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

FORM 10-Q

(Mark One)

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

For the quarterly period ended December 31, 2018

or

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

For the transition period from to

Commission file number 001-37929

Myovant Sciences Ltd.

(Exact name of registrant as specified in its charter)

Bermuda	**98-1343578**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
Suite 1, 3rd Floor **11-12 St. James's Square** **London** **SW1Y 4LB** **United Kingdom**	
(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 o

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

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

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

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

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

The number of shares outstanding of the Registrant's common shares, $0.000017727 par value per share, on February 1, 2019, was 70,812,541.

MYOVANT SCIENCES LTD.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED DECEMBER 31, 2018

TABLE OF CONTENTS

	Page
PART I. FINANCIAL INFORMATION	
Item 1. Financial Statements:	
Condensed Consolidated Balance Sheets as of December 31, 2018 and March 31, 2018 (Unaudited)	4
Condensed Consolidated Statements of Operations for the Three and Nine Months Ended December 31, 2018 and 2017 (Unaudited)	5
Condensed Consolidated Statements of Comprehensive Loss for the Three and Nine Months Ended December 31, 2018 and 2017 (Unaudited)	6
Condensed Consolidated Statements of Shareholders' Equity for the Nine Months Ended December 31, 2018 and 2017 (Unaudited)	7
Condensed Consolidated Statements of Cash Flows for the Nine Months Ended December 31, 2018 and 2017 (Unaudited)	9
Notes to Condensed Consolidated Financial Statements (Unaudited)	11
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	23
Item 3. Quantitative and Qualitative Disclosures About Market Risk	36
Item 4. Controls and Procedures	36
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	37
Item 1A. Risk Factors	37
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	72
Item 3. Defaults Upon Senior Securities	72
Item 4. Mine Safety Disclosures	72
Item 5. Other Information	72
Item 6. Exhibits	73
Signatures	74

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	December 31, 2018	March 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 183,003	$ 108,624
Prepaid expenses and other current assets	12,396	5,139
Income tax receivable	767	1,000
Total current assets	196,166	114,763
Property and equipment, net	1,693	1,273
Other assets	3,811	3,065
Total assets	$ 201,670	$ 119,101
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 5,471	$ 4,578
Interest payable	429	282
Accrued expenses	48,388	30,265
Due to RSL, RSI and RSG	66	1,960
Current maturities of long-term debt	1,520	—
Total current liabilities	55,874	37,085
Deferred rent	1,132	408
Deferred interest payable	773	255
Long-term debt, less current maturities	97,156	43,624
Total liabilities	154,935	81,372
Commitments and contingencies (Note 10)		
Shareholders' equity:		
Common shares, par value $0.000017727 per share, 564,111,242 shares authorized, 70,801,521 and 60,997,856 issued and outstanding common shares at December 31, 2018 and March 31, 2018, respectively	1	1
Additional paid-in capital	473,518	266,178
Accumulated other comprehensive income	227	24
Accumulated deficit	(427,011)	(228,474)
Total shareholders' equity	46,735	37,729
Total liabilities and shareholders' equity	$ 201,670	$ 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 December 31,		Nine Months Ended December 31,	
	2018	2017	2018	2017
Operating expenses:				
Research and development[1]	$ 58,434	$ 34,875	$ 163,588	$ 76,753
General and administrative[2]	10,686	6,640	29,738	16,963
Total operating expenses	69,120	41,515	193,326	93,716
Interest expense, net	1,634	904	4,831	904
Other (income) expense, net	(121)	(429)	147	(225)
Loss before income taxes	(70,633)	(41,990)	(198,304)	(94,395)
Income tax (benefit) expense	—	(213)	233	607
Net loss	$ (70,633)	$ (41,777)	$ (198,537)	$ (95,002)
Net loss per common share — basic and diluted	$ (1.04)	$ (0.70)	$ (3.01)	$ (1.60)
Weighted average common shares outstanding — basic and diluted	67,616,419	59,629,486	65,873,779	59,446,140

[1] Includes $41 and $1,958 of costs allocated from RSL, RSI, and RSG during the three months ended December 31, 2018 and 2017, respectively, and $2,524 and $3,061 of costs allocated from RSL, RSI, and RSG during the nine months ended December 31, 2018 and 2017, respectively. Also includes share-based compensation expense (see Note 9).

[2] Includes $470 and $1,183 of costs allocated from RSL, RSI, and RSG during the three months ended December 31, 2018 and 2017, respectively, and $2,644 and $2,692 of costs allocated from RSL, RSI, and RSG during the nine months ended December 31, 2018 and 2017, respectively. Also includes share-based compensation expense (see Note 9).

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 December 31,		Nine Months Ended December 31,	
	2018	2017	2018	2017
Net loss	$ (70,633)	$ (41,777)	$ (198,537)	$ (95,002)
Other comprehensive (loss) income:				
Foreign currency translation adjustment	(150)	(379)	203	(231)
Total other comprehensive (loss) income	(150)	(379)	203	(231)
Comprehensive loss	$ (70,783)	$ (42,156)	$ (198,334)	$ (95,233)

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 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 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 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
Share-based compensation expense	—	—	4,529	—	—	4,529
Capital contribution — share-based compensation	—	—	196	—	—	196
Capital contribution from RSI and RSG	—	—	212	—	—	212
Foreign currency translation adjustment	—	—	—	(72)	—	(72)
Issuance of shares in secondary public equity offering, net of commissions and offering costs of $5.1 million	3,533,399	—	74,391	—	—	74,391
Issuance of shares upon exercise of stock options and vesting of RSUs	60,271	—	460	—	—	460
Net loss	—	—	—	—	(65,770)	(65,770)
Balance at September 30, 2018	68,484,888	1	430,101	377	(356,378)	74,101
Share-based compensation expense	—	—	4,669	—	—	4,669
Capital contribution — share-based compensation	—	—	125	—	—	125
Capital contribution from RSI and RSG	—	—	384	—	—	384
Foreign currency translation adjustment	—	—	—	(150)	—	(150)
Shares issued to NovaQuest, net of issuance costs	2,286,284	—	37,982	—	—	37,982
Issuance of shares upon exercise of stock options and vesting of RSUs	30,349	—	257	—	—	257
Net loss	—	—	—	—	(70,633)	(70,633)
Balance at December 31, 2018	70,801,521	$ 1	$ 473,518	$ 227	$ (427,011)	$ 46,735

	Common Shares		Common Shares Subscribed	Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount					
Balance at March 31, 2017	60,275,757	$ 1	$ (1)	$ 251,733	$ 140	$ (85,097)	$ 166,776
Adjustment to adopt ASU 2016-09	—	—	—	122	—	(122)	—
Shares issued to settle the warrant liability to Takeda	4,432	—	—	58	—	—	58
Share-based compensation expense	564,111	—	—	1,954	—	—	1,954
Capital contribution — share-based compensation	—	—	—	247	—	—	247
Foreign currency translation adjustment	—	—	—	—	264	—	264
Net loss	—	—	—	—	—	(23,317)	(23,317)
Balance at June 30, 2017	60,844,300	1	(1)	254,114	404	(108,536)	145,982
Share-based compensation expense	—	—	—	2,519	—	—	2,519
Capital contribution — share-based compensation	—	—	—	230	—	—	230
Foreign currency translation adjustment	—	—	—	—	(116)	—	(116)
Issuance of shares upon exercise of stock options	4,936	—	—	12	—	—	12
Net loss	—	—	—	—	—	(29,908)	(29,908)
Balance at September 30, 2017	60,849,236	1	(1)	256,875	288	(138,444)	118,719
Share-based compensation expense	—	—	—	3,046	—	—	3,046
Capital contribution — share-based compensation	—	—	—	247	—	—	247
Foreign currency translation adjustment	—	—	—	—	(379)	—	(379)
Issuance of shares upon exercise of stock options	1,798	—	—	4	—	—	4
Shares issued to NovaQuest, net of issuance costs of $0.1 million	138,361	—	—	1,857	—	—	1,857
Warrants issued with debt financing	—	—	—	481	—	—	481
Net loss	—	—	—	—	—	(41,777)	(41,777)
Balance at December 31, 2017	60,989,395	$ 1	$ (1)	$ 262,510	$ (91)	$ (180,221)	$ 82,198

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)

	Nine Months Ended December 31,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (198,537)	$ (95,002)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	13,763	8,243
Depreciation	298	167
Amortization of debt discount and issuance costs	1,378	390
Foreign currency translation adjustment	203	(231)
Other	596	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(7,235)	(2,058)
Deferred tax assets	—	208
Income tax receivable	233	(502)
Other assets	(146)	(2,098)
Accounts payable	893	(1,238)
Interest payable	147	—
Accrued expenses	18,079	8,838
Due to RSL, RSI and RSG	(1,894)	653
Deferred rent	724	259
Deferred interest payable	518	105
Net cash used in operating activities	(170,980)	(82,266)
Cash flows from investing activities:		
Purchase of property and equipment	(718)	(375)
Net cash used in investing activities	(718)	(375)
Cash flows from financing activities:		
Cash proceeds from issuance of common shares in secondary public equity offering, net of issuance costs paid	74,391	—
Cash proceeds from issuance of common shares in “at-the-market” equity offering, net of issuance costs paid	57,315	—
Cash proceeds from issuance of common shares in Private Placement with RSL	22,500	—
Cash proceeds from debt financings, net of financing costs paid	54,000	28,803
Cash proceeds from issuance of common shares to NovaQuest, net of issuance costs paid	38,000	1,857
Cash proceeds from stock option exercises	771	16
Cash paid to NovaQuest for annual debt administration fee	(300)	—
Net cash provided by financing activities	246,677	30,676
Net change in cash, cash equivalents and restricted cash	74,979	(51,965)
Cash, cash equivalents and restricted cash, beginning of period	108,624	180,838
Cash, cash equivalents and restricted cash, end of period	$ 183,603	$ 128,873
Non-cash financing activities:		
Stock options exercised receivables, included in prepaid expenses and other current assets	$ (22)	$ —
Deferred financing costs included in accrued expenses	$ 26	$ 137
Offering costs included in accrued expenses	$ 18	$ —
Warrant issued to Hercules	$ —	$ 481

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

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 relugolix in combination with low-dose estradiol and a progestin for the treatment of heavy menstrual bleeding associated with uterine fibroids and for pain associated with endometriosis, relugolix as monotherapy at a higher dose for advanced prostate cancer, and an additional product candidate, MVT-602, an oligopeptide kisspeptin-1 receptor agonist, for the treatment of female infertility as part of 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, preparing for and advancing the clinical development of its product candidates, and preparing for the potential future regulatory approvals and commercialization of relugolix.

The Company has incurred, and expects to continue to incur, significant operating losses and negative cash flows as it continues to develop its product candidates and prepares for the potential future regulatory approvals and commercialization of relugolix. 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. See Note 2, "Summary of Significant Accounting Policies—Going Concern and Management's Plans."

