Quarters of such Rolling Forecast from the quantity that was forecasted for the same period in the then immediately prior Rolling Forecast, and (ii) Takeda incurs any non-cancellable costs for purchase of [***] that (A) is no longer needed to Manufacture Drug Substance under this Agreement as a result of such reduction and (B) cannot be used or sold by Takeda or its Affiliates for some other purpose, including to satisfy Takeda's own requirements for [***], then Myovant shall pay Takeda [***] *provided, however,* that in no event shall Myovant be obligated to [***].

(b) **Storage Fees** . If Myovant notifies Takeda that Myovant wishes to delay the delivery of Drug Substance forecast during the first [***] Calendar Quarters of any Rolling Forecast and requests that Takeda store [***] for use in the Manufacture of such delayed Drug Substance, then Myovant and Takeda will discuss reasonable storage fees that would, upon written agreement, be paid by Myovant for storage of such [***].

6.2 Delivery. Subject to Section 19.1 hereof, Takeda shall supply the Drug Substance under a Purchase Order as accepted in accordance with Section 6.1.3(a) by way of delivery pursuant to Article 8 hereof. If Takeda is unable to meet the specified delivery date thereunder, Takeda shall notify Myovant as soon as reasonably practicable after becoming aware thereof, and both Parties shall promptly discuss with each other the then optimal solution in good faith. By way of example, Takeda may provide to Myovant an alternative delivery date which is as close to the originally agreed delivery date as reasonably possible. Delivery by Takeda of up to [***] of the quantity of Drug Substance under a given Purchase Order shall be accepted by Myovant in full satisfaction of Takeda's obligation to supply such Purchase Order, subject to Myovant's inspection of the Drug Substance in accordance with Section 9.1 hereof.

6.2.1 Shelf-Life . With respect to the Manufacture of Drug Substance under this Agreement, the length of time that elapses between the date that such Drug Substance was Manufactured and the date that such Drug Substance must be re-tested as determined by Takeda (the " **Shelf-Life** ") shall be no less than [***] months. For Drug Substance with a Shelf-Life of [***] months, the remaining Shelf-Life at the time such Drug Substance is delivered to Myovant shall be no less than [***] months. For Drug Substance with a Shelf-Life of [***] months, the remaining Shelf-Life at the time such Drug Substance is delivered to Myovant shall be no less than [***] months. In the case of such remaining Shelf-Life at delivery being (or anticipated to be) less than the foregoing, then Takeda shall notify Myovant promptly after Takeda's receipt of the applicable Purchase Order and may deliver the Drug Substance on a schedule agreed to in writing by Myovant.

6.2.2 Testing by Takeda. Prior to delivery by Takeda pursuant to Section 8.1 hereof, Takeda shall undertake release testing to obtain a Quality Release for each batch of the Drug Substance that is Manufactured pursuant to a Purchase Order and in accordance with the terms of the Quality Agreement.

6.2.3 Provision of Records. With each batch of Drug Substance delivered by Takeda pursuant to Section 8.1 hereof, Takeda shall provide all Batch Documentation for such batch, including a certificate of analysis, Quality Release and certificate of conformance, in accordance with the terms of the Quality Agreement.

6.2.4 Delayed Deliveries. Takeda shall notify Myovant as soon as reasonably practicable after becoming aware that it will not be able to deliver the Drug Substance by the delivery date specified in the relevant Purchase Order as accepted in accordance with Section 6.1.3(a), and both Parties shall promptly discuss with each other the then optimal solution in good faith. If Takeda delivers Drug Substance more than [***] days after the delivery date specified in the relevant Purchase Order and such failure is not attributable to Myovant, then Takeda shall allocate inventory of Drug Substance in accordance with Section 6.5 hereof. Except as expressly set forth in this Agreement or otherwise agreed on by the Parties in writing, if Takeda materially fails to deliver Drug Substance by the delivery dates under the applicable Purchase Order(s) as accepted for [***] consecutive Calendar Quarters in a Fiscal Year, then Myovant shall have the right to terminate this Agreement pursuant to Section 18.2.1 hereof.

6.3 Notice of Potential Inability to Supply. Takeda shall inform Myovant of any events that may prevent Takeda from fulfilling its supply obligations with respect to amounts of Drug Substance pursuant to any portion of any Firm Order as soon as reasonably practicable after becoming aware of such events. In the event Takeda notifies Myovant of a potential inability to supply Drug Substance, the Parties shall promptly discuss with each other the then optimal solution in good faith. If Takeda's inability to fulfill its supply obligation is due to the [***] and/or [***] or because [***] of Takeda and/or its supplier is such that Takeda and/or its supplier is unable to meet the demand for Drug Substance requested by Myovant, and except as otherwise set forth herein, [***], including Myovant and Takeda, by way of example, in such proportion as the [***].

6.4 Supply Shortage; Allocation . Notwithstanding anything to the contrary herein, within [***] days after the occurrence of any failure to deliver at least [***] of the quantities of Drug Substance in accordance with Purchase Orders as accepted for delivery in [***] consecutive Calendar Quarters (a " **Supply Shortage** "), and except as otherwise set forth herein and upon consultation with Myovant in good faith, then Takeda shall allocate deliveries of Drug Substance in accordance with Section 6.5 hereof. Takeda shall use its commercially reasonable efforts to minimize the duration of any Supply Shortage

6.5 Allocation . If an event occurs that requires Takeda to allocate Drug Substance in accordance with either Section 6.2.4 (Delayed Delivery) or Section 6.4 (Supply Shortage) hereof (an " **Allocation Event** "), then Takeda shall: (a) provide Myovant, no later than [***] after the Allocation Event, with [***]; (b) allocate and deliver to Myovant, as soon as possible but no later than [***] after such Allocation Event, that [***] (such fraction, the " **Allocation Proportion** "); and (c) [***] pursuant to all applicable Purchase Orders, deliver to Myovant no later than the [***] a quantity of Drug Substance equal to the [***], in addition to [***]. For example and without limitation, if Takeda is obligated to deliver [***].

ARTICLE 7
MANUFACTURING

7.1 Conformance with GMP. Takeda shall Manufacture and supply the Drug Substance that conforms to GMPs, Applicable Laws, the Specifications, the Quality Agreement and any other applicable terms of this Agreement, including Sections 6.2.1 (Expiration Date) and 7.4 (Manufacturing Location) hereof.

7.2 Modifications. Takeda shall not modify the Specifications, Manufacturing, and testing processes, in each case, employed with regard to the Manufacture of the Drug Substance or any component thereof, including the [***] (a " **Manufacturing Change** "), other than in accordance with this Section 7.2.

7.2.1 Modifications Required by Regulatory Authorities in Myovant Territory . Notwithstanding anything to the contrary herein, if any Regulatory Authority in the Licensee Territory requires, even before, upon or after its Regulatory Approval as applicable to the Drug Substance supplied hereunder, that Myovant implement a Manufacturing Change (each, a " **Required Modification** "), then Takeda shall, upon receipt of written notice from Myovant describing in reasonable detail such Required Modification, discuss in good faith such Required Modification, including its [***], and prepare and deliver to Myovant, as soon as possible but no later than [***] days after such notice, a written reasonable estimate of (a) [***] for implementing such Required Modification, (b) a [***] such Required Modification, (c) any [***] to fulfill Firm Orders and (d) [***] substantially in connection with such Required Modification (collectively, the " **Estimate** "). The Parties shall discuss with each other such Estimate in good faith to reach agreement thereon, including but not limited to any change in Firm Orders [***] Myovant shall pay for Drug Substance, as well as any regulatory impacts on the TAK-385 Licensed Product or TAK-385 Licensed Compound for the Takeda Territory. Upon the mutual written agreement on any terms and conditions as applicable (the " **Manufacturing Change Order** "), both Parties shall duly: (i) implement the applicable Regulatory Modification(s) in accordance with the Manufacturing Change Order; and (ii) provide each other with all Regulatory Materials that are required by Regulatory Authorities in the Licensee Territory and Takeda Territory in connection with such Required Modification.

