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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2022

or

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

For the transition period from _____ to _____

Commission file number 001-37929

Myovant Sciences Ltd.

(Exact name of registrant as specified in its charter)

Bermuda	**98-1343578**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
7th Floor **50 Broadway** **London** **SW1H 0DB** **United Kingdom**	
(Address of principal executive offices)	**Not Applicable** (Zip Code)

Registrant's telephone number, including area code: **+44 (207) 400 3351**

Securities registered pursuant to Section 12(b) of the Act:

Title of each Class	Trading Symbol	Name of each exchange on which registered
Common Shares, $0.000017727 par value per share	MYOV	New York Stock Exchange

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	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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

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

The number of shares outstanding of the Registrant's common shares, $0.000017727 par value per share, on October 21, 2022 was 96,802,808.

MYOVANT SCIENCES LTD.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2022

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In this Quarterly Report on Form 10-Q ("Quarterly Report"), references to "Myovant," "the Company," "we," "us" and "our" refer to Myovant Sciences Ltd. and its wholly-owned subsidiaries on a consolidated basis, unless the context otherwise provides.

All brand names or trademarks appearing in this Quarterly Report are the property of their respective owners. This Quarterly Report may contain references to our proprietary intellectual property, including among others, trademarks for our products, ORGOVYX® and MYFEMBREE®. These trademarks and trade names are the property of Myovant or the property of our wholly-owned subsidiaries and are protected under applicable intellectual property laws. Solely for convenience, our trademarks and trade names referred to in this Quarterly Report may appear without the ® or other symbols, but such references are not intended to indicate in any way that the Company will not assert, to the fullest extent under applicable law, its rights to these trademarks and trade names.

Risk Factor Summary

Below is a summary of the material factors that make an investment in our common shares speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under the heading "Risk Factors" in Item 1A of Part II of this Quarterly Report. The below summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should consider carefully the risks and uncertainties described under "Risk Factors" in Item 1A of Part II of this Quarterly Report as part of your evaluation of an investment in our common shares.

Risks Related to the Proposed Acquisition of Myovant by Sumitovant

- The conditions to the proposed Merger as set forth in the Merger Agreement may not be satisfied or waived in a timely manner or at all, or the Merger Agreement may be terminated in accordance with its terms, which could negatively impact our business, financial condition, results of operations, and the price of our common shares.
- The announcement of the proposed Merger could negatively impact our business, financial condition, or results of operations.
- The Merger Agreement contains provisions that may discourage a third party from acquiring us prior to the completion of the Merger.
- Attending to matters related to the proposed Merger could divert our management's focus from our ongoing business operations.
- We have incurred, and will continue to incur, direct and indirect costs as a result of the transactions related to the Merger Agreement.

Risks Related to Commercialization of Our Drug Products

- Our success depends in part on the successful commercialization of our drug products. To the extent our drug products are not commercially successful, our business, financial condition and results of operations will be materially harmed.
- Our drug products may fail to achieve the degree of market acceptance by physicians, patients, third-party payers or others in the medical community necessary for commercial success, which would negatively impact our business.
- If we and our collaboration or commercialization partners are unable to effectively market and sell our drug products, the commercialization of our drug products will not be successful and our business will be harmed.
- Failure to successfully obtain coverage and reimbursement for ORGOVYX and MYFEMBREE in the United States, or the availability of coverage only at limited levels, would diminish our ability to generate net product revenue.
- We face substantial competition in the commercialization of our approved drug products and our operating results will suffer if we fail to compete effectively.

- If we or our collaboration or commercialization partners are found to have improperly promoted unapproved uses of our drug products, we may be subject to restrictions on the sale or marketing of our drug products and significant fines, penalties, sanctions and product liability claims, and our image and reputation within the industry and marketplace could be harmed.

Risks Related to Our Financial Position and Capital Requirements

- If we do not have adequate funds to cover our development and commercialization activities, we may have to raise additional capital or curtail or cease operations. We may not be able to obtain funding through public or private offerings of our capital shares, debt financings, collaboration or licensing arrangements, or other sources.
- We may never achieve or maintain profitability.

Risks Related to Our Business Operations

- The terms of the Sumitomo Pharma Loan Agreement place restrictions on our operating and financial flexibility.
- We do not have our own manufacturing capabilities and rely on third parties to produce clinical and commercial supplies of drug substance and drug product. If these third parties do not perform as we expect, do not maintain their regulatory approvals, or become subject to other negative circumstances, it may result in a delay in our ability to develop and commercialize our products.