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, or U.S., 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 U.S. Securities and Exchange Commission, or the 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 and nine months ended December 31, 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 included 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 the evaluation of the Company's ability to continue as a going concern, 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) Going Concern and Management's Plans

The Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the unaudited condensed consolidated financial statements are issued. During the nine months ended December 31, 2018, the Company incurred net losses of $198.5 million and used $171.0 million of cash and cash equivalents in operations. The Company expects to continue to incur significant and increasing operating losses and negative cash flows as it continues to develop its product candidates and prepares for the potential future regulatory approvals and commercialization of relugolix. The Company has not generated any revenue to date and does not expect to generate product revenue unless and until it successfully completes development and obtains regulatory approval for one of its product candidates. Based on its current operating plan, the Company expects that its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements through at least the first quarter of its fiscal year ending March 31, 2020, and to enable it to announce top-line data from the first Phase 3 clinical trial for 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. The Company anticipates that it will continue to incur net losses for the foreseeable future.

To continue as a going concern, the Company will need, among other things, additional capital resources. The Company continually assesses multiple options to obtain additional funding to support its operations, including through financing activities in public or private capital markets, financing arrangements with Roivant Sciences, potential business development activities and cost containment measures. Management can provide no assurances that any sources of a sufficient amount of financing will be available to the Company on favorable terms, if at all. Although the Company believes that it will continue to raise capital to fund its operations as it has in the past, ASC 240-40, *Going Concern*, does not allow the Company to consider future financing activities in its assessment of the Company's future cash burn for the purpose of its liquidity assessment.

These factors raise substantial doubt about the Company's ability to continue as a going concern for the one-year period following the date that these unaudited condensed consolidated financial statements were issued. The accompanying unaudited condensed consolidated financial statements and footnotes have been prepared on the basis that the Company will continue as a going concern, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of the Company to continue as a going concern.

(D) 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. Potentially dilutive common shares have been excluded from the diluted net loss per common share computations in all periods presented because such securities have an anti-dilutive effect on net loss per common share due to the Company's net loss. There are no reconciling items used to calculate the weighted-average number of total common shares outstanding for basic and diluted net loss per common share data.

At December 31, 2018 and 2017, potentially dilutive securities were as follows:

	December 31,	
	2018	2017
Options	5,351,908	3,409,366
Restricted share awards (unvested)	987,193	1,269,249
Restricted stock units (unvested)	40,325	15,000
Warrants	73,710	49,800
Total	6,453,136	4,743,415

(E) Cash, Cash Equivalents, and Restricted Cash

Cash and cash equivalents include cash deposits in banks and all highly liquid investments that are readily convertible to cash. The Company considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. The Company maintains cash deposits and cash equivalents in highly-rated, federally-insured financial institutions in excess of federally insured limits. The Company has established guidelines relative to diversification and maturities to maintain safety and liquidity. The Company has not experienced any credit losses related to these financial instruments and does not believe that it is exposed to any significant credit risk related to these instruments.

Restricted cash consists of legally restricted deposits held as compensating balances against the Company's corporate credit card program. This amount will remain deposited with the bank for the duration of the corporate credit card program as the agreements require the Company to maintain compensating balances against its corporate credit card program. Cash as reported in the unaudited condensed consolidated statements of cash flows includes the aggregate amounts of cash, cash equivalents, and restricted cash as presented on the unaudited condensed consolidated balance sheets. Cash as reported in the unaudited condensed consolidated statements of cash flows consists of (in thousands):

	December 31, 2018	December 31, 2017
Cash and cash equivalents	$ 183,003	$ 128,873
Restricted cash[(1)]	600	—
Total cash, cash equivalents and restricted cash	$ 183,603	$ 128,873

[(1)] Included in other assets on the unaudited condensed consolidated balance sheets.

(F) Fair Value Measurements

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

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

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

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

The Company's financial instruments include cash, cash equivalents consisting of money market funds, accounts payable and debt. Cash, cash equivalents, 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 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.

(G) Recently Adopted Accounting Standards

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, which amends certain SEC material in Topic 740 for the income tax accounting implications of the Tax Cuts and Jobs Act and was effective immediately. The adoption of ASU No. 2018-05 did not have a material impact on the Company's consolidated financial statements and related disclosures.

In November 2016, the FASB issued ASU No. 2016-18 "*Statement of Cash Flows* (Topic 230)*: Restricted Cash (a consensus of the FASB Emerging Issues Task Force).*" ASU 2016-18 requires that restricted cash be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period amounts shown in the statements of cash flows. ASU 2016-18 is effective for annual reporting periods beginning after December 15, 2017 and is required to be adopted using a retrospective approach, if applicable, with early adoption permitted. The Company adopted ASU 2016-18 on April 1, 2018. The adoption of ASU 2016-18 did not have a material impact on the Company's consolidated financial statements and related disclosures.

(H) Recently Issued Accounting Standards

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 plans to adopt this standard as of April 1, 2019. The Company has implemented a process to identify its outstanding lease portfolio and is currently evaluating its outstanding leases to determine the impact the new standard will have on its consolidated financial statements. The Company expects that the adoption of this standard will result in the recognition of an asset for the right to use a leased facility on the Company's consolidated balance sheet, as well as the recognition of a liability for the lease payments remaining on the lease. While the consolidated balance sheet presentation is expected to change, the Company does not expect a material change to the consolidated statements of operations and comprehensive loss or cash flows.

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 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—Fair Value Measurements

At December 31, 2018, assets measured at fair value consisted of money market funds, which are included in cash and cash equivalents in the accompanying unaudited condensed consolidated balance sheet. There were no assets measured at fair value at December 31, 2017. The following table summarizes these assets (in thousands):

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 65,328	$ —	$ —	$ 65,328
Total assets	$ 65,328	$ —	$ —	$ 65,328

Money market funds are included in Level 1 of the fair value hierarchy and are valued at the closing price reported by an actively traded exchange.

Note 4—Accrued Expenses

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

	December 31, 2018	March 31, 2018
Accrued R&D expenses	$ 42,607	$ 25,988
Accrued compensation-related expenses	3,925	2,792
Accrued professional fees	417	566
Accrued other expenses	1,439	919
Total accrued expenses	$ 48,388	$ 30,265

Note 5—Financing Arrangements

(A) NovaQuest

In October 2017, the Company, and its subsidiaries, 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 had 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 was obligated to purchase up to $20.0 million of the Company's common shares on a pro rata basis, subject to certain terms and conditions, through December 31, 2018. The equity purchase price for each such purchase would 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 committed that it would issue at least $30.0 million aggregate principal amount of notes through December 31, 2018, subject to certain terms and conditions. The Company issued $6.0 million aggregate principal amount in October 2017 and $54.0 million aggregate principal amount in December 2018. With the 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, and with the issuance of $54.0 million aggregate principal amount of notes in December 2018, NovaQuest also purchased 1,082,977 common shares for $18.0 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 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 committed that it would 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 would be equal to 105% of the average of the volume-weighted average price for the five consecutive trading days immediately prior to the relevant purchase date. In December 2018, the Company exercised this option and issued and sold 1,203,307 common shares for $20.0 million in accordance with the terms of the NovaQuest Equity Purchase Agreement.

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, net in the Company's unaudited condensed consolidated statements of operations. During the three and nine months ended December 31, 2018, interest expense, net included $0.1 million and $0.3 million of amortized deferred financing costs related to the NovaQuest notes. During the three and nine months ended December 31, 2017, interest expense, net included $0.1 million of amortized deferred financing costs related to the NovaQuest notes. During the three months ended December 31, 2018, the Company paid NovaQuest an annual debt administration fee of $0.3 million.

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

	December 31, 2018	March 31, 2018
Principal amount	$ 60,000	$ 6,000
Less: unamortized debt issuance costs	(891)	(854)
Loan payables less unamortized debt issuance costs	59,109	5,146
Less: current maturities	—	—
Long-term debt, net of current maturities and unamortized debt issuance costs	$ 59,109	$ 5,146

(B) Hercules

In October 2017, the Company, and its subsidiaries, as guarantors, and Hercules Capital, Inc., or Hercules, entered into a Loan Agreement, or the Hercules Loan Agreement, which provided 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 9.50% at December 31, 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 in July 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 July 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 was 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, net 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	7.00

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, net in the Company's unaudited condensed consolidated statements of operations. During the three and nine months ended December 31, 2018, interest expense, net included $0.3 million and $1.0 million of amortized debt discount and issuance costs related to the Term Loans. During the three and nine ended December 31, 2017, interest expense, net included $0.3 million of amortized debt discount and issuance costs related to the Term Loans.

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

	December 31, 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	(3,053)	(4,142)
Loan payables less unamortized debt discount and issuance costs	39,567	38,478
Less: current maturities	(1,520)	—
Long-term debt, net of current maturities and unamortized debt discount and issuance costs	$ 38,047	$ 38,478

Note 6—Related Party Transactions

(A) Services Agreements

In July 2016, the Company entered into a 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 based upon the relative percentage of time utilized on Company matters by the respective employee. 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 December 31, 2018 and 2017, the Company incurred expenses (inclusive of third party pass thru costs billed to the Company) of $0.4 million and $2.9 million, respectively, inclusive of the mark-up. Under the Services Agreements, for the nine months ended December 31, 2018 and 2017, the Company incurred expenses (inclusive of third party pass thru costs billed to the Company) of $4.6 million and $5.0 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, RSG, and the Company's employees, the Company recorded share-based compensation expense of $0.1 million and $0.2 million, respectively, for the three months ended December 31, 2018 and 2017 and $0.5 million and $0.7 million, respectively, for the nine months ended December 31, 2018 and 2017. Refer to Note 9 for further details.

(C) Private Placement with RSL

See Note 8(B) for information regarding the Private Placement with RSL.

Note 7—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 (benefit) for income taxes is primarily based on income taxes in the U.S. for federal, state and local taxes. The Company's effective tax rate for the three months ended December 31, 2018 and 2017 was 0.00% and 0.51%, respectively. The Company's effective tax rate for the nine months ended December 31, 2018 and 2017 was (0.12)% and (0.64)%, respectively. The effective tax rate 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 U.S. The Act revises the U.S. corporate income tax by, among other things, lowering the corporate income tax rate from a top marginal tax rate of 35% to a flat tax rate of 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 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. As a result of finalizing the Company's fiscal 2018 operating results, the issuance of new interpretive guidance, and other analyses performed, the Company finalized its accounting related to the impacts of the Act and recorded immaterial measurement period adjustments in the period ended December 31, 2018.

Note 8—Shareholders' Equity

(A) Underwritten Secondary Public Equity Offering of Common Stock

In July 2018, the Company completed an underwritten secondary public equity offering of 3,333,334 of its common shares at a public offering price of $22.50 per common share. Subsequently, in August 2018, the Company issued and sold an additional 200,065 common shares upon the partial exercise of the underwriters' over-allotment option at a 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 in connection with the underwritten secondary public equity offering, including the over-allotment option, were approximately $74.4 million.

(B) 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.