7.2.2 Modifications *Not* Required by Regulatory Authorities . If either Party wishes to make any Manufacturing Change other than a Required Modification (an " **Optional Modification** "), then such Party shall notify the other Party in writing of such proposed Optional Modification. Promptly thereafter, the Parties shall discuss in good faith (a) [***] Optional Modification, (b) its [***] for the Manufacturing of Drug Substance or Drug Product or on any Regulatory Approvals or applications for Regulatory Approvals anywhere in the world for any TAK-385 Licensed Product and (c) [***] Optional Modification.

7.3 Continuous Improvement. The Parties, through the JMWG, JRC and other *ad hoc* meetings held between the Parties from time to time during the Term, shall make reasonable efforts to strive to identify ways to improve the processes for Manufacture of the Drug Substance and optimize the costs of Manufacture and the price for Drug Substance. Without limiting the generality of the foregoing, the JMWG shall develop [***] for Manufacture of the Drug Substance, and shall [***]. In the event that either Party, or any of their respective Affiliates, Subcontractors or Sublicensees, identifies or otherwise becomes aware of any measures for improving performance of the Manufacturing obligations hereunder, then such Party shall promptly notify the other Party of such improvement, and the Parties shall negotiate in good faith each Party's responsibility for implementing such measures and associated costs. Without limiting the generality of the foregoing, no later than [***] days following the end of each Fiscal Year (or upon such other frequency as mutually agreed upon by the Parties), the JMWG shall cooperate to create a written proposal describing [***] in the Manufacture of Drug Substance that have been identified pursuant to this Agreement ("[***] **Report** "), including any input received from Myovant and Takeda for achieving [***]. The Parties, through the JMWG, shall consider in good faith the [***] Report to develop a plan for implementing such changes in the Manufacture of Drug Substance hereunder.

7.4 Manufacturing Location. Subject to the terms and conditions of change control in accordance with the Quality Agreement, Takeda shall duly Manufacture the Drug Substance supplied hereunder at the [***] by using the [***].

7.5 Quality Agreement. Upon the full execution of this Agreement and no later than [***] days thereafter, the Parties shall use commercially reasonable efforts to enter into the Quality Agreement, which shall define roles and responsibilities, change control, release authority, GMP requirements, sampling, testing and retain plans, specifications, preventative maintenance, dispute resolution and other aspects related to quality of Drug Substance, including the [***]. The Quality Agreement shall be governed by this Agreement. In the case of any conflict with the terms of Quality Agreement, the terms of this Agreement shall prevail.

ARTICLE 8
DELIVERY, TITLE AND RISK OF LOSS

8.1 Shipment Terms; Title; Risk of Loss. All Drug Substance shall be delivered to Myovant or the Qualified Designees, [***], shipped by a common carrier designated by Myovant in the Purchase Order, at Myovant's expense. Title and risk of loss shall transfer to Myovant, and delivery shall be deemed to have occurred, when [***]. Myovant shall procure, at its cost, [***] to the Drug Substance for the shipping.

8.2 Importer of Record, etc. Myovant shall be responsible for any and all aspects whatsoever of the shipping of Drug Substance hereunder, including but not limited to: (a) customs and other regulatory clearance of the Drug Substance; (b) payment of all tariffs, duties, customs, fees, expenses and charges payable in connection with the exportation, importation and delivery of the Drug Substance; and (c) keeping all records, documents, correspondence and tracking information required by Applicable Laws arising out of or in connection with the exportation, importation and delivery of such Drug Substance.

ARTICLE 9
NON-CONFORMING PRODUCT/RETURNS

9.1 Claims for Detectable Defects. Myovant shall notify Takeda within [***] days after receipt by Myovant or its designated dosage form manufacturer of any shipment of the Drug Substance supplied by or on behalf of Takeda of the existence and nature of any defect in or failure of the Drug Substance to comply with Section 5.1 or Section 7.1 hereof at the time of delivery hereunder that could have been detected by a reasonable physical inspection of the Drug Substance at such time (" **Detectable Defects** "). If such notice is not provided within such [***] day period, then such Drug Substance shall be deemed not to have any Detectable Defects, Myovant shall be deemed to have accepted the Drug Substance, and Takeda shall have no further responsibility for such Detectable Defects. For the purposes hereof, a non-conformity relating to stability of the Drug Substance shall not be considered a Detectable Defect.

9.2 Claims for Non-Detectable Defects. Myovant shall notify Takeda within [***] Business Days upon discovery of any defect in or failure of the Drug Substance to comply with Section 5.1 or Section 7.1 hereof that is not a Detectable Defect. Claims that are submitted by Myovant shall state the nature of the alleged defect, including how such alleged defect was discovered, in detail reasonably sufficient to enable Takeda to identify the nature of the alleged defect or to dispute the same, and to determine that the defect existed at the time of delivery.

9.3 Provision of Samples. Myovant shall, when notifying Takeda of an alleged defect, provide samples of any allegedly defective Drug Substance and copies of written reports or investigations performed by or on behalf of Myovant on such allegedly defective Drug Substance.

9.4 Referral to Independent Laboratory. In the event of a dispute between the Parties as to any defect in a Drug Substance, including whether a defect was a Detectable Defect or whether such defect existed at the time of delivery hereunder, that cannot be resolved within [***] days of a claim being made to Takeda pursuant to Section 9.1 or Section 9.2 hereof, the matter shall promptly (but in no case later than [***] Business Days after the expiration of such [***] day period) be submitted to an independent, qualified laboratory to be mutually agreed between the Parties. Such independent laboratory will examine the Drug Substance at issue and determine the existence and, if relevant, the timing of any defect in the Drug Substance. The decision of such independent laboratory shall be binding on the Parties, except in the case of fraud. Myovant shall bear the costs of such independent laboratory if such independent laboratory finds that the Drug Substance was not defective or that such defect did not exist at the time of delivery hereunder. Takeda shall bear the costs of such independent laboratory if such independent laboratory finds that the Drug Substance was defective at the time of delivery hereunder.

9.5 [***]; Defective Product. Following a claim from Myovant pursuant to Section 9.1 or Section 9.2 hereof, and without limiting any of Myovant's remedies with respect to any breach by Takeda of this Agreement or otherwise hereunder, Takeda's sole obligation with respect to replacing defective Drug Substance in the event that Takeda accepts Myovant's claim as valid or the independent, qualified laboratory as duly agreed above in Section 9.4 hereof decides in favor of Myovant's claim, shall be to either, at Myovant's election, (a) provide Myovant, within [***] days after Takeda's receipt of the written notice of election by Myovant, with [***] or (b) [***]. Any Drug Substance that is agreed or determined to be defective shall be, as directed by Takeda, either destroyed by Myovant or returned to Takeda, in both cases at Takeda's expense. Except for Takeda's obligations under Article 11 and Article 17 hereof, Takeda shall have no liability for defective Drug Substance other than as provided in this Article 9.

ARTICLE 10
STORAGE, HANDLING AND TRANSPORT

10.1 Takeda's Responsibilities. Before the delivery of Drug Substance hereunder, the Drug Substance and [***] to be used for the Manufacture thereof shall be stored, handled, packaged, and transported in accordance with the requirements of this Agreement, the Quality Agreement and all Applicable Laws. Takeda shall maintain appropriate quality assurance and quality control standards and record-keeping practices, including systems, resources and procedures in order to satisfy these obligations.