Risks Related to Clinical Development and Regulatory Approval

- Clinical studies are very expensive, time consuming, difficult to design and implement, and involve uncertain outcomes. Clinical study failures can occur at any stage of clinical studies, and we could encounter problems that cause us to suspend, abandon or repeat clinical studies. We cannot predict with any certainty the timing for commencement or completion of current or future clinical studies.
- The results of our clinical studies may not support our proposed claims for our product candidates. The results of previous clinical studies may not be predictive of future results, and interim or top-line data may be subject to change or qualification based on the complete analysis of data.
- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, and inherently unpredictable. If we are not able to obtain required regulatory approvals for our product candidates, our ability to generate net product revenue will be materially impaired.
- Adverse events associated with our product candidates could cause us, regulatory authorities, other reviewing entities or clinical study sites to interrupt, delay, request modification of, or halt clinical studies and could result in the denial of regulatory approval.

Risks Related to Our Dependence on Third Parties

- We are dependent upon our relationships with collaboration and commercialization partners to further develop, fund, manufacture, and commercialize our drug products and our product candidates. If such relationships are unsuccessful, or if a collaboration or commercialization partner terminates its collaboration or commercialization agreement with us, it could negatively impact our ability to conduct our business and generate net product revenue. Failure by a collaboration or commercialization partner to perform its duties under its collaboration or commercialization agreement with us (e.g. financial reporting or internal control compliance) may negatively affect us.
- We are reliant on third parties to conduct, manage, and monitor our clinical studies, and if those third parties perform in an unsatisfactory manner, it may harm our business.

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.

- 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.

Risks Related to Our Being a Controlled Company

- We have agreements with Sumitovant, our majority shareholder, and with Sumitovant's parent, Sumitomo Pharma, and their affiliates, including Sunovion, that may be perceived to create conflicts of interest which, if other investors perceive that Sumitovant or Sumitomo Pharma will not act in the best interests of all of our shareholders, may affect the price of our common shares and have other effects on our company.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2022	March 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 341,960	$ 406,704
Accounts receivable, net	33,762	23,296
Marketable securities	29,330	27,483
Inventories	23,047	7,584
Prepaid expenses and other current assets	31,868	22,498
Amount due from related party	943	580
Total current assets	460,910	488,145
Property and equipment, net	2,708	2,944
Operating lease right-of-use asset	7,026	7,961
Other assets	13,330	20,961
Total assets	$ 483,974	$ 520,011
Liabilities and shareholders' deficit		
Current liabilities:		
Accounts payable	$ 8,215	$ 12,250
Accrued expenses and other current liabilities	84,081	68,594
Deferred revenue	117,231	100,564
Amounts due to Pfizer	38,939	32,563
Cost share advance from Pfizer	—	33,818
Operating lease liability	2,374	2,148
Amounts due to related parties	851	393
Total current liabilities	251,691	250,330
Deferred revenue, non-current	379,321	375,706
Long-term operating lease liability	5,788	7,041
Long-term debt, less current maturities (related party)	358,700	358,700
Other liabilities	1,723	1,711
Total liabilities	997,223	993,488
Commitments and contingencies (Note 9)		
Shareholders' deficit:		
Common shares, par value $0.000017727 per share, 564,111,242 shares authorized, 96,557,652 and 94,858,446 issued and outstanding at September 30, 2022 and March 31, 2022, respectively	2	2
Additional paid-in capital	823,021	795,935
Accumulated other comprehensive loss	(17,285)	(17,285)
Accumulated deficit	(1,318,987)	(1,252,129)
Total shareholders' deficit	(513,249)	(473,477)
Total liabilities and shareholders' deficit	$ 483,974	$ 520,011

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

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

	Three Months Ended September 30,		Six Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
Product revenue, net	$ 49,947	$ 21,063	$ 91,298	$ 32,617
Pfizer collaboration revenue	54,577	25,172	79,718	54,681
Accord license revenue	—	—	50,000	—
Richter license and milestone revenue	300	31,667	300	31,667
Total revenues	104,824	77,902	221,316	118,965
Operating costs and expenses:				
Cost of product revenue	4,942	2,622	9,857	3,654
Collaboration expense to Pfizer	22,418	8,565	40,434	13,826
Selling, general and administrative [(1)]	84,259	58,781	163,291	119,993
Research and development	26,916	26,280	50,806	57,160
Total operating costs and expenses	138,535	96,248	264,388	194,633
Loss from operations	(33,711)	(18,346)	(43,072)	(75,668)
Interest expense [(2)]	4,813	3,494	9,013	6,999
Interest income	(1,018)	(100)	(1,504)	(178)
Loss before income taxes	(37,506)	(21,740)	(50,581)	(82,489)
Income tax expense (benefit)	8,113	(149)	16,277	762
Net loss and comprehensive loss	$ (45,619)	$ (21,591)	$ (66,858)	$ (83,251)
Net loss per common share — basic and diluted	$ (0.47)	$ (0.23)	$ (0.70)	$ (0.90)
Weighted average common shares outstanding — basic and diluted	96,211,190	92,355,150	95,801,991	92,019,987

[(1)] Includes $1,241 and $2,404 of related party expense (inclusive of third-party pass-through costs) for the three and six months ended September 30, 2022, respectively. Includes $1,173 and $2,447 of related party expense (inclusive of third-party pass-through costs) for the three and six months ended September 30, 2021, respectively. See Note 5.