(C) 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 and nine months ended December 31, 2018, the Company issued and sold none and 2,767,129, respectively, 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 underwriting commissions and offering costs payable by the Company. The Company currently has approximately $40.6 million of capacity available under its "at-the-market" equity offering program.

(D) Issuance of Equity Instruments to NovaQuest and Hercules

In October 2017, the Company issued and sold 138,361 common shares to NovaQuest for $2.0 million in accordance with the terms of the NovaQuest Securities Purchase Agreement. In December 2018, the Company issued and sold 1,082,977 common shares to NovaQuest for $18.0 million in accordance with the NovaQuest Securities Purchase Agreement and issued and sold 1,203,307 common shares to NovaQuest for $20.0 million in accordance with the NovaQuest Equity Purchase Agreement. In October 2017, the Company issued a Warrant to Hercules exercisable for 49,800 of its common shares at an exercise price of $15.06 per common share and in March 2018, the Company issued a Warrant to Hercules exercisable for an aggregate of 23,910 of its common shares at an exercise price of $18.82 per common share. Additional information is included in Note 5, "Financing Arrangements."

(E) Takeda Warrant Liability

During the year ended March 31, 2018, the Company issued 4,432 common shares to Takeda pursuant to a warrant which expired on April 30, 2017.

Note 9—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 December 31, 2018, a total of 2.2 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 is as follows:

	Number of Options
Options outstanding at March 31, 2018	3,549,405
Granted	2,097,210
Exercised	(102,463)
Forfeited	(192,244)
Options outstanding at December 31, 2018	5,351,908
Options vested and expected to vest at December 31, 2018	5,351,908
Options exercisable at December 31, 2018	1,392,679

(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 is as follows:

	Number of Shares
Unvested balance at March 31, 2018	1,213,735
Granted	29,700
Vested	(215,917)
Unvested balance at December 31, 2018	1,027,518

(D) Share-Based Compensation Expense

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

	Three Months Ended December 31,	
	2018	2017
Share-based compensation expense recognized as:		
R&D expenses	$ 1,840	$ 1,041
G&A expenses	2,954	2,252
Total	$ 4,794	$ 3,293

	Nine Months Ended December 31,	
	2018	2017
Share-based compensation expense recognized as:		
R&D expenses	$ 5,247	$ 2,580
G&A expenses	8,516	5,663
Total	$ 13,763	$ 8,243

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 9(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 for awards granted pursuant to the 2016 Plan was approximately $48.6 million at December 31, 2018 and is expected to be recognized over a weighted-average period of approximately 2.98 years.

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

(1) Stock Options Granted to RSI Employees:

During the three months ended December 31, 2018 and 2017, the Company recorded share-based compensation expense related to stock options granted to RSI employees of $17,745 and $7,293, respectively. During the nine months ended December 31, 2018 and 2017, the Company recorded share-based compensation expense related to stock options granted to RSI employees of $47,721 and $0.2 million, respectively. At December 31, 2018, total unrecognized compensation expense related to stock options granted to RSI employees was $0.1 million, which is expected to be recognized over a period of approximately 1.63 years. This share-based compensation expense is included in R&D and G&A expenses in the accompanying unaudited condensed consolidated statements of operations.

(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, RSG and the Company's employees, the Company recorded share-based compensation expense of $0.1 million and $0.2 million, respectively, for the three months ended December 31, 2018 and 2017, and $0.5 million and $0.7 million, respectively, for the nine months ended December 31, 2018 and 2017.

The RSL common share awards and RSL options granted by RSL to RSL, RSI, RSG and the Company's 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. 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 December 31, 2018, the performance conditions had not been met and were deemed not probable of being met. For the three and nine months ended December 31, 2018 and 2017, the Company recorded no share-based compensation expense related to these RSL RSUs. At December 31, 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 10—Commitments and Contingencies

The Company has entered into commitments under its license agreement with Takeda, services agreements with RSI and RSG (See Note 6(A)), and financing agreements with NovaQuest and Hercules (See Note 5). 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 CMO 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.

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 U.S. 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 in combination with low-dose estradiol and a progestin, relugolix monotherapy 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;
- the anticipated future regulatory submissions and the timing of, and our ability to, obtain and maintain regulatory approvals for relugolix in combination with low-dose estradiol and a progestin, relugolix monotherapy, MVT-602 and any future product candidates;
- our plans to commercialize relugolix, if approved;
- our ability to achieve commercial sales of any approved products, whether alone or in collaboration with others;
- our ability to obtain reimbursement coverage for our products when commercialized;
- the rate and degree of market acceptance and clinical utility of any approved products;
- our ability to initiate and continue relationships with third-party clinical research organizations and manufacturers;
- our ability to quickly and efficiently identify and develop 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;
- our estimates regarding our results of operations, financial condition, liquidity, capital requirements, access to capital, prospects, growth and strategies;
- our ability to continue to fund our operations with the cash and cash equivalents currently on hand;
- our ability to raise additional capital;
- industry trends;
- developments and projections relating to our competitors or our industry; and
- the success of competing drugs that are or may become available.

Such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors known and unknown that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, 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 in combination with low-dose estradiol and a progestin for the treatment of heavy menstrual bleeding associated with uterine fibroids and for pain associated with endometriosis, and relugolix as a monotherapy at a higher dose for advanced prostate cancer. In addition, we are developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, for the treatment of female infertility as a part of assisted reproduction. 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, preparing for and advancing the clinical development of our product candidates and preparing for the potential regulatory approvals and commercialization of relugolix.

Financial History

We have incurred, and expect to continue to incur, significant operating losses and negative cash flows as we continue to develop our product candidates and prepare for the potential future regulatory approvals and commercialization of relugolix. 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 have funded our operations primarily from the issuance and sale of our common shares and from the issuance of notes to NovaQuest Capital Management, or NovaQuest, and from the Term Loans we have with Hercules Capital, Inc., or Hercules. Through December 31, 2018, our sources of funding have primarily consisted of:

- In November 2016, we completed our initial public offering, or IPO, in which we sold 14,500,000 common shares at a price of $15.00 per 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. In October 2017, March 2018, and December 2018, we obtained gross proceeds of $33.0 million, $15.0 million, and $92.0 million, respectively, from these financing arrangements. As of December 31, 2018, the financing arrangements have been fully drawn. Additional information is included in Note 5, "Financing Arrangements," to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.
- On April 2, 2018, we entered into a share purchase agreement, or the Purchase Agreement, with Roivant Sciences Ltd., or RSL, our controlling shareholder, 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 and nine months ended December 31, 2018, we issued and sold none and 2,767,129, respectively, 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 underwriting commissions and offering costs payable by us. We currently have approximately $40.6 million of capacity available under our "at-the-market" equity offering program.
- In July 2018, we completed an underwritten secondary public equity offering of 3,333,334 of our common shares at a public offering price of $22.50 per common share. Subsequently, in August 2018, we issued and sold an additional 200,065 common shares upon the partial exercise of the underwriters' over-allotment option at a 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 in connection with the underwritten secondary public equity offering, including the over-allotment option, were approximately $74.4 million.

As of December 31, 2018, and March 31, 2018, we had an accumulated deficit of $427.0 million and $228.5 million, respectively. We recorded net losses of $70.6 million and $41.8 million for the three months ended December 31, 2018 and 2017, respectively, and $198.5 million and $95.0 million for the nine months ended December 31, 2018 and 2017, respectively. As of December 31, 2018, we had $183.0 million of cash and cash equivalents available to us, 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.

Our Product Candidates

Relugolix

We are currently developing relugolix in three target indications: heavy menstrual bleeding associated with uterine fibroids; pain associated with endometriosis; and advanced prostate cancer. Relugolix is an oral, once-daily, small molecule that acts as a GnRH receptor antagonist that binds to and inhibits GnRH receptors in the anterior pituitary gland. Inhibition of GnRH receptors decreases the release of gonadotropins (luteinizing hormone 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 for relugolix. Lowering estrogen levels decreases heavy menstrual bleeding in women with uterine fibroids and reduces the pelvic pain associated with endometriosis. We are developing relugolix, 40 mg orally once daily, administered in combination with estradiol (1.0 mg) and a progestin (0.5 mg norethindrone acetate), with the goal of optimizing estradiol levels to maximize the benefit of relugolix on the symptoms of uterine fibroids and endometriosis, while mitigating side effects from a low-estrogen state (e.g., hot flashes or bone mineral density loss). We expect to launch in our women's health indications with a once-daily oral fixed-dose formulation of relugolix, estradiol and norethindrone acetate. Decreasing testosterone has been shown to slow growth and progression of advanced prostate cancer, including when the disease recurs or the prostate-specific antigen, or PSA, is rising following prostatectomy or radiation therapy, and is the central objective of treatment with relugolix, 120 mg orally once daily following a single dose 360 mg loading dose. 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, and in January 2019 Takeda and ASKA Pharmaceutical Co., Ltd. announced that Takeda obtained marketing authorization in Japan for Relumina® Tablets 40 mg (generic name: relugolix) for the improvement of symptoms of uterine fibroids (heavy menstrual bleeding, lower abdominal pain, lower back pain, and anemia).

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 (1.0 mg estradiol and 0.5 mg norethindrone acetate) 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 have completed enrollment in the two replicate LIBERTY 1 (N=388) and LIBERTY 2 (N=382) trials. Eligible women completing the initial 24-week period are 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 and efficacy of longer-term treatment. Women completing the open-label extension study will be offered the opportunity to participate in a randomized withdrawal study to provide up to two years of safety and efficacy data for relugolix in combination with low-dose estradiol and a progestin and information about the need for maintenance therapy. We are also conducting a one-year observational study of bone mineral density in women with uterine fibroids or endometriosis to provide additional context for our phase 3 clinical programs.

Top-line results for the LIBERTY 1 trial are expected in the second quarter of calendar 2019 and top-line results from the LIBERTY 2 trial are expected in the third quarter of calendar 2019. We expect to file the New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, for relugolix to treat heavy menstrual bleeding associated with uterine fibroids in the fourth quarter of calendar 2019.

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. On January 8, 2019, Takeda and ASKA Pharmaceutical Co., Ltd. announced that Takeda obtained marketing authorization in Japan for Relumina® Tablets 40 mg (generic name: relugolix) for the improvement of symptoms of uterine fibroids (heavy menstrual bleeding, lower abdominal pain, lower back pain, and anemia). The Phase 3 data from each of the trials described above will be available to us, and may be used to support our anticipated NDA submission to the FDA. Although we will be solely responsible for obtaining FDA approval for relugolix in the U.S., the FDA can accept the results of clinical trials conducted outside the U.S. 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.

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

We initiated a Phase 3 clinical program in June 2017, evaluating relugolix in women with pain associated with endometriosis. 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 (1.0 mg estradiol and 0.5 mg norethindrone acetate); 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 80-week period, or a total treatment period of 104 weeks, to evaluate the safety of longer-term treatment. We currently expect to complete enrollment for the SPIRIT 1 and SPIRIT 2 trials in calendar 2019 with top line results expected in the first quarter of calendar 2020.