10.2 Myovant Storage, Handling and Transport of Drug Substance. Upon or after the delivery of Drug Substance hereunder, Myovant shall be responsible to store, handle and transport the Drug Substance in accordance with the terms hereof, obtain at its sole expense all equipment, facilities and personnel necessary therefor and pay all other costs and expenses in connection therewith. If Myovant, for any reason (other than as a result of a claim for a defect pursuant to Section 9.1 or Section 9.2 hereof), refuses to take delivery or possession of any Drug Substance, Myovant shall, notwithstanding Section 17.2 hereof, promptly upon receipt of an invoice from Takeda, reimburse Takeda for [***] fees that Takeda may have incurred prior to such refusal by Myovant.

10.3 Notice of Inspections by Regulatory Authorities. The Parties' obligations with respect to any inspections or audits by any Regulatory Authority related to the Drug Substance shall be governed by Section 5.3 hereof and the Quality Agreement.

ARTICLE 11
RECALL

The Parties' obligations with respect to a recall of the Drug Substance or Drug Product shall be governed, as applicable, by the Quality Agreement and the License Agreement, including Section 6.4.2 (Recalls) of the License Agreement; provided, however, that for purposes of this Article 11: (a) Takeda shall have the obligations of TPIZ under such Section 6.4.2, and Myovant shall have the obligations of Myovant Ltd. thereunder; and (b) all references in such Section 6.4.2 to the License Agreement shall refer to this Agreement.

ARTICLE 12
TECHNICAL SUPPORT SERVICES

[Intentionally left blank]

[***] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

12.1 Technical Support Services. Beginning on the Effective Date and continuing until the termination of this Agreement, upon the mutual agreement at the reasonable request of Myovant, Takeda may provide Myovant or the Qualified Designees with reasonable technical, regulatory, CMC and other related services in support of the Manufacturing of Drug Substance or Drug Product that Takeda is not required to provide under any other provision of this Agreement (the " **Technical Support Services** "). Any Technical Support Services provided by Takeda shall be documented in work orders, executed by both Parties and substantially in the form attached as Exhibit C (each a " **Project Work Order** "). Such Technical Support Services may be provided from Takeda's or its Affiliates' facilities unless otherwise expressly set forth in a Project Work Order. Unless otherwise expressly provided in a Project Work Order, any Inventions or other Information arising out of Takeda's performance of the any Technical Support Services shall be governed by Article 14 of this Agreement. In furtherance of the Technical Support Services, the Parties may agree that Takeda will ship small quantities of Drug Substance or Drug Product to Myovant or the Qualified Designees. Unless otherwise agreed on by the Parties in the applicable Project Work Order, any such shipment shall be subject to the applicable terms and conditions, including but not limited to those in Article 8 or Article 9, of this Agreement.

12.2 Reimbursement for Additional Technical Support Services. Myovant shall compensate Takeda for those FTEs providing the Additional Technical Support Services as described in Schedule 4.2.3 hereto, and shall reimburse Takeda for all reasonable documented out-of-pocketed expenses incurred by Takeda to perform Additional Technical Support Services, *provided that* , unless otherwise agreed in a Project Work Order, any such out-of-pocket expenditure over [***] shall be approved in advance by Myovant. Takeda shall invoice Myovant within [***] days after the end of each Calendar Quarter for [***] incurred by Takeda during the preceding Calendar Quarter for the Additional Technical Support Services, which shall include a record of FTE hours by individual and date and a brief description of work performed, and Myovant shall pay such invoice in accordance with Article 13 hereof.

ARTICLE 13
PAYMENT TERMS

13.1 Payment Terms. Myovant shall pay any amount invoiced by Takeda pursuant to this Agreement that is not disputed in writing by Myovant within [***] days after receipt of such invoice, subject to the terms and conditions, as applicable to Drug Substance not having Detectable Defects, in Section 9.1 hereof. Myovant shall make all payments for invoices issued by Takeda in Japanese Yen by wire-transfer to Takeda's account designated below or to such other account as Takeda may specify by written notice to Myovant in accordance with Section 19.2 hereof.

Bank Name:	[***]
Branch:	[***]
Address:	[***]
Account #:	[***]
Beneficiary's Name:	Takeda Pharmaceutical Company Limited
Beneficiary's Address:	[***]

13.2 Taxes. Myovant shall pay any applicable taxes, including [***] imposed by relevant taxing authorities as a result of payments it makes to Takeda pursuant to this Agreement (" **Payments** "). All [***] tax, gross receipts tax and foreign withholding tax, applicable to payments Myovant makes to Takeda pursuant to this Agreement shall be the sole responsibility of Takeda. Each Party will provide to the other Party any resale exemption, multiple points of use certificates, treaty certification and other exemption information reasonably requested by the other Party.

13.3 Late Payment. If Myovant fails to pay and fails to dispute any invoiced amount within [***] days of receipt of such invoice, simple interest shall thereafter accrue on the sum due to Takeda until the date of payment at the per annum rate of [***] over the then-current prime rate quoted by Citibank in New York City or the maximum rate allowable by Applicable Laws, whichever is lower.

ARTICLE 14
INTELLECTUAL PROPERTY

Any Inventions or other Information arising in furtherance of this Agreement shall be subject to the Parties' obligations set forth in the License Agreement, including those set forth in Article 10 of the License Agreement; provided, however, that for purposes of this Article 14: (a) Takeda shall have the obligations of TPIZ under Article 10 of the License Agreement and Myovant shall have the obligations of Myovant Ltd. under Article 10 of the License Agreement; and (b) all references in Article 10 to the License Agreement shall refer to this Agreement.

ARTICLE 15
CONFIDENTIALITY

A Party's obligations with respect to any Confidential Information of the other Party received in furtherance of this Agreement shall be governed by the License Agreement, including Article 12 of the License Agreement; provided, however, that for purposes of this Article 15: (a) Takeda shall have the obligations of TPIZ under Article 12 of the License Agreement and Myovant shall have the obligations of Myovant Ltd. under Article 12 of the License Agreement; and (b) all references in Article 12 to the License Agreement shall refer to this Agreement.

ARTICLE 16
REPRESENTATIONS AND WARRANTIES

16.1 Mutual Representations, Warranties and Covenants. Each Party hereby represents, warrants and covenants to the other Party that:

16.1.1 Corporate Existence. As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated.

16.1.2 Corporate Power, Authority and Binding Agreement. As of the Effective Date, (a) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (b) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (c) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

16.1.3 Debarment. As of the Effective Date, neither it nor any of its Affiliates (a) has been debarred by a Regulatory Authority, (b) is subject to debarment proceedings by a Regulatory Authority or (c) will use, in any capacity, in connection with the activities to be performed under this Agreement, any Person that has been debarred, or who is the subject of debarment proceedings by any Regulatory Authority. If either Party learns that a Person performing on its behalf under this Agreement has been debarred by any Regulatory Authority, or has become the subject of debarment proceedings by any Regulatory Authority, such Party shall promptly notify the other Party and shall prohibit such Person from further performance on its behalf under this Agreement.

16.2 Further Takeda Representations, Warranties and Covenants.

16.2.1 Takeda (a) represents and warrants that it is, as of the Effective Date, in compliance with the representations and warranties described in Section 11.2.7 (No Debarment) of the License Agreement, and (b) covenants that it will at all times during the Term comply with the covenants described in Section 11.3.2 (No Debarment) of the License Agreement; provided, however, for purposes of this Section 16.2.1, Takeda shall have the obligations of TPIZ under Section 11.2.7 and Section 11.3.2 of the License Agreement. If Takeda breaches this Section 16.2.1, then Myovant may terminate this Agreement in accordance with Section 18.2.1 (Termination for Material Breach), provided that the cure period stated therein shall not apply and Myovant may terminate this Agreement immediately upon written notice to Takeda in the case of such debarment against Takeda itself.