[(2)] Includes $4,813 and $8,445 of interest expense under the Sumitomo Pharma Loan Agreement for the three and six months ended September 30, 2022, respectively. Includes $2,885 and $5,789 of interest expense under the Sumitomo Pharma Loan Agreement for the three and six months ended September 30, 2021, respectively. See Note 5(C).

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

MYOVANT SCIENCES LTD.
Condensed Consolidated Statements of Shareholders' Deficit
(unaudited; in thousands, except share data)

	Common Shares		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Deficit
	Shares	Amount				
Balance at March 31, 2022	94,858,446	$ 2	$ 795,935	$ (17,285)	$ (1,252,129)	$ (473,477)
Share-based compensation	—	—	10,001	—	—	10,001
Issuance of shares upon exercise of stock options and release of share awards	798,586	—	1,191	—	—	1,191
Net loss	—	—	—	—	(21,239)	(21,239)
Balance at June 30, 2022	95,657,032	2	807,127	(17,285)	(1,273,368)	(483,524)
Share-based compensation	—	—	11,901	—	—	11,901
Issuance of shares upon exercise of stock options and release of share awards	900,620	—	3,993	—	—	3,993
Net loss	—	—	—	—	(45,619)	(45,619)
Balance at September 30, 2022	96,557,652	$ 2	$ 823,021	$ (17,285)	$ (1,318,987)	$ (513,249)

	Common Shares		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Deficit
	Shares	Amount				
Balance at March 31, 2021	91,000,869	$ 2	$ 709,466	$ (17,285)	$ (1,046,148)	$ (353,965)
Share-based compensation	—	—	11,262	—	—	11,262
Share-based compensation liabilities reclassified to equity upon settlement of awards	—	—	1,862	—	—	1,862
Share-based compensation reclassified to current liabilities	—	—	(1,377)	—	—	(1,377)
Issuance of shares upon exercise of stock options and release of share awards	941,774	—	4,252	—	—	4,252
Net loss	—	—	—	—	(61,660)	(61,660)
Balance at June 30, 2021	91,942,643	2	725,465	(17,285)	(1,107,808)	(399,626)
Share-based compensation	—	—	11,863	—	—	11,863
Share-based compensation liabilities reclassified to equity upon settlement of awards	—	—	16,297	—	—	16,297
Share-based compensation reclassified to current liabilities	—	—	(915)	—	—	(915)
Issuance of shares upon exercise of stock options and release of share awards	1,135,146	—	11,045	—	—	11,045
Net loss	—	—	—	—	(21,591)	(21,591)
Balance at September 30, 2021	93,077,789	$ 2	$ 763,755	$ (17,285)	$ (1,129,399)	$ (382,927)

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

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

	Six Months Ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (66,858)	$ (83,251)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	21,423	23,125
Depreciation	670	716
Non-cash interest expense	568	1,210
Amortization of operating lease right-of-use assets	935	820
Changes in operating assets and liabilities:		
Accounts receivable	(10,466)	(10,832)
Inventories	(14,984)	(3,530)
Prepaid expenses and other current assets	(9,328)	(4,414)
Amount due from related party	(363)	—
Other assets	8,399	1,798
Accounts payable	(4,083)	(9,519)
Accrued expenses and other current liabilities	15,487	1,722
Deferred revenue	20,282	28,652
Amounts due to Pfizer	6,376	18,003
Cost share advance from Pfizer	(34,386)	(38,304)
Operating lease liabilities	(1,027)	(869)
Amounts due to related parties	458	(209)
Other liabilities	12	(1,696)
Net cash used in operating activities	(66,885)	(76,578)
Cash flows from investing activities:		
Purchases of marketable securities	(24,647)	(94,448)
Maturities of marketable securities	22,800	7,035
Purchases of property and equipment	(386)	(361)
Net cash used in investing activities	(2,233)	(87,774)
Cash flows from financing activities:		
Proceeds from stock option exercises	5,142	15,135
Net cash provided by financing activities	5,142	15,135
Net change in cash, cash equivalents and restricted cash	(63,976)	(149,217)
Cash, cash equivalents and restricted cash, beginning of period	416,804	677,480
Cash, cash equivalents and restricted cash, end of period	$ 352,828	$ 528,263
Supplemental Disclosures of Non-Cash Financing and Investing Information:		
Change in fair value of share-based awards recorded to additional paid-in capital	$ —	$ 2,292
Equipment purchases included in accounts payable	$ 48	$ 352
Reclassification of share-based compensation liabilities to additional paid-in capital upon settlement of awards	$ —	$ 18,159
Stock options exercised receivable, included in prepaid expenses and other current assets	$ 42	$ 162