Our Phase 3 Program for the Treatment of Advanced Prostate Cancer

We initiated a Phase 3 clinical trial in March of 2017, evaluating the safety and efficacy of relugolix in men with advanced prostate cancer, which we refer to as the HERO trial. We believe 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 for approval in those regions should it be successful.

The HERO trial has completed enrollment after randomizing 934 men with advanced prostate cancer who require androgen deprivation therapy in a 2:1 ratio to treatment with either oral relugolix 120 mg once daily (after a single oral loading dose of 360 mg) or a depot injection of leuprolide (per national or regional product label) for a period of at least 48 weeks. Based on FDA discussions, we believe that we will be required to conduct only one Phase 3 trial with a single relugolix arm to gain approval for relugolix in men with advanced prostate cancer in the U.S. 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 such as Europe and Japan. We expect to present top-line results from the HERO trial in the fourth quarter of calendar 2019 and to submit the U.S. NDA filing in early calendar 2020.

In addition, we filed an amendment to the HERO protocol to continue to enroll approximately 120 additional men with metastatic prostate cancer with the objective of prospectively demonstrating that relugolix can delay the time to progression to the lethal state of the disease, castration-resistant prostate cancer, as compared to leuprolide. We believe that relugolix, a direct GnRH receptor antagonist, has the potential to delay the time to castration-resistant disease as compared with leuprolide, a GnRH agonist, because relugolix more rapidly suppresses testosterone and PSA and more fully suppresses follicle-stimulating hormone than leuprolide.

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 previously evaluated in over 150 men. MVT-602 is an oligopeptide kisspeptin-1 receptor agonist. Kisspeptin, the ligand, is a naturally-occurring peptide that stimulates GnRH release and is required for puberty and maintenance of normal reproductive function, including production of sperm, follicular maturation and ovulation, and production of estrogen and progesterone in women and testosterone in men. MVT-602 is being developed as a potential treatment for female infertility in women as part of assisted reproduction, such as in vitro fertilization, 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.

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

Further assessment of the exposure-response profile of MVT-602 administered is being conducted in a Phase 2a study during the pre-ovulatory phase in approximately 70 fertile women undergoing a controlled ovarian stimulation. This study has completed enrollment and top-line results are expected to be reported in the first half of calendar 2019. This study is intended to provide information for dose selection for a study of MVT-602 in infertile women seeking pregnancy.

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 and 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 clinical programs. Our research and development, or R&D, expenses include program-specific costs, as well as unallocated costs.

Program-specific costs include:

- third-party costs, 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 primarily 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 in the near term as we continue to support the clinical development of our relugolix and MVT-602 clinical studies, prepare to seek regulatory approval for our product candidates, establish a medical affairs function, and expand our employee base. Product candidates in later stages of clinical development, such as relugolix, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our share-based compensation expense to increase as we continue to increase our number of 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, professional fees for legal, consulting, accounting, auditing and tax services, rent and facilities expense, information technology costs, general overhead, costs billed to us under the Services Agreements, and share-based compensation expense and other costs allocated to us from RSL.

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

Results of Operations

The following table summarizes our results of operations for the three and nine months ended December 31, 2018 and 2017 (in thousands):

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 58,434	$ 34,875	$ 163,588	$ 76,753
General and administrative	10,686	6,640	29,738	16,963
Total operating expenses	69,120	41,515	193,326	93,716
Interest expense, net	1,634	904	4,831	904
Other (income) expense, net	(121)	(429)	147	(225)
Loss before income taxes	(70,633)	(41,990)	(198,304)	(94,395)
Income tax (benefit) expense	—	(213)	233	607
Net loss	$ (70,633)	$ (41,777)	$ (198,537)	$ (95,002)

Research and Development Expenses

For the three and nine months ended December 31, 2018 and 2017, our R&D expenses consisted of the following (in thousands):

	Three Months Ended December 31,		
	2018	2017	Change
Program-specific costs:			
Relugolix	$ 47,800	$ 29,095	$ 18,705
MVT-602	1,779	899	880
Unallocated costs:			
Share-based compensation	1,840	1,041	799
Personnel expense	6,353	3,213	3,140
Services Agreements	—	192	(192)
Other expense	662	435	227
Total R&D expenses	$ 58,434	$ 34,875	$ 23,559

	Nine Months Ended December 31,		
	2018	2017	Change
Program-specific costs:			
Relugolix	$ 134,023	$ 63,498	$ 70,525
MVT-602	4,820	943	3,877
Unallocated costs:			
Share-based compensation	5,247	2,580	2,667
Personnel expense	16,279	8,131	8,148
Services Agreements	748	501	247
Other expense	2,471	1,100	1,371
Total R&D expenses	$ 163,588	$ 76,753	$ 86,835

R&D expenses increased by $23.6 million, to $58.4 million, in the three months ended December 31, 2018 compared to $34.9 million in the three months ended December 31, 2017, primarily due to increases in expenses as a result of the progress of our ongoing Phase 3 clinical trials of relugolix, which were initiated in 2017, as well as additional personnel-related expenses and MVT-602 clinical trial expenses. R&D expenses in the three months ended December 31, 2018 consisted primarily of CRO, clinical drug supply and other study-related costs of $49.6 million, personnel expenses of $6.4 million and share-based compensation expense of $1.8 million, of which $40,921 was allocated to us by RSL.

R&D expenses for the three months ended December 31, 2017 consisted primarily of CRO, clinical drug supply and other study-related costs of $28.4 million, personnel expenses of $3.2 million, share-based compensation expense of $1.0 million, $0.1 million of which was allocated to us by RSL, and costs billed to us under the Services Agreements of $1.9 million, including unallocated personnel expenses and third-party pass thru costs associated with our ongoing clinical and other research programs.

R&D expenses increased by $86.8 million, to $163.6 million, in the nine months ended December 31, 2018 compared to $76.8 million in the nine months ended December 31, 2017, primarily due to increases in expenses as a result of the progress of our ongoing Phase 3 clinical trials of relugolix, which were initiated in 2017, as well as additional personnel-related expenses and MVT-602 clinical trial expenses. R&D expenses in the nine months ended December 31, 2018 consisted primarily of CRO, clinical drug supply and other study-related costs of $137.2 million, personnel expenses of $16.3 million, share-based compensation expense of $5.2 million, of which $0.2 million was allocated to us by RSL, and costs billed to us under the Services Agreements of $2.3 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 nine months ended December 31, 2017 consisted primarily of CRO, clinical drug supply and other study-related costs of $61.9 million, personnel expenses of $8.1 million, share-based compensation expense of $2.5 million, $0.2 million of which was allocated to us by RSL, and costs billed to us under the Services Agreements of $2.8 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 $4.0 million, to $10.7 million, in the three months ended December 31, 2018 compared to $6.6 million in the three months ended December 31, 2017, primarily due to an increase in employee salaries, benefits and share-based compensation expense resulting from additional headcount to support the growth of our operations, increases in professional service fees, and increases in other administrative expenses. G&A expenses in the three months ended December 31, 2018 consisted primarily of personnel-related and general overhead expenses of $5.8 million, share-based compensation expense of $3.0 million, of which $0.1 million was allocated to us by RSL, legal and professional fees of $1.0 million, rent and other facilities related costs of $0.5 million and costs of $0.4 million allocated to us from RSL.

G&A expenses for the three months ended December 31, 2017 consisted primarily of personnel-related and general overhead expenses of $2.7 million, share-based compensation expense of $2.3 million, including $0.2 million allocated to us by RSI and RSL, legal and professional fees of $0.6 million, and costs of $1.0 million billed to us under the Services Agreements, including personnel expenses, overhead allocations and third-party costs.

G&A expenses increased by $12.8 million, to $29.7 million, in the nine months ended December 31, 2018 compared to $17.0 million in the nine months ended December 31, 2017, primarily due to an increase in employee salaries, benefits and share-based compensation expense resulting from additional headcount to support the growth of our operations, increases in professional service fees, and increases in other administrative expenses. G&A expenses in the nine months ended December 31, 2018 consisted primarily personnel-related and general overhead expenses of $14.6 million, share-based compensation expense of $8.5 million, of which $0.3 million was allocated to us by RSL, costs of $2.3 million billed to us under the Services Agreements, including personnel expenses, overhead allocations and third-party pass thru costs, legal and professional fees of $2.7 million and rent and other facilities related costs of $1.6 million.

G&A expenses for the nine months ended December 31, 2017 consisted primarily of personnel-related and general overhead expenses of $6.9 million, share-based compensation expense of $5.7 million, including $0.5 million allocated to us by RSI and RSL, legal and professional fees of $2.2 million, and costs of $2.2 million billed to us under the Services Agreements, including personnel expenses, overhead allocations and third-party costs.

Interest Expense, net

Interest expense, net consists 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, partially offset by interest income earned on cash equivalents. Interest expense, net, was $1.6 million and $4.8 million for the three and nine months ended December 31, 2018, respectively, and $0.9 million for the three and nine months ended December 31, 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 issuance of notes to NovaQuest and the funds received from our Term Loans with Hercules.

As of December 31, 2018, we had $183.0 million of cash and cash equivalents available to us, 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.

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

Capital Requirements

We recorded net losses of $70.6 million and $41.8 million for the three months ended December 31, 2018 and 2017, respectively, and net losses of $198.5 million and $95.0 million for the nine months ended December 31, 2018 and 2017, respectively. As of December 31, 2018, we had an accumulated deficit of $427.0 million.

We have incurred, and expect to continue to incur, significant operating losses and negative cash flows as we continue to develop our product candidates and prepare for the potential future regulatory approvals and commercialization of relugolix. 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, anticipated regulatory filings, and our expenditures on other R&D and G&A activities. We anticipate that our capital requirements will be significant as we:

- advance our Phase 3 programs of relugolix in combination with estradiol and a progestin for the treatment of heavy menstrual bleeding associated with uterine fibroids and for pain associated with endometriosis and relugolix as monotherapy at a higher dose for advanced prostate cancer;
- conduct a Phase 2a clinical trial in healthy female volunteers to characterize the dose-response relationship in a 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, commercial, 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;
- 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
- continue to operate as a public company.

Our primary use of cash has been to fund the development of relugolix and MVT-602. We expect our operating expenses to continue to increase over the near term as we expand our operations to continue to develop our product candidates and prepare for the potential future regulatory approvals and commercialization of relugolix.

Based on our current operating plan, we expect that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through at least the first quarter of our fiscal year ending March 31, 2020, and to enable us to receive top-line data from the first Phase 3 clinical trial for 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. We anticipate that we will continue to incur net losses for the foreseeable future. To continue as a going concern, we will need, among other things, additional capital resources. We continually assess multiple options to obtain additional funding to support our operations, including through financing activities in public or private capital markets, financing arrangements with Roivant Sciences, potential business development activities and cost containment measures. We can provide no assurances that any sources of a sufficient amount of financing will be available to us on favorable terms, if at all. Although we believe that we will continue to raise capital to fund our operations as we have in the past, ASC 240-40, *Going Concern*, does not allow us to consider future financing activities in our assessment of our future cash burn for the purpose of our liquidity assessment. If we are unable to raise capital in sufficient amounts and on terms acceptable to us, we may have to significantly delay, scale back, or discontinue operations.