16.2.2 Takeda hereby represents, warrants and covenants to Myovant that all Drug Substance supplied pursuant to this Agreement, upon delivery to Myovant or the Qualified Designees in accordance with Section 8.1 hereof:

(a) will have been Manufactured, tested, released, stored, supplied and otherwise handled in accordance with all Applicable Laws and GMPs, and the applicable Specifications;

(b) will have been Manufactured in facilities that are in compliance with Applicable Laws;

(c) will have been Manufactured in accordance with the Quality Agreement and will conform with the certificates provided pursuant to the Quality Agreement;

(d) shall not be adulterated or misbranded within the meaning of the FFDCA; and

(e) may be introduced into interstate commerce pursuant to the FFDCA.

16.3 Myovant Representation, Warranties and Covenants. Myovant hereby represents, warrants and covenants to Takeda that it shall discharge its obligations pursuant to this Agreement in accordance with all Applicable Laws as well as the License Agreement.

16.4 Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, THERE ARE NO REPRESENTATIONS OR WARRANTIES OR COVENANTS OF ANY KIND, EXPRESS OR IMPLIED, WRITTEN OR ORAL, MADE BY TAKEDA (OR ANY OF ITS AFFILIATES), WITH RESPECT TO THE DRUG SUBSTANCE OR OTHERWISE, INCLUDING: (A) ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE; (B) ANY IMPLIED WARRANTIES ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE IN THE TRADE; (C) ANY WARRANTY OF DESCRIPTION OR OTHERWISE CREATED BY ANY AFFIRMATION OF FACT OR PROMISE OR SAMPLE OR MODEL; OR (D) NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

ARTICLE 17
INDEMNIFICATION; NO CONSEQUENTIAL DAMAGES; INSURANCE

17.1 Indemnification Under the License Agreement. The Parties agree that the indemnification of any Losses resulting from the Claim shall be governed by the License Agreement, including Article 15 thereof; provided, however, that for purposes of this Section 17.1: (a) Takeda shall have the obligations of TPIZ under Article 15 of the License Agreement and Myovant shall have the obligations of Myovant Ltd. under Article 15 of the License Agreement; and (b) all references in Article 15 to the License Agreement shall refer to this Agreement, including in clause (c) of Section 15.1 (Indemnification by Licensee) of the License Agreement and clause (c) of Section 15.2 (Idemnification by Takeda) of the License Agreement.

17.2 No Consequential or Punitive Damages. The Parties agree that the limitation of liability hereunder shall be governed by the License Agreement, including Section 16.4 thereof.

17.3 Insurance. Each Party agrees to procure and maintain in full force and effect during the Term insurance policies in accordance with its obligations under the License Agreement, including Section 16.4 thereof.

ARTICLE 18
TERM AND TERMINATION

18.1 Term. This Agreement shall commence on the Effective Date and unless earlier terminated in accordance with the terms hereof, shall continue until the fifth (5 th) anniversary of the Effective Date (the " **Initial Term** "). At the end of the Initial Term, this Agreement shall continue automatically for additional consecutive one (1) year periods (each, a " **Renewal Term** ," and together with the Initial Term, the " **Term** ") under the same terms and conditions unless earlier terminated in accordance with the terms hereof or unless a Party provides at least twelve (12) calendar months' written notice of non-renewal or otherwise to the other Party prior to expiration of the then-current Initial Term or Renewal Term, as applicable.

18.2 Termination.

18.2.1 Termination for Material Breach. Either Party shall be entitled to terminate this Agreement in the event that the other Party commits a material breach of this Agreement and such other Party fails to cure such breach within ninety (90) days of receiving a notice of default from the non-defaulting Party, by giving a notice of termination to such other Party (after expiration of such cure period, if applicable), with the termination to take effect on the date specified therein.

18.2.2 Termination for Bankruptcy. Either Party may terminate this Agreement by written notice to the other Party upon occurrence of any of the following events: (a) a voluntary petition of bankruptcy is filed by the other Party in any court of competent jurisdiction; (b) an involuntary petition for bankruptcy of the other Party is filed by such Party's creditors in any court of competent jurisdiction and is not vacated within [***] calendar days after filing; (c) a receiver is appointed or applied for to manage any part of a Party's assets related to this Agreement; or (d) this Agreement is assigned by the other Party for the benefit of its creditors.

18.2.3 Termination for Convenience. Each Party shall have the right to terminate this Agreement in whole or in part, including without limitation any and all Project Work Orders then-in-effect, for any rational reason upon one hundred eighty (180) days' prior written notice to the other Party; provided, however, that all Purchase Orders or Firm Orders, including the Initial Firm Order, that duly exist hereunder as of the effective date of such termination shall remain in effect and be binding on both Parties until the full performance thereof.

18.2.4 Termination of License Agreement . Without limiting the generality of the foregoing, in the event that the License Agreement is terminated in accordance with its terms, this Agreement, including without limitation any Purchase Order(s) or Project Work Orders then-in-effect, shall automatically terminate in its entirety as of the effective date of termination of the License Agreement.

18.3 Consequences of Termination.

18.3.1 Technology Transfer. Following the expiration or any termination of this Agreement (other than due to the termination of the License Agreement), Takeda shall, and shall ensure its Affiliates and Subcontractors, at Myovant's reasonable request: provide the Transition Services as set forth in Section 4.2.3 hereof in order to minimize the interruption of the flow of work caused by: such expiration or termination of this Agreement; and, shall continue to supply Drug Substance to Myovant applying the terms and conditions of this Agreement *mutatis mutandis* until the completion of such Transition Services. All reasonable costs and expenses incurred by Takeda therefor shall be borne by Myovant; *provided, however,* that in the event that Myovant terminates this Agreement pursuant to Section 18.2.1 (Termination for Material Breach) hereof, then, notwithstanding any other provision of this Agreement to the contrary, all such reasonable costs and expenses shall be borne by Takeda.

18.3.2 Termination of the License Agreement by Myovant. If this Agreement terminates in accordance with Section 18.2.3 because the License Agreement is terminated by Myovant Ltd. pursuant to Sections 13.3 (Termination for Material Breach), 13.7 (Termination for Patent Challenge) or 13.8 (Termination for Insolvency) of the License Agreement, due to a reason attributable to TPIZ, then, unless otherwise agreed on by the Parties in writing and so far as legally permissible:

(a) Myovant shall be released from any liability to Takeda for any Purchase Order(s) and any Firm Orders then in effect for Drug Substance and for the [***] hereunder; and

(b) Myovant shall have no liability with respect to raw materials on hand or work in progress at Takeda hereunder as of the effective date of such termination.

18.3.3 Other Terminations of the License Agreement. Except for (a) TPIZ's termination of the License Agreement pursuant to Sections 13.3 (Termination for Material Breach), 13.6 (Termination for Cessation of Activities), 13.7 (Termination for Patent Challenge) or 13.8 (Termination for Insolvency) thereof and (b) Myovant's termination of the License Agreement pursuant to Section 13.2 (Termination at Will) thereof, and unless otherwise agreed on by the Parties in writing, the following provisions shall apply if this Agreement terminates in accordance with Section 18.2.4 (Termination of License Agreement) hereof because the License Agreement is terminated by either party thereto, including by Myovant pursuant to Section 13.3 (Termination for Material Breach), by Myovant pursuant to Section 13.4 (Termination by Licensee for Safety Reasons), by Myovant pursuant to Section 13.5 (Termination for Commercial Viability), or by Myovant pursuant to Section 13.8 (Termination for Insolvency), subject to any provisions in the License Agreement as applicable:

(a) Myovant may cancel any Purchase Order or other binding commitments without any liability for such cancelations except that Myovant shall reimburse Takeda within [***] days of the effective date of termination for any and all unrecoverable costs and expenses whatsoever, including but not limited to any and all non-cancellable or otherwise sunk costs for [***], reasonably accrued to or incurred by Takeda theretofore; *provided, however,* that, upon such termination, Takeda makes its commercially reasonable efforts to minimize such costs and expenses by canceling commitments (including for [***]) and substituting other production; and,

(b) Takeda shall repurchase all remaining inventory of Drug Substance in possession of Myovant and its Affiliates or Sublicensees as of the effective date of such termination at the price for which such inventory was purchased by Myovant hereunder; provided, however, that Myovant makes its commercially reasonable efforts to minimize such inventory, upon consultation with Takeda, ensuring an uninterrupted supply of the Drug Product as needed for the patients in the Licensee Territory.