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

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

Note 1—Organization and Summary of Significant Accounting Policies

Description of Business

Myovant Sciences Ltd. (together with its wholly-owned subsidiaries, the "Company" or "Myovant") is a biopharmaceutical company that aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. Founded in 2016, the Company has executed multiple successful Phase 3 clinical trials across oncology and women's health leading to three regulatory approvals by the United States ("U.S.") Food and Drug Administration ("FDA"): (1) ORGOVYX® (relugolix 120 mg), which was approved in the U.S. in December 2020 as the first and only oral gonadotropin-releasing hormone ("GnRH") receptor antagonist for the treatment of adult patients with advanced prostate cancer; (2) MYFEMBREE® (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg), which was approved in the U.S. in May 2021 as the first and only once-daily oral GnRH treatment for the management of heavy menstrual bleeding associated with uterine fibroids; and (3) MYFEMBREE which was approved in August 2022 for the management of moderate to severe pain associated with endometriosis, establishing MYFEMBREE as the first and only once-daily oral GnRH treatment approved for both uterine fibroids and endometriosis.

In July 2021, the European Commission ("EC"), and in August 2021, the United Kingdom ("U.K.") Medicines and Healthcare products Regulatory Agency ("MHRA"), approved RYEQO® (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) as the first and only long-term, once-daily oral treatment in the European Union ("EU") and U.K., respectively, for moderate to severe symptoms of uterine fibroids in adult women of reproductive age. In April 2022, the EC, and in June 2022, the MHRA, approved ORGOVYX (relugolix 120 mg) as the first and only oral androgen deprivation therapy for advanced hormone-sensitive prostate cancer in the EU and U.K., respectively.

In June 2022, the FDA accepted for review the Company's supplemental New Drug Application ("sNDA") that proposes updates to the U.S. Prescribing Information based on the safety and efficacy data from the Phase 3 LIBERTY randomized withdrawal study of MYFEMBREE in premenopausal women with heavy menstrual bleeding due to uterine fibroids for up to two years. The FDA set a Prescription Drug User Fee Act ("PDUFA") goal date of January 29, 2023 for this sNDA. MYFEMBREE is also being evaluated for contraceptive efficacy in women with heavy menstrual bleeding associated with uterine fibroids or endometriosis-associated pain who are 18 to 50 years of age and at risk for pregnancy. The Company is also developing MVT-602, an investigational oligopeptide kisspeptin-1 receptor agonist, which has completed a Phase 2a study for the treatment of female infertility as a part of assisted reproduction.

Since its inception, the Company has funded its operations primarily from the issuance and sale of its common shares, from debt financing arrangements, and more recently from the upfront and milestone payments it has received from its collaboration and commercialization partners, as well as net revenues generated from sales of ORGOVYX and MYFEMBREE in the U.S.

The Company's majority shareholder is Sumitovant Biopharma Ltd. ("Sumitovant"), a wholly-owned subsidiary of Sumitomo Pharma Co., Ltd. ("Sumitomo Pharma"), the name of which prior to April 1, 2022 was Sumitomo Dainippon Pharma Co., Ltd. As of September 30, 2022, Sumitovant directly, and Sumitomo Pharma indirectly, beneficially own 50,041,181, or approximately 51.8%, of the Company's outstanding common shares.

On October 23, 2022, Myovant, Sumitovant, Zeus Sciences Ltd., a wholly owned subsidiary of Sumitovant ("Merger Sub"), and, solely with respect to Article IX and Annex A of the Merger Agreement, Sumitomo Pharma, entered into an Agreement and Plan of Merger (the "Merger Agreement") providing for the merger of Merger Sub with and into Myovant (the "Merger"), with Myovant continuing as the surviving company following the Merger as a wholly owned subsidiary of Sumitovant (the "Surviving Company"). Subject to the terms and conditions set forth in the Merger Agreement, in the event the Merger is consummated, holders of the Company's common shares (other than Excluded Shares, Parent Owned Shares and Dissenting Shares (as each such term is defined in the Merger Agreement)) will be entitled to receive $27.00 per share in cash, without interest and less any applicable withholding taxes (the "Per Share Merger Consideration"). See Note 5(A) for more details on the Merger Agreement.