Until such time, if ever, as we can generate substantial product revenue from sales of relugolix, MVT-602, or any future product candidate, we expect to finance our operations through a combination of cash and cash equivalents on hand, 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 nine months ended December 31, 2018 and 2017 (in thousands):

	Nine Months Ended December 31,	
	2018	**2017**
Net cash used in operating activities	$ (170,980)	$ (82,266)
Net cash used in investing activities	$ (718)	$ (375)
Net cash provided by financing activities	$ 246,677	$ 30,676

Operating Activities

For the nine months ended December 31, 2018, we used $171.0 million in operating activities primarily due to our ongoing development and clinical trials for relugolix and MVT-602. This was primarily attributable to a net loss for the period of $198.5 million, along with an increase of $7.2 million in prepaid expenses and other current assets and a decrease of $1.9 million in amounts due to RSL, RSI and RSG. These amounts were partially offset by an increase in accrued expenses of $18.1 million and an increase in accounts payable of $0.9 million which were primarily due to the progress of our ongoing Phase 3 clinical trials of relugolix, $13.8 million of non-cash share-based compensation expense as a result of an increase in headcount, and $1.7 million of total depreciation and amortization expense.

For the nine months ended December 31, 2017, we used $82.3 million in operating activities primarily due to our ongoing development and clinical trials for relugolix. This was primarily attributable to a net loss for the period of $95.0 million, increases of $2.1 million in other assets and $2.1 million in prepaid expenses and other current assets along with a decrease of $1.2 million in accounts payable. These amounts were partially offset by an increase in accrued expenses of $8.8 million, $8.2 million of share-based compensation and $0.6 million of total depreciation and amortization expense.

Investing Activities

For the nine months ended December 31, 2018, $0.7 million was used in investing activities, all for the purchase of property and equipment.

For the nine months ended December 31, 2017, $0.4 million was used in investing activities, all for the purchase of property and equipment.

Financing Activities

For the nine months ended December 31, 2018, financing activities provided $246.7 million of cash. This was primarily due to the net proceeds of $74.4 million we received from the issuance and sale of 3,533,399 common shares in our underwritten secondary public equity offering (including the partial exercise of the underwriters' over-allotment option), $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, proceeds of $22.5 million we received from the sale of 1,110,015 common shares to RSL in a private placement, net proceeds from debt financings with NovaQuest of $54.0 million, and net proceeds of $38.0 million from the issuance and sale of 2,286,284 common shares to NovaQuest. In addition, we received cash proceeds of $0.8 million from the exercise of stock options under our 2016 Equity Incentive Plan and paid an annual debt administration fee of $0.3 million to NovaQuest under the NovaQuest Securities Purchase Agreement.

For the nine months ended December 31, 2017, financing activities provided $30.7 million of cash. This was primarily due to the net proceeds from debt financings of $28.8 million and net proceeds from the issuance of common shares of $1.9 million.

Contractual Obligations

In May 2018, we entered into a Commercial Manufacturing and Supply Agreement with Takeda, or the Takeda Commercial Supply Agreement. See Note 10, "Commitments and Contingencies" to our unaudited condensed consolidated financial statements contained herein for a further discussion of this agreement.

During the nine months ended December 31, 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 U.S. 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 evaluation of our ability to continue as a going concern, 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.

Our investment policy establishes guidelines for the investment of surplus cash in a conservative and diversified investment portfolio which seeks to provide adequate liquidity for our operations while minimizing the loss of any principal. The securities permitted under our investment policy may be subject to market risk related to changes in interest rates and other market factors. We manage our sensitivity to these risks by investing in short-term, investment grade marketable securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, we do not believe that a hypothetical 10% change in market rates would have a material impact on the realized value of our investments. As of December 31, 2018, we had cash and cash equivalents of $183.0 million, consisting of money market funds and non-interest-bearing cash deposits denominated in the U.S. dollar and Swiss franc. As of March 31, 2018, we had cash of $108.6 million, consisting of non-interest bearing cash deposits denominated in the U.S. dollar and Swiss franc.

We also have certain 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 December 31, 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 December 31, 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 December 31, 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 believe our current cash and cash equivalents will be sufficient to fund our business only for a limited amount of time, and if we are not able to raise additional funds, we may be unable to continue as a going concern.

As of December 31, 2018, we had approximately $183.0 million of cash and cash equivalents. Based on our current operating plan, we believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through at least the first quarter of our fiscal year ending March 31, 2020, and to enable us to announce top-line data from the first Phase 3 clinical trial for one of our women's health 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. We anticipate that we will continue to incur net losses for the foreseeable future. These factors raise substantial doubt about our ability to continue as a going concern for the one-year period following the filing of this Quarterly Report on Form 10-Q. We may be forced to delay or reduce the scope of our development programs and/or limit or cease our operations if we are unable to obtain additional funding to support our current operating plan. Management's plans in this regard are described in Note 2 of the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. In the event that these plans cannot be effectively realized, there can be no assurance that we will be able to continue as a going concern.

We will require substantial 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. 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.

Our current funds will not be sufficient for us to compete all necessary development activities and commercially launch relugolix. Accordingly, we will need to obtain substantial further funding through other public or private offerings of our capital shares, debt financing, collaboration and licensing arrangements, or other sources. 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 additional 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 be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

We 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, preparing for and advancing our product candidates through clinical development, conducting global clinical trials, and preparing for potential future regulatory approvals and 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 the 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 operating losses since our inception and expect to continue to incur significant operating losses and negative cash flows; 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 $198.5 million and $143.3 million for the nine months ended December 31, 2018 and year ended March 31, 2018, respectively, and, as of December 31, 2018, we had an accumulated deficit of $427.0 million.

We expect to continue to incur significant operating losses and negative cash flows as we continue to develop our product candidates and prepare for the potential future regulatory approvals and commercialization of relugolix. 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.

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 and launched by AbbVie in August 2018. The launch and commercialization of ORILISSA™ or other competing drugs 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, or if we are unable to obtain a favorable price for relugolix, 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 in combination with low-dose estradiol and a progestin for our women's health indications of uterine fibroids and endometriosis, relugolix monotherapy for men with prostate cancer, 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 in combination with low-dose estradiol and a progestin, relugolix monotherapy, 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 revenue 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 one or both formulations of 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 from 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 adequate 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 a progestin for our women's health indications, its potential commercial opportunity and competitive advantage could be limited.

GnRH antagonists, like relugolix, may cause loss of bone mineral density due to the induced hypoestrogenic state that may limit duration of use. This risk, and a related risk of hot flush, may be mitigated by the co-administration of low-dose estradiol and a progestin. A key part of our relugolix clinical development strategy is to formulate a fixed-dose combination of relugolix with low-dose estradiol and a progestin 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 in the U.S., we expect to seek approval for relugolix tablets co-packaged with commercially available low-dose estradiol and a 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 can be developed and approved. 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 a progestin product co-packaged. We are conducting bridging studies to support the submission of NDAs or comparable foreign 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 diversifying our product development risk by identifying and acquiring or in-licensing novel product candidates. We may fail to identify and acquire or in-license product candidates, including for reasons discussed in these risk factors and also:

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

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

We rely on agreements with Takeda to provide rights to the core intellectual property relating to our existing product candidates and to supply us with clinical and commercial trial material to support development and potential commercialization 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 the License Agreement, 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 clinical 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. We are paying for the expenses related to such transfer. If Takeda fails to fulfill its obligations to manufacture and supply clinical and/or commercial quantities of relugolix 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 currently rely on Roivant Sciences, Inc. and Roivant Sciences GmbH to provide various services for us.

We currently 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 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, the level of support we receive from RSI and RSG has decreased and we expect that it will continue to decrease in the near term. As a result, we will be required to replace many of these services with our own internally developed teams or engage external professional 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, clinical, medical affairs, operations and other functions. Many of the other pharmaceutical companies we compete against for qualified personnel and consultants have greater financial and other resources, more favorable risk profiles and a longer operating history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these opportunities may be more appealing to high-quality candidates and consultants than what we have to offer. 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 time and attention away from our day-to-day activities. The expected growth may also require significant capital expenditures and divert financial resources from other projects. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate or grow revenue could be adversely affected, and we may not be able to implement our business strategy. As a result, our future financial performance and our ability to complete clinical development, obtain regulatory approval, and commercialize 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 or legal standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees, contractors, advisers, including principal investigators, consultants, commercial collaborators, service providers, and other vendors, or those of our affiliates, may engage in fraudulent, illegal activity, or other misconduct. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA or other regulatory bodies, including: those laws that require the reporting of true, complete, and accurate information to such regulatory bodies; laws that require manufacturing by current Good Manufacturing Practice, or cGMP, standards; federal, state and foreign healthcare fraud and abuse laws and data privacy laws; or laws and regulations that require the true, complete, and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive regulations intended to prevent fraud, kickbacks, self-dealing, bribery, corruption, antitrust violations, and other abusive practices. See the Risk Factors titled “Our current and future relationships with investigators, healthcare professionals, consultants, third-party payors, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties,” “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 or legal 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 future earnings and profits, additional reporting requirements, and regulatory oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, 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 Protection Regulation, or the GDPR, which introduced strict requirements for processing personal data of individuals within the European Union, or the EU; and
- failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, the United Kingdom Bribery Act 2010, and similar antibribery and anticorruption laws in other jurisdictions, for example by failing to maintain accurate information and control over sales or distributors' activities.

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

Our 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 or liabilities that adversely affect our financial performance.

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 or disclosure, 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, intellectual property 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, and could result in liabilities that adversely affect our financial performance. 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.

The results of the United Kingdom's referendum on withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business.

In June 2016, the United Kingdom, or UK, held a referendum in which voters approved an exit from the EU, commonly referred to as "Brexit." This referendum has created political and economic uncertainty, particularly in the UK and the EU, and this uncertainty may persist for years. A withdrawal could, among other outcomes, disrupt the free movement of goods, services and people between the UK and the EU, and result in increased legal and regulatory complexities, as well as potential higher costs of conducting business in Europe. This is particularly the case if the UK and the EU do not reach agreement on how the UK will exit the EU, commonly referred to as a "hard Brexit." The UK's vote to exit the EU could also result in similar referendums or votes in other European countries in which we do business. Given the lack of comparable precedent, it is unclear what financial, trade and legal implications the withdrawal of the UK from the EU would have and how such withdrawal would affect us.

For example, Brexit could result in the UK or the EU significantly altering its regulations affecting the clearance or approval of our product candidates that are developed in the UK. Brexit could also affect the clearance or timing of the release of our clinical materials into the UK or the EU. Any such delays could result in our clinical study sites not having sufficient clinical materials and could adversely affect the timing and completion of our clinical trials. Any new regulations could add time and expense to the conduct of our business, as well as the process by which our products receive regulatory approval in the UK, the EU and elsewhere. In addition, the announcement of Brexit and the withdrawal of the UK from the EU have had and may continue to have, particularly in the case of a hard Brexit, a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these effects of Brexit, among others, could adversely affect our business, our results of operations, liquidity and financial condition.