18.3.4 Termination of this Agreement by Takeda for Myovant's Material Breach or Bankruptcy . If this Agreement is terminated by Takeda pursuant to Section 18.2.1 (Termination for Material Breach) or Section 18.2.2 (Termination for Bankruptcy) hereof, Myovant shall not be released from any liability to Takeda for any Purchase Order(s) and any Firm Orders then in effect for Drug Substance and for the [***] hereunder.

18.3.5 Termination of this Agreement by Myovant for Takeda's Material Breach or Bankruptcy. If this Agreement is terminated by Myovant pursuant to Section 18.2.1 (Termination for Material Breach) or Section 18.2.2 (Termination for Bankruptcy) hereof, then, unless otherwise agreed on by the Parties in writing and so far as legally permissible, Myovant may elect to cancel any Purchase Order(s) without any liability for amounts due thereunder and shall be released from any liability to Takeda for any Purchase Order(s) and any Firm Orders then in effect for Drug Substance and for the [***] hereunder.

18.3.6 Termination of this Agreement by Either Party for Convenience. If this Agreement is terminated by either Party pursuant to Section 18.2.3 (Termination for Convenience) hereof, then: (a) each Party shall pay the other Party any and all amounts due and owing hereunder existing as of the effective date of such termination; and (b) all Purchase Orders or Firm Orders, including the Initial Firm Order, that duly exist hereunder as of the effective date of such termination shall remain in effect and be binding on both Parties until the full performance thereof.

18.4 Survival of Rights and Obligations. Termination or expiration of this Agreement shall not relieve a Party of any obligation to make a payment that was owed prior to or on the effective date of such termination, including amounts invoiced prior to such termination or expiration, nor prejudice either Party's right to obtain performance of any obligation provided for in this Agreement that expressly survives termination or expiration, including for Purchase Orders and Firm Orders that are not cancelled in accordance with Section 18.3 hereof. All provisions of this Agreement that, in accordance with their terms, are intended to have effect after the expiration or termination of this Agreement shall survive such termination or expiration, including Sections 3.1 (Price) (solely for such surviving Purchase Orders and Firm Orders), 3.2 (Invoicing), 3.3 (Currency; Exchange Rate), 4.2.5 (Improvements to Manufacturing Technology), 5.3 (Communication with Regulatory Authorities), 6.1.2 (Binding Quantities) (solely for such surviving Purchase Orders and Firm Orders), 6.1.3 (Purchase Orders) (solely for such surviving Purchase Orders and Firm Orders), 6.2 (Delivery) (solely for such surviving Purchase Orders and Firm Orders), 6.3 (Notice of Potential Inability to Supply) (solely for such surviving Purchase Orders and Firm Orders), 6.4 (Supply Shortage; Allocation) (solely for such surviving Purchase Orders and Firm Orders), 10.2 (Myovant Storage, Handling and Transport of Drug Substance), 12.2 (Reimbursement for Additional Technical Support Services), 16.4 (Disclaimer), 18.3 (Consequences of Termination), 18.4 (Survival of Rights and Obligations) and 18.5 (Remedies) and Articles 1 (Definitions), 4 (Technology Transfer) (except for its Section 4.2.5 (Improvements to Manufacturing Technology); and, solely to the extent necessary to fulfill any obligation to a Regulatory Authority after such termination or expiration), 7 (Manufacturing) (solely for such surviving Purchase Orders and Firm Orders), 8 (Delivery, Title and Risk of Loss) (solely for such surviving Purchase Orders and Firm Orders), 9 (Non-Conforming Product/Returns), 11 (Recall), 13 (Technical Support Services), 14 (Intellectual Property), 15 (Confidentiality), 17 (Indemnification; No Consequential Damages; Insurance) and 19 (General Provisions) hereof.

18.5 Remedies. Except as otherwise expressly provided herein, exercise by a Party of its rights under this Article 18 shall not limit remedies which may otherwise be available to a Party in law or equity.

ARTICLE 19
GENERAL PROVISIONS

19.1 Force Majeure Event. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by a force majeure and the nonperforming Party promptly provides notice of such prevention to the other Party. For the purposes hereof, a "force majeure" means a cause beyond the affected Party's reasonable control, including acts of God, fires, floods, earthquakes, labor strikes, acts of war, terrorism or civil unrest. Such excusal shall be continued so long as the condition constituting such force majeure continues and the nonperforming Party takes reasonable efforts to mitigate the condition. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder at the time of such force majeure because of such force majeure. If a force majeure persists for more than [***] days, the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such force majeure.

19.2 Notices. Any notice, request, or other communication permitted or required under this Agreement will be in writing, will refer specifically to this Agreement and will be hand delivered or sent by a recognized overnight delivery service, expenses prepaid, or by facsimile (with transmission confirmed), to the following addresses or to such other addresses as a Party may designate by written notice in accordance with this Section 19.2:

If to Takeda:

Takeda Pharmaceutical Company Limited
1-1, Doshomachi 4-chome,
Chuo-ku, Osaka 540-8645
Attention: Vice President, Production Control Department
Facsimile: [***]

[***] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

If to Myovant:

Myovant Sciences GmbH
Viaduktstrasse 8
4051 Basel
Switzerland
Copy to:

Myovant Sciences, Inc.
2000 Sierra Point Parkway
9th Floor
Brisbane, CA 94005
Attention: General Counsel

19.3 Dispute Resolution. Any dispute, controversy, or claim between the Parties that may arise from time to time pursuant to this Agreement relating to either Party's rights or obligations hereunder that is not resolved through good faith negotiation between the Parties shall be resolved in accordance with Article 14 of the License Agreement.

19.4 Audits. Each Party will maintain complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of the calculation of any amounts due under this Agreement. In accordance with Section 9.6 of the License Agreement, each Party shall have the right to have an independent certified public accountant verify the accuracy of the calculation of such amounts due under this Agreement. In addition, in accordance with the Quality Agreement, Myovant shall have the right, upon at least [***] Business Days' notice to Takeda, and such date to be reasonably agreed upon by the Parties, either by itself or through independent outside auditors or consultants, not more than [***] during the Term of this Agreement, unless reasonable cause is shown, to inspect and audit, at its sole expense and during normal business hours and in a manner that does not interfere unreasonably with operations, any areas in Takeda's Manufacturing facility or any other facilities in which any portion of the Manufacturing, packaging or other activities with respect to any Drug Substance or [***] is performed. The information obtained during the course of such audit shall be considered Confidential Information and subject to Section 3.4 (Subcontractors) and the provisions of Article 12 (Confidentiality) of the License Agreement.

19.5 Relationship of the Parties. It is expressly agreed that Takeda, on the one hand, and Myovant, on the other hand, will be independent contractors and that the relationship between the two Parties will not constitute a partnership, joint venture or agency. Neither Takeda nor Myovant will have the authority to make any statements, representations or commitments of any kind, or to take any action which will be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party will be employees of that Party and not of the other Party and all expenses and obligations incurred by reason of such employment will be for the account and expense of such Party.