Basis of Presentation and Principles of Consolidation

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 U.S. generally accepted accounting principles ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements.

In the opinion of management, the accompanying unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q ("Quarterly Report") reflect all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the Company's condensed consolidated balance sheets as of September 30, 2022 and March 31, 2022, and its condensed consolidated statements of operations and comprehensive loss, and shareholders' deficit for the three and six months ended September 30, 2022 and 2021, and its condensed consolidated statements of cash flows for the six months ended September 30, 2022 and 2021. The March 31, 2022 condensed consolidated balance sheet was derived from audited consolidated financial statements, but does not include all disclosures required by U.S. GAAP. The results for interim periods are not necessarily indicative of results for the entire fiscal year or any other interim period. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the Company's previously filed audited consolidated financial statements and the related notes thereto included in the Company's Annual Report on Form 10-K ("Annual Report") for the fiscal year ended March 31, 2022, filed with the U.S. Securities and Exchange Commission (the "SEC") on May 11, 2022.

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 ("ASC") and Accounting Standards Update ("ASU"), issued by the Financial Accounting Standards Board ("FASB"). The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Dollar amounts reported in millions within this Quarterly Report are computed based on the amounts in thousands, and therefore, the sum of components may not equal the total amount reported in millions due to rounding.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires the Company's management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the condensed consolidated financial statements and the accompanying notes, and the reported amounts of revenue and expenses during the reported periods. Actual results could differ materially from those estimates.

On an ongoing basis, the Company's management evaluates its estimates, including those related to valuation of inventories, impairment testing for long-lived-assets, variables used in calculating the fair value of the Company's equity awards, expected achievement of performance-based vesting criteria for equity awards, variable consideration and other relevant inputs impacting the gross and net revenue recognition, contingent liabilities, recoverability of deferred tax assets, determination of lease term, research and development ("R&D") expenses and accruals, and effective income tax rates. Management bases estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities as of the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period, that are not readily apparent from other sources. Estimates and assumptions are periodically reviewed considering changes in circumstances, facts, or experience. Changes in estimates and assumptions are reflected in reported results in the period in which they become known. In addition, management's assessment of the Company's ability to continue as a going concern involves the estimation of the amount and timing of future cash inflows and outflows.

Summary of Significant Accounting Policies

The accounting policies used by the Company in its presentation of interim financial results are consistent with those described in Note 2 to the Company's audited consolidated financial statements included in its Annual Report for the fiscal year ended March 31, 2022, filed with the SEC on May 11, 2022. There have been no significant changes in the Company's significant accounting policies from those disclosed in its Annual Report for the fiscal year ended March 31, 2022.

Reclassification

Certain reclassification has been made to the unaudited condensed consolidated statements of cash flows for the six months ended September 30, 2021 to place them on a comparable basis with the six months ended September 30, 2022, regarding the presentation of amortization of operating lease right-of-use assets of $0.8 million. The reclassification had no effect on the previously reported results of operations. The reclassification had no effect on previously reported cash flows from operating activities in the unaudited condensed consolidated statements of cash flows.

Liquidity and Capital Resources

As of September 30, 2022, the Company had approximately $371.3 million in cash, cash equivalents, and marketable securities. The Company believes that its existing cash, cash equivalents, and marketable securities will be sufficient to fund its anticipated operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of this Quarterly Report.

In future periods, if the Company's cash, cash equivalents, marketable securities, and amounts that it expects to generate from product sales and/or third-party collaboration payments are not sufficient to enable the Company to fund its operations, the Company may need to raise additional funds in the form of equity, debt, or from other sources. There can be no assurances that such funding sources will be available at terms acceptable to the Company, or at all. If the Company has insufficient funding to meet its working capital needs, it could be required to delay, limit, reduce, or terminate its drug development programs, commercialization efforts, and/or limit or cease operations.

As of September 30, 2022, the Company had approximately $41.3 million of borrowing capacity available to it under the Sumitomo Pharma Loan Agreement (see Note 5(C)). As of September 30, 2022, the Company is also eligible to earn up to $3.5 billion, $122.2 million, and $90.5 million of additional milestone payments from Pfizer Inc. ("Pfizer"), Gedeon Richter Plc. ("Richter"), and Accord Healthcare, Ltd. ("Accord"), respectively, as well as potential royalty payments from Richter and Accord. See Note 8 for additional information about the Pfizer Collaboration and License Agreement, the Richter Development and Commercialization Agreement, and the Accord License Agreement.