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

We are subject to federal and state laws and regulations requiring that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, federal and state security breach notification laws, state health information privacy laws and federal and state consumer protection laws impose requirements regarding the collection, use, disclosure and storage of personal information. In addition, in June 2018, California enacted the California Consumer Privacy Act, or CCPA, which takes effect on January 1, 2020. The CCPA gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that may increase data breach litigation. Although the CCPA includes exemptions for certain clinical trials data, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. Some observers note that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the U.S., which could increase our potential liability, increase our compliance costs and adversely affect our business.

We may also be subject to or affected by foreign laws and regulations, including regulatory guidance, governing the collection, use, disclosure, security, transfer and storage of personal data, such as information that we collect about patients and healthcare providers in connection with clinical 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 GDPR, which introduces strict requirements for processing personal data. The GDPR increases our compliance burden with respect to data protection, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and leverage information about them. The processing of sensitive personal data, such as information about health conditions, entails heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR provides for breach reporting requirements, more robust regulatory enforcement and fines of up to the greater of 20 million euros or 4% of annual global revenue. While companies are afforded some flexibility in determining how to comply with the GDPR's various requirements, significant effort and expense are required to ensure continuing compliance with the GDPR. Moreover, the requirements under the GDPR may change periodically or may be modified, and such changes or modifications could have an adverse effect on our business operations if compliance becomes substantially costlier than under current requirements. It is possible that each of these privacy laws may be interpreted and applied in a manner that is inconsistent with our practices. Further, Brexit has created uncertainty with regard to data protection regulation in the UK. In particular, it is unclear whether, post Brexit, the UK will enact data protection legislation equivalent to the GDPR and how data transfers to and from the United Kingdom will be regulated. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

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 are implementing 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 to reap the benefits of the ERP system. Any such transformation involves risk inherent in the conversion to a new 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 control 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 the U.S. Securities and Exchange Commission, or the SEC, reporting obligations related to our management's assessment of our internal control over financial reporting, or result in the issuance of an adverse opinion on the effectiveness of internal control over financial reporting by our independent registered public accounting firm. 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 in combination with low-dose estradiol and a progestin, relugolix monotherapy, and MVT-602, are still in development and will require extensive clinical testing resulting in sufficiently positive outcomes before we are prepared to submit an NDA or other similar application for regulatory approval. 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 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 very 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/or clinical trial sites, the terms of which can be subject to extensive negotiations 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 cGCP, or cGMP regulations, that we are exposing participants to unacceptable health risks, or if the FDA or other regulatory authority, as the case may be, finds deficiencies in our Investigational New Drug application, or IND, or other submissions or the manner in which the clinical trials are conducted. Therefore, we cannot predict with any certainty the timing 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.

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 candidates 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.

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. In addition, the FDA may not agree that clinical trial results are sufficient for approval for any product candidate. 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 obtained market authorization in Japan from the Ministry of Health, Labour and Welfare for Relumina® Tablets 40 mg (generic name: relugolix) for the improvement of symptoms of uterine fibroids (heavy menstrual bleeding, lower abdominal pain, lower back pain, and anemia). Favorable announcements by Takeda 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 post marketing adverse events regarding Relumina® are reported, or subsequent announcements by Takeda regarding relugolix are unfavorable, it could negatively impact our clinical development plans for relugolix.

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, has been approved by the FDA for the management of moderate to severe pain associated with endometriosis and was 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, pain associated with endometriosis, and/or advanced prostate cancer and against MVT-602 for the treatment of female infertility as part of assisted reproduction. Many of our current and potential future competitors have significantly more experience commercializing drugs 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 or opt to take an approved product.

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, or 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, clinical, product development, and commercial personnel;
- obtain patent or other proprietary protection for our medicines;
- obtain required regulatory approvals;
- obtain market access, coverage and adequate reimbursement from third-party payors; and
- successfully collaborate with pharmaceutical companies in the discovery, development, and commercialization of new medicines.

The availability and pricing of our competitors' products could limit the demand and the price we are able to charge for any product candidate we develop. 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 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.

In addition, if the competing drugs that are mechanistically similar to our product candidates do not meet the expectations of the marketplace or have safety or efficacy issues, the market perception of our product candidates may be negatively affected, and the commercial performance of our product candidates may suffer.

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, formulations, 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 in combination with low-dose estradiol and a progestin, relugolix monotherapy, 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 regulatory approval of an NDA from the FDA or similar regulatory authorities outside of the U.S. is received.

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 approvals 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 in combination with low-dose estradiol and a progestin 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 pain associated with endometriosis, 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 approvals, 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, the FDA has raised concern about a potential increase in the risk of diabetes and certain cardiovascular diseases in men with prostate cancer treated with GnRH agonists. Further, on May 18, 2018, the European Medicines Agency, or the EMA, 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. In August 2018, Allergan, Inc. announced that it received a Complete Response letter from the FDA in which the FDA cited safety concerns regarding Esmya post-marketing reports outside the U.S., indicated that Esmya could not be approved in its current form, and requested additional information. Although Esmya is in a different class of drugs from relugolix, the review of post-marketing events of liver toxicity for Esmya by regulatory bodies may lead to increased scrutiny regarding liver function for GnRH antagonists. Further, if post marketing adverse events related to Relumina® are reported, it could negatively impact our clinical development plans for relugolix.

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

- regulatory authorities may withdraw their approval of the product or require a Risk Evaluation and Mitigation Strategy, 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;
- we may be required to conduct post-marketing studies or clinical trials;
- 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. 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 risks and regulatory difficulties.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising, and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment of registration and drug listing requirements, continued compliance with cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of drug product samples to physicians, recordkeeping, and cGCP requirements for any clinical 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 regulatory authorities believe that we are in violation of these restrictions, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act in the U.S., and other comparable regulations in foreign jurisdictions, relating to the promotion of prescription drugs may lead to enforcement actions and investigations by the FDA, Department of Justice, State Attorney Generals and other foreign regulatory agencies alleging violations of U.S. federal and state health care fraud and abuse laws, as well as state consumer protection laws and comparable laws in foreign jurisdictions.

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

- 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;
- whether diagnosis and treatment rates increase for the diseases our products treat; and
- any restrictions on the use of our product together with other medications.

Because we expect sales of relugolix 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.

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 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.

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 qualified and 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, marketing and distribution 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, marketing and distribution of our product candidates, if approved, for certain markets overseas; however, it might be difficult for us to find third parties that are willing to enter into such transactions on acceptable economic terms or at all. We also will be competing with many other companies as we seek sales partners for our product candidates and we may not be able to compete successfully against those other firms. We cannot assure you that we will be able to establish or maintain such collaborative arrangements on terms favorable to us, 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 sales, marketing and distribution, the financial returns to us will depend on our future collaborators' capabilities. If any such future collaborator terminates its collaboration with us or fails to perform or satisfy its obligations to us, the sales, marketing and distribution of our product candidates would be delayed or may not occur and our business and prospects could be materially and adversely affected.

If we are unable to 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 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 over 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 channels, charitable organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws regulate the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our products for which we obtain marketing approval. Such laws include, among others:

- the federal Anti-Kickback Statute, 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 certain healthcare providers, known as covered entities, 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
- 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 to resolve allegations of non-compliance with these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Even the mere issuance of a subpoena or the fact of an investigation alone, regardless of the merit, may result in negative publicity, a drop in our share price, and other harm to our business, financial condition, and results of operations. Defending against any such actions can be costly, time- consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

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 presidential 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, titled "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, commonly known as the individual mandate. 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, the Centers for Medicare and Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the current administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

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. At the federal level, the current presidential administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, on May 11, 2018, President Trump released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs, that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services has already begun the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. Although a number of these, and other potential proposals will require authorization through additional legislation to become effective, Congress and the current presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, individual states in the U.S. are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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 1 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. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

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 CMOs. Takeda has retained rights to further develop and commercialize relugolix in Japan and certain other Asian countries and has announced that it has 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. We expect that manufacturing support provided by Takeda will be sufficient for us to complete our ongoing Phase 3 programs for relugolix. In April 2016, we acquired exclusive worldwide rights to MVT-602 for all human diseases and conditions. Takeda is no longer developing this compound. We expect that the 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 for us to complete further Phase 2 and 3 clinical studies for MVT-602, which we have not secured. Further, 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 a 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 product. 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 the 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 a progestin;

- failure of the drug substance transferred from Takeda or our other CMOs 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 monotherapy, a fixed-dose combination product or co-packaging of relugolix and low-dose estradiol and a 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 also lead to clinical trial delays, cost overruns, delay or failure to obtain regulatory approval or impact our ability to successfully commercialize our products, as well as potential product liability litigation, product recalls or product withdrawals. Some of these events could be the basis for FDA or other regulatory authority action, including injunction, recall, seizure, or total or partial suspension of production.

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

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

We rely upon CROs to monitor and manage data for our clinical programs, as well as 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 the sponsor of those studies.

While we have agreements governing their activities, our CROs are not our employees, and we do not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical 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. Also, see the Risk Factor titled “If we fail to comply with applicable U.S. and foreign privacy and data protection laws and regulations, we may be subject to liabilities that adversely affect our business, operations and financial performance.”

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

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.

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 NDA or marketing authorization application filed with the FDA, the EMA, or other regulatory authority for any product candidate for which we are seeking marketing approval, and

significant delays can occur if 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 materials from our suppliers was interrupted for any reason, we may be unable to ship commercial products that may be approved for marketing or supply our products in development for clinical 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.

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 54.2% of our outstanding common shares as of December 31, 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 in combination with low-dose estradiol and a progestin, relugolix monotherapy, 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 maintain effective internal control over financial reporting;
- 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 December 31, 2018, RSL beneficially owns approximately 54.2% 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 common shares sold in our IPO, through our "at-the market" equity offering program and in our 2018 public offering, as well as shares issued upon the exercise of options granted to persons other than our officers and directors and other shares held by our non-affiliated shareholders, 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 a 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, including $100.0 million of our common shares under our "at-the market" equity offering program described below, as well as the resale of up to 49,800 common shares held by Hercules, and in 2018 sold 3,533,399 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. Through December 31, 2018, we have sold an aggregate of 2,767,129 shares for aggregate net proceeds of $57.3 million in this "at-the-market" equity offering program. 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 and increasing 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 and these expenses will continue to increase further as we will cease to be an "emerging growth company" as defined in the Jumpstart Our Business Startup Act of 2012, or the JOBS Act, beginning in April 2019. We will lose our status as an "emerging growth company" on March 31, 2019, as the market value of our common shares held by non-affiliates exceeded $700.0 million as of September 30, 2018. 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. In addition, as a result of the loss of our status as an "emerging growth company," we will be required to include in our annual report beginning with our fiscal year ending March 31, 2019, an attestation report on internal control over financial reporting issued by our independent registered public accounting firm, which will increase the fees charged by our independent registered public accounting firm.