19.6 Designation of Affiliates. Each Party may discharge any obligations and exercise any rights hereunder through delegation of its obligations or rights to any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement will be a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

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19.7 Assignment. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective heirs, successors and permitted assigns. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, which consent shall not be unreasonably withheld, delayed or conditions; *provided, however* , that Myovant may, without Takeda's prior written consent (but with a written notice to Takeda in a timely manner): (a) assign its rights and obligations under this Agreement in whole or in part to one or more of its Affiliates; and (b) assign this Agreement in connection with the sale or other transfer of all or substantially all of the assets of the business to which this Agreement relates (whether such transaction occurs by way of a sale of assets, merger, consolidation or similar transaction); *provided, further,* that any assignment by Myovant shall be permitted only if such assignment is consistent with Sections 5.5 and 5.6 of the License Agreement. Any successor or assignee of rights or obligations permitted hereunder will, in writing to the other Party, expressly assume performance of such rights or obligations. Any permitted assignment will be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 19.7 will be null, void and of no legal effect.

19.8 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision will be considered severed from this Agreement and will not serve to invalidate any remaining provisions hereof. The Parties will make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

19.9 Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party will not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

19.10 Construction; Rules of Construction. Interpretation of this Agreement will be governed by the following rules of construction: (a) words in the singular will be held to include the plural and vice versa, and words of one gender will be held to include the other gender as the context requires; (b) references to the terms "Section", "Exhibit", or "Schedule" are to a Section, Exhibit, or Schedule of this Agreement unless otherwise specified; (c) the terms "hereof", "hereby", "hereto", and derivative or similar words refer to this entire Agreement; (d) references to "$" or "Dollars" will mean the currency of the United States; (e) the word "including" and words of similar import when used in this Agreement will mean "including without limitation," unless otherwise specified; (f) the word "or" will not be exclusive; (g) references to "written" or "in writing" include in electronic form; (h) the titles and headings contained in this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement; (i) each of the Parties has participated in the negotiation and drafting of this Agreement and if an ambiguity or question of interpretation should arise, this Agreement will be construed as if drafted jointly by the Parties and no presumption or burden of proof will arise favoring or burdening either Party by virtue of the authorship of any of the provisions in this Agreement or any interim drafts of this Agreement; (j) the word "shall" will be construed to have the same meaning and effect as the word "will"; (k) references to "days" will mean calendar days, unless otherwise specified; and (l) a reference to any Person includes such Person's successors and permitted assigns.

19.11 Further Assurance. Each Party will duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof.

19.12 Governing Law. This Agreement was prepared in the English language, which language will govern the interpretation of, and any dispute regarding, the terms of this Agreement. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof will be governed by and construed under the laws of the State of New York, without giving effect to any choice of law principles that would require the application of the laws of a different state.

19.13 Entire Agreement. This Agreement, including the Exhibits and Schedules hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof, except for the License Agreement as expressly set forth herein. There are no covenants, promises, agreements, warranties, representations, conditions, or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change, or addition to this Agreement will be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party. For clarity, if the Parties wish to modify any Exhibit or Schedule hereto, a modifying Exhibit or Schedule may be substituted for such Exhibit or Schedule without an amendment to this Agreement in its entirety; provided that such modifying Exhibit or Schedule is fully executed by a duly authorized representative of each Party, whereupon such modifying Exhibit or Schedule shall be deemed to replace the corresponding prior Exhibit or Schedule. In the event of any inconsistency between this Agreement and the Licensee Agreement, unless expressly stated to the contrary herein, the terms contained in the License Agreement will control. In the event of any inconsistency between the body of this Agreement and the Exhibits or Schedules to this Agreement or any subsequent agreements ancillary to this Agreement, unless otherwise expressly stated to the contrary in such Exhibit, Schedule or subsequent ancillary agreement, the terms contained in this Agreement will control.

19.14 Counterparts. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. This Agreement may be executed by facsimile, .pdf or other electronically transmitted signatures and such signatures will be deemed to bind each Party hereto as if they were the original signatures.

[Signature Page Follows.]

[***] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

IN WITNESS WHEREOF, THIS COMMERCIAL MANUFACTURING & SUPPLY AGREEMENT IS EXECUTED by the respective duly authorized representatives of the Parties, effective as of the Effective Date.

MYOVANT SCIENCES GMBH		**TAKEDA PHARMACEUTICAL COMPANY LIMITED**	
Signature:	/s/ Mark Altmeyer	Signature:	/s/ [***]
Name:	Mark Altmeyer	Name:	[***]
Title:	Director	Title:	Head of [***]
Date:	June 1, 2018	Date:	28. May. 2018

[***] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

EXHIBIT A

SPECIFICATIONS

Test item	Analytical Procedure	Acceptance criteria
[***]	[***]	[***]

[***] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

EXHIBIT B

TRANSITION PLAN

Item	Takeda	Myovant	Myovant initial [***]
[***]	[***]	[***]	[***]

Activities	Comments	Timeline
[***]	[***]	[***]

[***] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

EXHIBIT C

FORM OF PROJECT WORK ORDER

PWO # ***[INSERT]***

This Project Work Order #__ (this " **Work Order** "), is entered into as of _____, 20__ (the " **Work Order Effective Date** "), by and between Takeda Pharmaceutical Company Limited (" **Takeda** "), and Myovant Sciences GmbH (" **Myovant** "), pursuant and subject to the terms and conditions of that certain Commercial Manufacturing & Supply Agreement, dated _____, 2018, by and between Takeda and Myovant (the " **Agreement** "). Any capitalized term not otherwise defined herein shall have the meaning set forth in the Agreement. In the event of any conflict between the Agreement and any provision of this Work Order, the Agreement will control unless the Parties' mutual agreement to alter the terms of the Agreement is expressly set forth in this Work Order as fully executed, and such alteration shall only apply to this Work Order and shall not be construed as an amendment to the terms of the Agreement. Takeda and Myovant, intending to be legally bound, hereby agree to following terms:

1. Description of Services: ***[INSERT]***
2. Project Start Date: ***[INSERT]***
3. Estimated Completion Date: ***[INSERT]***
4. Purchase Order No.: ***[INSERT]***
5. Fees: ***[INSERT]***
6. Expenses: ***[INSERT]***
7. Payment Terms and Schedule: ***[INSERT]***
8. Other Terms (if any): ***[INSERT]***

[Signature page follows.]

[***] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

IN WITNESS WHEREOF, the Parties have caused this Project Work Order to be executed and delivered by their respective duly authorized representatives as of the Work Order Effective Date.