Net Loss per Common Share

Basic net loss per common share is computed by dividing net loss available to common shareholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing net loss by the weighted-average number of common shares and potentially dilutive shares of common stock outstanding during the period. Potential dilutive securities outstanding include stock options, restricted stock units, performance stock units, and warrants. During all periods presented, the Company incurred net losses. Accordingly, the effect of any common share equivalents would have been anti-dilutive during those periods and are not included in the calculation of diluted weighted-average number of common shares outstanding.

The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per common share for the periods indicated because their inclusion would have been anti-dilutive:

	September 30,	
	2022	2021
Stock options	5,301,175	7,747,596
Restricted stock units and performance stock units (unvested)	7,829,202	4,734,445
Warrants	73,710	73,710
Total	13,204,087	12,555,751

Recently Issued Accounting Standards Not Yet Adopted

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting,* which provides optional expedients and exceptions for applying generally accepted accounting principles to contracts, hedging relationships, and other transactions affected by reference rate reform if certain criteria are met. These amendments apply only to contracts, hedging relationships, and other transactions that reference the London Interbank Offered Rate ("LIBOR") or another reference rate expected to be discontinued because of reference rate reform. The amendments are effective prospectively for all entities as of March 12, 2020 through December 31, 2022, and subject to a proposed extension to December 31, 2024. The Company's outstanding debt with Sumitomo Pharma bears a variable interest rate that is indexed off of 3-month LIBOR, for which publication is expected to be discontinued on June 30, 2023. In the event that 3-month LIBOR becomes unavailable, the Company and Sumitomo Pharma will negotiate in good faith to select an alternative interest rate in accordance with the Sumitomo Pharma Loan Agreement. The Company has not yet

adopted this guidance and is currently evaluating the potential impact the adoption of this standard will have on its consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses* (Topic 326): *Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model that requires the use of forward-looking information to calculate credit loss estimates. It also eliminates the concept of other-than-temporary impairment and requires credit losses on available-for-sale debt securities to be recorded through an allowance for credit losses instead of as a reduction in the amortized cost basis of the securities. ASU 2016-13 was effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2019. Early adoption was permitted, including adoption in any interim period. In February 2020, the FASB issued ASU 2020-02, *Financial Instruments-Credit Losses* (Topic 326) and Leases (Topic 842) - *Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 119 and Update to SEC Section on Effective Date Related to Accounting Standards Update No. 2016-02, Leases* (Topic 842), which amended the effective date of the original pronouncement for smaller reporting companies. ASC 2016-13 and its amendments will be effective for annual and interim periods beginning after December 15, 2022 for smaller reporting companies. The Company is currently assessing the impact the adoption of this new standard will have on its consolidated financial statements and related disclosures.

Note 2—Revenue Components

The following table provides information about the Company's revenues (in thousands):

	Three Months Ended September 30,		Six Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
Product revenue, net:				
ORGOVYX	$ 43,319	$ 18,663	$ 79,353	$ 29,142
MYFEMBREE	6,403	629	10,402	1,704
Richter product supply and royalties	225	1,771	1,543	1,771
Total product revenue, net	49,947	21,063	91,298	32,617
Pfizer collaboration revenue:				
Amortization of upfront payment	20,974	20,974	41,948	41,948
Amortization of regulatory milestones	33,603	4,198	37,770	12,733
Total Pfizer collaboration revenue	54,577	25,172	79,718	54,681
Accord license revenue	—	—	50,000	—
Richter license and milestone revenue	300	31,667	300	31,667
Total revenues	$ 104,824	$ 77,902	$ 221,316	$ 118,965

Product Revenue, net

The Company generates product revenue from sales of ORGOVYX and MYFEMBREE in the U.S. The Company records product revenue net of estimated discounts, chargebacks, rebates, product returns, and other gross-to-net revenue deductions.

For the six months ended September 30, 2022, product revenue, net also includes revenues related to product supply to Richter of $1.1 million, and for the three and six months ended September 30, 2022 product revenue, net also includes royalties on net sales of RYEQO in Richter's Territory of $0.2 million and $0.4 million, respectively. There was no revenue related to product supply to Richter for the three months ended September 30, 2022. For the three and six months ended September 30, 2021, product revenue, net also includes revenues related to product supply to Richter of $1.7 million, as well as royalties on net sales of RYEQO in Richter's Territory of less than $0.1 million.