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 needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. In addition, since we will no longer be an "emerging growth company," we will also be required to include in our annual report beginning with our fiscal year ending March 31, 2019, an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If we have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered public accounting firm, which could negatively impact the value of our common shares. We are also required to disclose significant changes in our internal control over financial reporting on a quarterly basis.

During the evaluation and testing process of our internal control over financial reporting, if we or our independent registered public accounting firm identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective and our independent registered public accounting firm will be required to provide an adverse opinion on the effectiveness of our internal control over financial reporting. 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, 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 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. Accordingly, we expect to be subject to U.K. taxation on our income and gains, except where an exemption applies. We may be treated as a dual resident company for U.K. tax purposes. As a result, our right to claim certain reliefs from U.K. tax may be restricted, and changes in law or practice in the United Kingdom could result in the imposition of further restrictions on our right to claim U.K. tax reliefs. We may also become subject to income, withholding or other taxes in certain jurisdictions by reason of our activities and operations, and it is also possible that taxing authorities in any such jurisdictions could assert that we are subject to greater taxation than we currently anticipate. Any such additional tax liability could adversely affect our results of operations.

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

We 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 U.S., which introduced a comprehensive set of tax reforms. Certain impacts of this legislation have been taken into account, including the reduction of the U.S. corporate income tax rate from a top marginal rate of 35 percent to a flat rate of 21 percent. Also, in September 2018, the Swiss Parliament approved a new tax bill known as Tax Proposal 17, which will enter into force in January 2020 absent a referendum that halts its effectiveness. Tax Proposal 17 would implement a set of changes to Swiss federal and cantonal tax laws, such as the amendment of the capital tax to provide a uniform rate of 0.1%, a new patent box regime, and a reduction in the statutory profit tax rate in Canton Basel-Stadt that will result in a combined Swiss federal and cantonal tax rate of 13.04%. We continue to assess the impact of such changes in tax laws on our business and may determine that changes to our structure, practice, tax positions or the manner in which we conduct our business are necessary in light of the Tax Act and Tax Proposal 17, in conjunction with the tax laws of other jurisdictions in which we operate. Such changes may nevertheless be ineffective in avoiding an increase in our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

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

Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in Europe (including the 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 U.S. 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 U.S. shareholders of a CFC generally are required to include currently in gross income such shareholders' share of the CFC's "Subpart F income", a portion of the CFC's earnings to the extent the CFC holds certain U.S. property, and a portion of the CFC's "global intangible low-taxed income" (as defined under Section 951A of the Code). Such U.S. shareholders are subject to current U.S. federal income tax with respect to such items, even if the CFC has not made an actual distribution to such shareholders. "Subpart F income" includes, among other things, certain passive income (such as income from dividends, interests, royalties, rents and annuities or gain from the sale of property that produces such types of income) and certain sales and services income arising in connection with transactions between the CFC and a person related to the CFC. "Global intangible low-taxed income" may include most of the remainder of a CFC's income over a deemed return on its tangible assets.

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, we believe that we were not a PFIC; however, with respect to the current and future taxable years, because the PFIC tests are based upon the value of our assets, including any goodwill and going concern value, and the nature and composition of our income and assets, which cannot be known at this time, we cannot predict whether we will or will not be classified as a PFIC. 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 have implemented structures and arrangements intended to mitigate the possibility that we will be classified as a PFIC. There can be no assurance that the IRS will not successfully challenge these structures and arrangements, which may result in an adverse impact on the determination of whether we are classified as a PFIC in the current and future taxable years.

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

Not applicable.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

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+	Compensation arrangement of Frank Torti's for his service as a member of the Board; and compensation arrangement of Myrtle Potter's for her service as the Chairman of the Board.	10-Q	001-37929	Item 5	11/08/2018
10.2+	Amended and Restated Employment Agreement, dated as of November 7, 2018, by and between Lynn Seely, M.D. and Myovant Sciences, Inc.	10-Q	001-37929	10.1	11/08/2018
10.3+	Amended and Restated Employment Agreement, dated as of November 7, 2018, by and between Frank Karbe and Myovant Sciences, Inc.	10-Q	001-37929	10.2	11/08/2018
10.4+	Amended and Restated Employment Agreement, dated as of November 7, 2018, by and between Matt Lang and Myovant Sciences, Inc.	10-Q	001-37929	10.3	11/08/2018
10.5+	Amended and Restated Employment Agreement, dated as of November 7, 2018, by and between Juan Camilo Arjona Ferreira, M.D. and Myovant Sciences, Inc.	10-Q	001-37929	10.4	11/08/2018
10.6+†	Employment Agreement, dated as of November 1, 2018, by and between Kim Sablich and Myovant Sciences, Inc.				
31.1†	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2†	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1†**	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2†**	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS XBRL	Instance Document				
101.SCH XBRL	Taxonomy Extension Schema				
101.CAL XBRL	Taxonomy Extension Calculation Linkbase				
101.DEF XBRL	Taxonomy Extension Definition Linkbase				
101.LAB XBRL	Taxonomy Extension Label Linkbase				
101.PRE XBRL	Taxonomy Extension Presentation Linkbase				

†Filed herewith.

+Indicates management contract or compensatory plan.

** 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: February 7, 2019

MYOVANT SCIENCES, INC.

EMPLOYMENT AGREEMENT

The Amended and Restated Employment Agreement (the "***Agreement***") is entered into as of November 1, 2018 by and between Kim Sablich (the "***Executive***") and Myovant Sciences, Inc. (the "***Company***").

RECITALS

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

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

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

AGREEMENT

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

1. EMPLOYMENT BY THE COMPANY.

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

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

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

1.4 Policies and Procedures. The employment relationship between the parties shall be governed by the Agreement and by the policies and practices established by the Company and/or the Board. In the

event that the terms of the Agreement differ from or are in conflict with the Company's policies or practices, the Agreement shall govern and control.

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

1.6 Start Date. The Executive's employment with the Company shall commence on December 1, 2018 (the "***Start Date***").

2. AT-WILL EMPLOYMENT.

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

3. COMPENSATION AND BENEFITS.

3.1 Salary. The Company shall pay the Executive a base salary at the annualized rate of $400,000 (the "***Base Salary***"), less payroll deductions and all required withholdings, payable in regular periodic payments in accordance with the Company's normal payroll practices. The Base Salary shall be prorated for any partial year of employment on the basis of a 365-day year. The Base Salary shall be subject to periodic review and may be increased from time to time in the Board's discretion.

3.2 Sign-on Bonus. The Company shall pay the Executive a sign-on bonus in a lump sum payment totaling $105,000, together with a tax gross-up payment representing additional compensation in an amount intended to offset, on an after-tax basis, the Executive's income taxes payable in respect of such bonus (collectively, the "***Sign-on Bonus***"). The payment of $105,000 will be paid within thirty (30) days after the Start Date. Should the Executive's employment terminate voluntarily without Good Reason or involuntarily for Cause, prior to the first anniversary of the Start Date, the Executive shall be required to repay the Sign-on Bonus less the amount of the tax gross-up.

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

objectives as set by the Board. The Board or a committee thereof reserves the right to modify the bonus criteria from year to year.

3.4 Equity.

(a) Subject to the terms of the Parent's 2016 Equity Incentive Plan (the "***Plan***") and approval of the grant by the Parent's board of directors (the "***Parent Board***") or a committee thereof, the Executive will be granted an option to purchase up to 133,500 shares of the Parent's common stock (the "***Initial Option***"). The Initial Option shall: (i) have an exercise price equal to the closing price of the Parent's common stock on the New York Stock Exchange on the grant date; (ii) be subject to a four (4)-year vesting period, with 25% of the Initial Option shares vesting on the first anniversary of the grant date and quarterly vesting thereafter, as well as any other terms contained in the grant agreements; and (iii) expire and cease to be exercisable on the ten (10)-year anniversary of the grant date. Under the Company's current grant date policy, option grants are effective on the 15th (or next business day) of the month next following the later of the date of approval of the option grant or the optionee's commencement of employment. The Initial Option will be governed by the Plan and other documents issued in connection with the grant.

(b) Subject and subsequent to the approval of the Board, the Executive will be granted 29,700 restricted stock units (the "RSUs") of the Parent to be issued under the Plan. The RSUs shall be subject to a 4-year vesting period, with 25% of the RSUs vesting after approximately one year and quarterly vesting thereafter, as well as any other terms contained in the grant agreement.

(c) The Executive will also be eligible to receive discretionary annual equity incentive grants in amounts commensurate with the Executive's position as Chief Commercial Officer (the "***Annual Equity Grants***").

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

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

3.7 Relocation. The Executive will be eligible to receive a relocation package to assist in her relocation to the Company's California office location. This relocation package will include packing and transportation of the Executive's household goods, business class airfare to relocate Executive and her family to the Bay Area, as well as transportation of up to two (2) automobiles. The relocation package will also include one (1) house-hunting trip for the Executive and her spouse. In addition, the Executive will be eligible to receive up to three months of temporary housing. The Executive shall have one year from the Start Date to utilize the relocation package. In addition, the Executive will be eligible to receive up to three months of temporary housing with a maximum amount of $27,000.

4. PROPRIETARY INFORMATION OBLIGATIONS.

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

5. TERMINATION OF EMPLOYMENT.

5.1 Termination Without Cause Or Resignation For Good Reason. If (i) the Executive's employment with the Company is terminated without Cause and other than due to the Executive's death or Disability or (ii) the Executive resigns for Good Reason (each, a "***Qualifying Termination***"), then the Company shall pay the Executive any earned but unpaid Base Salary accrued through the date of termination, at the rate then in effect, less standard deductions and withholdings. In addition, if the Executive furnishes to the Company an executed waiver and release of claims in a form to be provided by the Company, which may include an obligation for the Executive to provide reasonable transition assistance (the "***Release***"), that is nonrevocable prior to the Release Date, and if the Executive allows the Release to become effective in accordance with its terms, then the Executive shall receive the following benefits, subject to Section 5.6:

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

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

(c) Subject to Section 5.1(d), unless specifically provided otherwise in the applicable equity award agreement, the Executive shall be eligible to become fully vested in 25% of the then unvested portion of each of the Executive's then unvested and outstanding equity awards, including the Executive's then remaining unvested portion of any Annual Equity Grants and any other equity grants awarded. Such accelerated vesting shall be effective as of the tenth (10^{th}) day following the Release Date. In order to give effect to the intent of this provision, if the Executive is entitled to accelerated vesting of any equity award pursuant to this provision, then notwithstanding anything to the contrary set forth in the terms of such equity award (including any applicable equity incentive plan and equity award agreement), in no event will such equity award be forfeited or terminate prior to the effective date of such acceleration.