MYOVANT SCIENCES GMBH		**TAKEDA PHARMACEUTICAL COMPANY LIMITED**	
Signature:		Signature:	
Name:		Name:	
Title:		Title:	
Date:		Date:	

[***] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

EXHIBIT D

GLOSSARY

" **Applicable Law** " means any applicable federal, state, local, municipal, foreign, or other law, statute, legislation, constitution, principle of common law, code, treaty ordinance, regulation, rule, or order of any kind whatsoever put into place under the authority of any Governmental Authority, including the FFDCA, Prescription Drug Marketing Act, the Generic Drug Enforcement Act of 1993 (21 U.S.C. §335a et seq.), U.S. Patent Act (35 U.S.C. §1 et seq.), Federal Civil False Claims Act (31 U.S.C. §3729 et seq.), and the Anti-Kickback Statute (42 U.S.C. §1320a-7b et seq.), all as amended from time to time, together with any rules, regulations, and compliance guidance promulgated thereunder. "Applicable Law" will include the applicable regulations and guidance of the FDA and European Union (and national implementations thereof) that constitute Good Laboratory Practices, Good Manufacturing Practices, and Good Clinical Practices (and, if and as appropriate under the circumstances, ICH guidance or other comparable regulation and guidance of any applicable Governmental Authority). [*See License Agreement Section 1.4*]

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

" **Calendar Quarter** " means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30, and December 31; *provided, however* , that (a) the first Calendar Quarter of the Term will begin on the Effective Date and end on June 30, 2018 and (b) the last Calendar Quarter of the Term will end upon the expiration or termination of this Agreement. [*See License Agreement Section 1.10*]

" **Calendar Year** " means the twelve (12) month period ending on December 31; *provided, however* , that (a) the first Calendar Year of the Term will begin on the Effective Date and end on December 31, 2018 and (b) the last Calendar Year of the Term will end upon the expiration or termination of this Agreement. [*See License Agreement Section 1.11*]

" **Claim** " means any claim, suit, action, demand, or other proceeding brought by any Third Party. [*See License Agreement Sections 1.14, 15.1*]

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

" **CMC** " means chemistry, manufacturing, and controls. [*See License Agreement Section 1.16*]

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

“ **Confidential Information** ” means all non-public or proprietary Information disclosed by a Party to the other Party under this Agreement, which may include ideas, inventions, discoveries, concepts, compounds, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, know-how, trade secrets, technology, inventories, machines, techniques, development, designs, drawings, computer programs, skill, experience, documents, apparatus, results, clinical and regulatory strategies, regulatory documentation, information and submissions pertaining to or made in association with Regulatory Materials, data (including pharmacological, toxicological, and clinical data, raw data, analytical and quality control data, manufacturing data and descriptions, patent and legal data, market data, financial data or descriptions), devices, assays, chemical formulations, specifications, material, product samples and other samples, physical, chemical and biological materials and compounds, and the link, without regard as to whether any of the foregoing is marked “confidential” or “proprietary,” or disclosed in oral, written, graphic, or electronic form. Confidential Information will include the terms and conditions of this Agreement. [*See License Agreement Section 1.26*]

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

“ **Cover** ” or “ **Covered** ” or “ **Covering** ” means, with respect to a particular subject matter at issue and a relevant Patent Right, that the manufacture, use, sale, offer for sale, or importation of the subject matter would fall within the scope of a claim in the Patent Right. [*See License Agreement Section 1.30*]

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

“ **EMA** ” means the European Medicines Agency, or any successor thereto having the administrative authority to regulate the marketing of human pharmaceutical products or biological therapeutic products, delivery systems, and devices in the European Union. [*See License Agreement Section 1.37*]

“ **Endometriosis** ” means a condition resulting from the presence of endometrial tissue outside the uterus. [*See License Agreement Section 1.38*]

“ **Exploit** ” or “ **Exploitation** ” means to Develop, Manufacture, and Commercialize. When used as a verb, “Exploit” and “Exploiting” mean to engage in Exploitation and “Exploited” has a corresponding meaning. [*See License Agreement Section 1.41*]

“ **Field** ” means the treatment, prevention, cure, or control of any human disease, disorder, illness, or condition, including the Men’s Health Field and the Women’s Health Field. [*See License Agreement Section 1.44*]

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

“ **FDA** ” means the U.S. Food and Drug Administration, or any successor agency thereto. [*See License Agreement Section 1.42*]

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

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

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

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

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

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

" **ICH** " means International Conference on Harmonization. [*See License Agreement Section 1.56*]

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

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

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

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

“ **JNDA** ” means a Japanese new drug application and any other applicable submission to the PMDA for pharmaceutical, biologic, or device approval. [*See License Agreement Section 1.68*]

“ **Joint Inventions** ” means any Inventions that are made jointly by employees, agents, or independent contractors of each Party in the course of performing activities under this Agreement, together with all Intellectual Property Rights therein. [*See License Agreement Sections 1.61, 10.1*]

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

“ **Joint Patent Rights** ” means all Patent Rights Covering Joint Inventions. [*See License Agreement Section 1.71*]

“ **JRC** ” means the Joint Review Committee established pursuant to Section 2.2.1 of the License Agreement. [*See License Agreement Sections 1.73, 2.2.1*]

“ **Licensed Compound** ” means a TAK-385 Licensed Compound. [*See License Agreement Section 1.76*]

“ **Licensed Product** ” means any TAK-385 Licensed Product. [*See License Agreement Section 1.77*]

“ **Licensed Product IND** ” means any IND filed related to a Licensed Product, whether in existence as of the Effective Date or filed by a Party with a Regulatory Authority during the Term, including any supplements or amendments thereto. The Licensed Product INDs as of the Effective Date are set forth on Schedule 1.78(a) (TAK-385 Licensed Product INDs) of the License Agreement. [*See License Agreement Section 1.78*]

“ **Licensee Know-How** ” means all Information and Inventions Controlled by Licensee or its Affiliates (other than the Takeda Know-How and Joint Know-How) during the term that are necessary to Exploit a Licensed Compound or Licensed Product. Licensee Know-How excludes any Information contained within or Inventions Covered by a published Licensee Patent Right. [*See License Agreement Section 1.83*]

“ **Licensee Patent Rights** ” means all Patent Rights Controlled by Licensee or its Affiliates (other than the Takeda Patent Rights and Joint Patent Rights) as of the Effective Date or during the Term that Cover a Licensed Compound or any Licensed Product or are otherwise necessary to Exploit a Licensed Compound or a Licensed Product. [*See License Agreement Section 1.85*]

“ **Licensee Territory** ” means with respect to the TAK-385 Licensed Compound or a TAK-385 Licensed Product, worldwide excluding the Takeda Territory. [*See License Agreement Section 1.90*]

“ **MAA** ” means an application for Regulatory Approval (but excluding any application for approval of pricing or reimbursement for a Licensed Product by any Governmental Authority) filed with the EMA. [*See License Agreement Section 1.92*]

“ **Manufacture** ” or “ **Manufacturing** ” means all activities by or on behalf of a Party related to the manufacturing of a Licensed Compound or a Licensed Product, or any ingredient thereof, including test method development and stability testing, formulation, manufacturing scale-up, manufacturing for Development or Commercialization, labeling, filling, processing, packaging, in-process and finished Licensed Product or any ingredient thereof, quality assurance and quality control activities related to manufacturing and release of a Licensed Compound or a Licensed Product, ongoing stability tests, and regulatory activities related to any of the foregoing. When used as a noun, “Manufacture” or “Manufacturing” means any and all activities involved in Manufacturing. [*See License Agreement Section 1.94*]

“ **Men’s Health Field** ” means the treatment, prevention, cure, or control of symptoms associated with prostate cancer. [*See License Agreement Section 1.97*]

“ **NDA** ” means a (a) New Drug Application or supplemental New Drug Application as contemplated by Section 505(b) of the FFDCA, submitted to the FDA pursuant to 21 C.F.R. § 314, including any amendments thereto or (b) any comparable applications filed in or for countries or jurisdictions outside of the United States to obtain Regulatory Approval to Commercialize a Licensed Product in that country or jurisdiction. References to “NDA” herein will refer to a JNDA or MAA as applicable. [*See License Agreement Section 1.98*]

“ **Patent Office** ” means a Governmental Authority that administers and regulates patents, such as the Japan Patent Office, United States Patent and Trademark Office, or other similar Governmental Authority. [*See License Agreement Section 1.107*]