The activities and ending balances for each significant category of discounts and allowances (which constitutes variable consideration) for the six months ended September 30, 2022 were as follows (in thousands):

	Reserve -government and other incentives	Chargebacks and administrative fees	Returns	Sales Discounts	Total
Balance as of March 31, 2022	$ 13,734	$ 2,628	$ 3,028	$ 486	$ 19,876
Provision related to sales in the current year	54,248	14,169	1,838	2,627	72,882
Adjustments related to prior year sales	1,050	(741)	—	—	309
Credits and payments made during the current year	(39,056)	(12,273)	(5)	(2,481)	(53,815)
Balance as of September 30, 2022	$ 29,976	$ 3,783	$ 4,861	$ 632	$ 39,252

The total reserves described above are summarized as components of the Company's unaudited condensed consolidated balance sheets as follows (in thousands):

	September 30, 2022	March 31, 2022
Reduction of accounts receivable, net	$ 632	$ 486
Component of accrued expenses and other current liabilities	38,620	19,390
Total revenue-related reserves	$ 39,252	$ 19,876

Pfizer Collaboration Revenue

Pfizer collaboration revenue for the three and six months ended September 30, 2022 and 2021 consists of the partial recognition of the upfront payment the Company received from Pfizer upon entering into the Pfizer Collaboration and License Agreement in December 2020 and of the $100.0 million regulatory milestone payment the Company received from Pfizer that was triggered upon the FDA approval of MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids on May 26, 2021. Pfizer collaboration revenue for the three and six months ended September 30, 2022 also includes the partial recognition of the $100.0 million regulatory milestone payment the Company received from Pfizer that was triggered upon the FDA approval of MYFEMBREE for the management of moderate to severe pain associated with endometriosis on August 5, 2022. See Note 8(A) for additional information regarding the Pfizer Collaboration and License Agreement.

Accord License Revenue

Accord license revenue for the six months ended September 30, 2022 consists of the recognition of the upfront payment the Company received from Accord in May 2022 pursuant to the Accord License Agreement. There was no Accord license revenue for the three months ended September 30, 2022, or for the three and six months ended September 30, 2021. See Note 8(C) for additional information regarding the Accord License Agreement.

Richter License and Milestone Revenue

Richter license and milestone revenue for the three and six months ended September 30, 2021 consists of the recognition of a $15.0 million regulatory milestone payment that was triggered upon the EC approval of RYEQO for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age and $16.7 million of previously deferred revenue that was recognized upon the completion of the Company's delivery of the remaining substantive relugolix combination tablet data packages to Richter. Richter license and milestone revenue for the three and six months ended September 30, 2022 consists of a $0.3 million regulatory milestone payment that was triggered upon the approval of RYEQO for the uterine fibroids indication in Australia. See Note 8(B) for additional information regarding the Richter Development and Commercialization Agreement.

Note 3—Certain Balance Sheet Components

Cash, Cash Equivalents and Restricted Cash

The following represents a reconciliation of cash and cash equivalents on the unaudited condensed consolidated balance sheets to total cash, cash equivalents and restricted cash in the unaudited condensed consolidated statements of cash flows (in thousands):

	September 30,	
	2022	2021
Cash and cash equivalents	$ 341,960	$ 518,163
Restricted cash (included in other assets)	10,868	10,100
Total cash, cash equivalents and restricted cash	$ 352,828	$ 528,263

Cash and cash equivalents include cash deposits in banks and all highly liquid investments that are readily convertible to cash (maturity of three months or less at the time of purchase). Restricted cash consists of funds held or designated to satisfy the requirements of certain agreements that are restricted in their use. As of September 30, 2022 and 2021, restricted cash includes approximately $7.1 million, that is held in an escrow fund for use by Sunovion Pharmaceuticals Inc. (“Sunovion”), a subsidiary of Sumitomo Pharma, to manage payments for rebates, chargebacks, and similar fees pursuant to the Market Access Services Agreement (see Note 5(F)).

Inventories

Inventories consisted of the following (in thousands):

	September 30, 2022	March 31, 2022
Raw materials	$ 9,999	$ 663
Work in process	10,829	3,737
Finished goods	2,219	3,184
Total inventories	$ 23,047	$ 7,584

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	September 30, 2022	March 31, 2022
Accrued sales discounts, rebates, and allowances	$ 38,620	$ 19,390
Accrued compensation-related expenses	18,171	26,389
Accrued R&D expenses	7,081	6,955
Accrued commercial expenses	6,387	7,196
Accrued royalties payable to Takeda	3,769	2,470
Accrued professional fees	3,595	1,340
Accrued income tax payable	2,977	720
Accrued other expenses	2,864	3,309
Deferred product revenue	617	825
Total accrued expenses and other current liabilities	$ 84,081	$ 68,594

Note 4—Fair Value Measurements

The preparation of the Company’s unaudited condensed consolidated financial statements in accordance with U.S. GAAP requires certain assets and liabilities to be reflected at their fair value. 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 on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be

classified and disclosed into one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable. These levels are as follows:

- Level 1—inputs, which include unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access;
- Level 2—inputs, which include observable inputs other than Level 1 inputs, such as 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, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability; and
- Level 3—inputs, which include unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the underlying asset or liability. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies, or similar valuation techniques, as well as significant management judgement or estimation.