(d) Notwithstanding anything in this Agreement to the contrary, if, pursuant to another written plan, agreement or other arrangement with the Company, the Executive is entitled to benefits with respect to the Executive's outstanding equity awards that are more favorable to the Executive than the accelerated vesting benefit set forth in Section 5.1(c) or 5.3, or the extended post-termination exercise period benefit set forth in Section 5.3, as applicable, as determined by the Company in its sole discretion, then the Executive will not be entitled to the accelerated vesting benefit set forth in Section 5.1(c) or 5.3 (if the more favorable benefit is regarding accelerated vesting) or the extended post-termination exercise period benefit set forth in Section 5.3 (if the more favorable benefit is regarding an extended post-termination exercise period).

5.2 Other Termination. If the Executive resigns her employment at any time without Good Reason or the Executive's employment is terminated by the Company at any time for Cause or due to the Executive's death or Disability, the Company shall pay the Executive (or her estate) any earned but unpaid Base Salary accrued

through the date of such resignation or termination, at the rate then in effect, less standard deductions and withholdings. The Company shall thereafter have no further obligations to the Executive, except as may otherwise be required by law.

5.3 Change of Control. If the Executive's Qualifying Termination occurs within three (3) months before, upon or within eighteen (18) months after a Change of Control and the Executive satisfies the Release requirements set forth in Section 5.1, then the Executive shall receive the benefits set forth in Section 5.1 in accordance with the provisions of Section 5.1, subject to Section 5.6, plus the following benefits:

(i) Unless specifically provided or otherwise in the applicable equity award agreement, the Executive shall be eligible to become fully vested in 100% of the then unvested portion of each of the Executive's then unvested and outstanding equity awards, including the Executive's then remaining unvested portion of any Annual Equity Grants and any other equity grants awarded. Such accelerated vesting shall be effective as of the tenth (10^{th}) day following the Release Date; *provided*, *however*, that if such Qualifying Termination occurs within three (3) months before a Change of Control, then such accelerated vesting shall be effective as of the later of (x) the date of the Change of Control or (y) the tenth (10^{th}) day following the Release Date. In order to give effect to the intent of the provision, if the Executive is entitled to accelerated vesting of any equity award pursuant to the provision, then notwithstanding anything to the contrary set forth in the terms of such equity award (including any applicable equity incentive plan and equity award agreement), in no event will such equity award be forfeited or terminate prior to the effective date of such acceleration.

(ii) If such Qualifying Termination occurs within three (3) months before a Change of Control and the Executive is entitled to accelerated vesting of any equity award as a result of the foregoing clause (i), then with respect to any such equity award that is an option, the post-termination exercise period of such option will be extended such that the Executive will have three (3) months after the Change of Control to exercise any vested portion of such option; *provided*, *however*, that in no event may such option be exercised after the expiration of its original term.

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

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

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

(c) "***Good Reason***" shall mean the occurrence of any of the following events without the Executive's consent: (i) reduction of the Executive's Base Salary or in any of the percentages of the Base Salary payable as an Annual Performance Bonus as initially set forth herein or as the same may be increased from time to time; (ii) material reduction in the Executive's authority, duties or responsibilities, as compared to the Executive's authority, duties or responsibilities immediately prior to such reduction or any diminution of her title as Chief Commercial Officer; (iii) failure or refusal of a successor to the Company to materially assume the Company's

obligations under the Agreement in the event of a Change of Control; or (iv) once a principal location of employment is selected, a change in the Executive's principal location of employment, resulting in an increase in the Executive's one-way driving distance by more than thirty (30) miles from the Executive's then current principal residence on file with the Company; *provided, however*, that any resignation by the Executive shall only be deemed for Good Reason pursuant to the definition if: (1) the Executive gives the Company written notice of the Executive's intent to terminate for Good Reason within ninety (90) days following the first occurrence of the condition(s) that he believes constitute(s) Good Reason, which notice shall describe such condition(s); (2) the Company fails to remedy such condition(s) within thirty (30) days following receipt of the written notice (the "***Cure Period***"); and (3) the Executive voluntarily terminates her employment within thirty (30) days following the end of the Cure Period.

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

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

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

(iii) Any transaction or series of related transactions in which more than fifty percent (50%) of the Company's voting power is transferred, directly or indirectly, other than to Roivant Sciences Ltd. (directly or indirectly), and other than the sale by the Company, the Parent or any subsidiary of the Parent of stock in transactions the primary purpose of which is to raise capital for such company's operations and activities; or

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

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

For clarity, in the event that Roivant Sciences Ltd. no longer continues to own more than fifty percent (50%) of the Parent's common shares, such event will not constitute a Change of Control, unless such event is accompanied by a transaction or series of related transactions that or otherwise constitutes a Change of Control under clauses (i), (ii), (iii) or (iv) above.

If required for compliance with Section 409A of the Internal Revenue Code of 1986, as amended (the "***Code***") ("***Section 409A***"), in no event will an event be deemed a Change of Control if such event is not also a "change in the ownership of" the Company or the Parent, a "change in the effective control of" the Company or the Parent, or a "change in the ownership of a substantial portion of the assets of" the Company or the Parent, each as determined under Treasury Regulations Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder).

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

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

5.6 Section 409A Compliance.

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

(b) With regard to any provision herein that provides for reimbursement of costs and expenses or in-kind benefits, except as permitted by Section 409A, (i) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for any other benefit, (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any of the taxable year, and (iii) such payments shall be made on or before the last day of the Executive's taxable year following the taxable year in which the expense was incurred.

(c) The Company makes no representation or warranty and shall have no liability to the Executive or any other person if any provisions of the Agreement are determined to constitute deferred compensation subject to Section 409A but do not satisfy an exemption from, or the conditions of, Section 409A.

5.7 Section 280G.

(a) If any payment or benefit (including payments and benefits pursuant to the Agreement) that the Executive would receive in connection with a Change of Control or other transaction (the "***Transaction***") from the Company or otherwise ("***Transaction Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for the sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then the Company shall cause to be determined, before any amounts of the Transaction Payment are paid to the Executive, which of the following two alternative forms of payment would result in the Executive's receipt, on an after-tax basis, of the greater amount of the Transaction Payment notwithstanding that all or some portion of the Transaction Payment may be subject to the Excise Tax: (1) payment in full of the entire amount of the Transaction Payment (a "***Full Payment***"), or (2) payment of only a part of the Transaction Payment so that the Executive receives the largest payment possible without the imposition of the Excise Tax (a "***Reduced Payment***"). For purposes of determining whether to make a Full Payment or a Reduced Payment, the Company shall

cause to be taken into account the value of all applicable federal, state and local income and employment taxes and the Excise Tax (all computed at the highest applicable marginal rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction of such state and local taxes). If a Reduced Payment is made, (x) the Executive shall have no rights to any additional payments and/or benefits constituting the Transaction Payment, and (y) reduction in payments and/or benefits shall occur in the manner (the "***Reduction Method***") that results in the greatest economic benefit to the Executive as determined in the paragraph. If more than one method of reduction will result in the same economic benefit, the portions of the Transaction Payment shall be reduced pro rata (the "***Pro Rata Reduction Method***").

Notwithstanding the foregoing, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Transaction Payment being subject to taxes pursuant to Section 409A that would not or otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, will be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification will preserve to the greatest extent possible, the greatest economic benefit for the Executive as determined on an after-tax basis; (B) as a second priority, any amounts of the Transaction Payment that are contingent on future events (e.g., being terminated without Cause), will be reduced (or eliminated) before any amounts of the Transaction Payment that are not contingent on future events; and (C) as a third priority, any amounts of the Transaction Payment that are "deferred compensation" within the meaning of Section 409A will be reduced (or eliminated) before any amounts of the Transaction Payment that are not deferred compensation within the meaning of Section 409A.

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

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

6. ARBITRATION.

Except as or otherwise set forth below in connection with equitable remedies, any dispute, claim or controversy arising out of or relating to the Agreement or the Executive's employment with the Company (collectively, "***Disputes***"), including, without limitation, any dispute, claim or controversy concerning the validity, enforceability, breach or termination of the Agreement, if not resolved by the parties, shall be finally settled by arbitration in accordance with the then-prevailing Employment Arbitration Rules and Procedures of JAMS, as modified herein ("***Rules***"). The requirement to arbitrate covers all Disputes (other than disputes which by statute are not arbitrable) including, but not limited to, claims, demands or actions under the Age Discrimination in Employment Act (including Older Workers Benefit Protection Act); Americans with Disabilities Act; Civil Rights Act of 1866; Civil Rights Act of 1991; Executive Retirement Income Security Act of 1974; Equal Pay Act; Family and Medical Leave Act of 1993; Title VII of the Civil Rights Act of 1964; Fair Labor Standards Act; Fair Employment and Housing Act; any other provision of the California Labor, Government or Civil Code; IWC Wage Orders; and any other law, ordinance or regulation regarding discrimination or harassment or any terms or conditions of employment. Thee shall be one arbitrator who shall be

jointly selected by the parties. If the parties have not jointly agreed upon an arbitrator within twenty (20) calendar days of respondent's receipt of claimant's notice of intention to arbitrate, either party may request JAMS to furnish the parties with a list of names from which the parties shall jointly select an arbitrator. If the parties have not agreed upon an arbitrator within ten (10) calendar days of the transmittal date of such list, then each party shall have an additional five (5) calendar days in which to strike any names objected to, number the remaining names in order of preference, and return the list to JAMS, which shall then select an arbitrator in accordance with the Rules. The place of arbitration shall be San Francisco, California. By agreeing to arbitration, the parties hereto do not intend to deprive any court of its jurisdiction to issue a pre-arbitral injunction, including, without limitation, with respect to the NDA. The arbitration shall be governed by the Federal Arbitration Act, 9 U.S.C. §§ 1-16. Judgment upon the award of the arbitrator may be entered in any court of competent jurisdiction. Discovery shall be permitted in the arbitration as provided by Section 1283.05 of the California Code of Civil Procedure. The Company shall pay all administrative fees of JAMS in excess of $435 (a typical filing fee in court) and the arbitrator's fees and expenses. Each party shall bear its or her own costs and expenses (including attorney's fees) in any such arbitration and the arbitrator shall have no power to award costs and attorney's fees except as provided by statute or by separate written agreement between the parties. In the event any portion of the arbitration provision is found unenforceable by a court of competent jurisdiction, such portion shall become null and void leaving the remainder of the arbitration provision in full force and effect. The parties agree that all information regarding the arbitration, including any settlement thereof, shall not be disclosed by the parties hereto, except as or otherwise required by applicable law.

7. GENERAL PROVISIONS.

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

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

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

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

MYOVANT SCIENCES, INC.

By: /s/Lynn Seely, M.D.

Name: Lynn Seely, M.D.
Title: President and Chief Executive Officer

ACCEPTED AND AGREED:

/s/ Kim Sablich

KIM SABLICH

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: February 7, 2019

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: February 7, 2019

By: /s/ Frank Karbe

Frank Karbe

Principal Financial and Accounting Officer

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Myovant Sciences Ltd. (the "Company") for the period ended December 31, 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: February 7, 2019

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 December 31, 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: February 7, 2019

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.