“ **Patent Rights** ” means all: (a) patents, including any utility or design patent; (b) patent applications, including provisionals, non-provisionals, substitutions, divisionals, continuations, continuations in-part or renewals; (c) patents of addition, restorations, extensions, supplementary protection certificates, registration or confirmation patents, patents resulting from post-grant proceedings, re-issues, and re-examinations; (d) other patents or patent applications claiming priority directly or indirectly to: (i) any such specified patent or patent application specified in (a) through (c), or (ii) any patent or patent application from which a patent application specified in (a) through (c) claim direct or indirect priority; (e) inventor’s certificates; (f) other rights issued from a Governmental Authority similar to any of the foregoing specified in (a) through (e); and (g) in each of (a) through (f), whether such patent, patent application or other right arises in the U.S. or any other jurisdiction in the world. [*See License Agreement Section 1.108*]

“ **Person** ” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government. [*See License Agreement Section 1.111*]

“ **Phase III Clinical Trial** ” means a pivotal clinical trial of a pharmaceutical product, with a defined dose or a set of defined doses, which trial is designed to ascertain efficacy and safety of such product, for the purpose of enabling the preparation and submission of an NDA with the applicable Regulatory Authority and to provide an adequate basis for physician labeling, as described in 21 C.F.R. § 312.21(c), as amended (or its successor regulation), or, with respect to any other country or jurisdiction, the equivalent of such a clinical trial in such other country or jurisdiction. [*See License Agreement Section 1.113*]

“ **PMDA** ” means the Japanese Pharmaceuticals and Medical Devices Agency and any successor entity. [*See License Agreement Section 1.114*]

“ **Recall** ” means a Party’s removal or correction of a Licensed Product following (a) notice or request of any Regulatory Authority or (b) the good faith determination by such Party that an event, incident, or circumstance has occurred that required such a recall of such Licensed Product. A Recall does not include a market withdrawal or a stock recovery. [*See License Agreement Section 1.118*]

“ **Regulatory Authority** ” means any applicable Governmental Authority involved in granting Regulatory Approval or issuing a Recall for a Licensed Product in the Territory, including in the U.S. the FDA, in the E.U. the EMA, and in Japan the PMDA. [*See License Agreement Section 1.121*]

“ **Regulatory Approval** ” means any approval (including any supplement, amendment, amendment, or pre- and post-approval), license, registration, or authorization of any national, regional, state, or local regulatory authority, department, bureau, commission, council or other Governmental Authority, that is necessary for the Commercialization of a pharmaceutical product in a country or regulatory jurisdiction (including, where required, approval of any application for pricing or reimbursement for such pharmaceutical product by any regulatory authority). [*See License Agreement Section 1.120*]

“ **Regulatory Materials** ” means regulatory applications, filings, submissions, notifications, registrations, Regulatory Approvals, or other submissions, including any written correspondence or meeting minutes, made to, made with, or received from any Regulatory Authority, submitted to a Regulatory Authority (including all INDs, NDAs, and associated common technical documents) and any amendments and supplements thereto, and all data and other information contained in, and Regulatory Authority correspondence relating to, any of the foregoing. Regulatory Approvals may include the Licensed Product INDs, and amendments and supplements thereto. [*See License Agreement Section 1.123*]

“ **Sublicensee** ” means a Third Party granted a sublicense to a Party’s rights under the License Agreement. [*See License Agreement Sections 1.137, 3.3.1*]

“ **TAK-385 Licensed Compound** ” means (a) the chemical compound coded by Takeda as TAK-385 and the structure of which is set forth on Schedule 1.138 (TAK-385 Licensed Compound) of the License Agreement; (b) any compound other than TAK-385 that is Covered by any Takeda Patent Right set forth on Schedule 1.151 (Takeda Patent Rights) of the License Agreement that also Covers TAK-385; and (c) any [***] of any compound described in clause (a). [*See License Agreement Section 1.139*]

“ **TAK-385 Licensed Product** ” means any pharmaceutical product, including all forms, presentations, strengths, doses, and formulations (including any method of delivery) containing a TAK-385 Licensed Compound. [*See License Agreement Section 1.140*]

“ **Takeda Know-How** ” means (a) all Information and Inventions Controlled by Takeda or its Affiliates as of the Effective Date that are necessary or reasonably useful to Exploit a Licensed Compound or a Licensed Product and (b) all Information and Inventions developed after the Effective Date and Controlled by Takeda or its Affiliates (other than Licensee Know-How and Joint Know-How) during the Term that are necessary to Exploit a Licensed Compound or a Licensed Product. Takeda Know-How excludes any Information contained within or Inventions Covered by a published Takeda Patent Right. [*See License Agreement Section 1.147*]

“ **Takeda Patent Rights** ” means those Patent Rights set forth on Schedule 1.151 part (a) (TAK-385 Patent Rights) of the License Agreement, and all Patent Rights (other than Licensee Patent Rights and Joint Patent Rights Controlled by Takeda during the Term that Cover any Invention made by or on behalf of Takeda after the Effective Date that Covers a Licensed Compound or any Licensed Product or is otherwise necessary to Exploit any Licensed Compound or Licensed Product. [*See License Agreement Section 1.151*]

“ **Takeda Territory** ” means, solely related to the TAK-385 Licensed Compound and TAK-385 Licensed Products, Japan, China, Hong Kong, Indonesia, Korea, Malaysia, Philippines, Singapore, Taiwan, Thailand, and Vietnam, including, in each case, the territories and possessions of each of the foregoing. [*See License Agreement Section 1.156*]

[***] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

“ **Territory** ” means the Licensee Territory and the Takeda Territory. When used to refer to a Party’s Territory, “Territory” means the Licensee Territory with respect to Licensee and the Takeda Territory with respect to Takeda. [*See License Agreement Section 1.161*]

“ **Third Party** ” means a Person other than Takeda or Licensee or their respective Affiliates. For clarity, “Third Party” includes Excluded Affiliates. [*See License Agreement Section 1.162*]

“ **Trademark** ” means any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan, or other indicia of origin or ownership, including the goodwill and activities associated with each of the foregoing. [*See License Agreement Section 1.165*]

“ **Uterine Fibroids** ” means the condition in which a non-cancerous tumor originates from the uterus. [*See License Agreement Section 1.170*]

“ **Women’s Health Field** ” means the treatment, prevention, cure, or control of symptoms associated with Uterine Fibroids or Endometriosis. [*See License Agreement Section 1.173*]

Schedule 1.17
[***]

Chemical Composition:

[***]

Specification:

Item	Specification
[***]	[***]

[***] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule 3.1

Prices

[***]

[***] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule 4.2.3

Fee Schedule for Transition Services

[***]

[***] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule 6.1.1

Takeda Recipient of Rolling Forecasts

Takeda Contact:

[***]

[***] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule 6.1.2(a)

Initial Binding Order

[***]

[***] = Certain confidential information contained in this document, marked by brackets, is filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit 31.1

CERTIFICATION

I, Lynn Seely, certify that:

1. I have reviewed this 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

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

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: August 7, 2018

By: /s/ Lynn Seely

Lynn Seely

Principal Executive Officer

Exhibit 31.2

CERTIFICATION

I, Frank Karbe, certify that:

1. I have reviewed this Form 10-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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

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

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: August 7, 2018

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 June 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Lynn Seely, Principal Executive Officer of the Company, hereby certifies, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and 18 U.S.C. Section 1350, that to the best of her knowledge:

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

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

Date: August 7, 2018

By: /s/ Lynn Seely
Lynn Seely
Principal Executive Officer

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

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Myovant Sciences Ltd. (the "Company") for the period ended June 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Frank Karbe, Principal Financial Officer of the Company, hereby certifies, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and 18 U.S.C. Section 1350, that to the best of his knowledge:

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

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

Date: August 7, 2018

By: /s/ Frank Karbe

Frank Karbe

Principal Financial and Accounting Officer

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