For a description of the methods and assumptions that are used to estimate the fair value and determine the fair value hierarchy classification of each class of the Company's financial instruments, see Note 2, "Summary of Significant Accounting Policies," and Note 4, "Fair Value Measurements," to the Company's audited consolidated financial statements included in its Annual Report for the fiscal year ended March 31, 2022, filed with the SEC on May 11, 2022.

Financial Instruments Measured at Fair Value on a Recurring Basis

The following table summarizes the Company's financial assets measured at fair value on a recurring basis and their respective input levels based on the fair value hierarchy (in thousands):

	Fair Value Measurement Using:			
	Level 1	Level 2	Level 3	Total
As of September 30, 2022				
Assets:				
Money market funds [1]	$ 165	$ —	$ —	$ 165
Commercial paper [2]	—	154,164	—	154,164
U.S. treasury securities [3]	1,930	—	—	1,930
Total assets	$ 2,095	$ 154,164	$ —	$ 156,259

	Fair Value Measurement Using:			
	Level 1	Level 2	Level 3	Total
As of March 31, 2022				
Assets:				
Money market funds [1]	$ 69	$ —	$ —	$ 69
Commercial paper [2]	—	219,772	—	219,772
Total assets	$ 69	$ 219,772	$ —	$ 219,841

[1] Included in cash and cash equivalents.

[2] Includes $126.8 million in cash and cash equivalents and $27.4 million in marketable securities as of September 30, 2022. Includes $192.3 million in cash and cash equivalents and $27.5 million in marketable securities as of March 31, 2022.

[3] Included in marketable securities, non-current.

There were no liabilities measured at fair value on a recurring basis as of September 30, 2022 or March 31, 2022.

The Company does not intend to sell its marketable securities that are in an unrealized loss position, and it is not more likely than not that the Company will be required to sell its securities before recovery of their amortized cost basis, which may be at maturity. There were no realized gains or realized losses on marketable securities for the periods presented.

Financial Instruments Not Measured at Fair Value on a Recurring Basis

The Company recorded the cost share advance from Pfizer, which was included in Level 2 of the fair value hierarchy, at its estimated fair value as of the transaction date. As discussed in Note 8(A), on the transaction date, the cost share advance from Pfizer was discounted to fair value using the Company's estimated incremental borrowing rate over the period in which the cost share advance was expected to be utilized. The recorded amount was reduced each reporting period by the amount of Allowable Expenses applied to the cost share advance. As of September 30, 2022, the cost share advance from Pfizer has been fully utilized and no amounts remained outstanding on the Company's unaudited condensed consolidated balance sheet as of September 30, 2022. There were no non-recurring fair value assets as of September 30, 2022 and March 31, 2022.

Note 5—Related Party Transactions

As of September 30, 2022, Sumitovant directly, and Sumitomo Pharma indirectly, beneficially own 50,041,181, or approximately 51.8%, of the Company's outstanding common shares. The Company has agreements with Sumitovant, Sumitomo Pharma, and their affiliates, including Sunovion, a subsidiary of Sumitomo Pharma. Certain of these agreements are described below.

(A) Merger Agreement

On October 23, 2022, Myovant, Sumitovant, Merger Sub, and, solely with respect to Article IX and Annex A of the Merger Agreement, Sumitomo Pharma, entered into the Merger Agreement. Pursuant to the Merger Agreement, and subject to the terms and conditions set forth therein, at the closing of the merger contemplated thereby, Merger Sub will be merged with and into Myovant (the "Merger"), with Myovant continuing as the surviving company following the Merger as a wholly owned subsidiary of Sumitovant.

Subject to the terms and conditions set forth in the Merger Agreement, at the effective time of the Merger (the "Effective Time"), (i) each of Myovant's common shares, $0.000017727 par value per share (the "Common Share"), issued and outstanding immediately prior to the Effective Time (other than Excluded Shares, Sumitovant Owned Shares and Dissenting Shares (as each such term is defined below)) will automatically cease to exist, and each holder of a Common Share will cease to have any rights with respect thereto, except for the right to receive the Per Share Merger Consideration; (ii) any Common Share owned by Myovant or any direct or indirect wholly owned subsidiary of Myovant (each, an "Excluded Share") as of immediately prior to the Effective Time will be cancelled and will automatically cease to exist, and no consideration will be delivered in exchange therefor; (iii) each Common Share that is owned directly by Sumitovant as of immediately prior to the Effective Time (each, a "Sumitovant Owned Share") will remain outstanding and will constitute a fully paid and nonassesable common share of the Surviving Company; (iv) each Common Share held by a holder who, as of the Effective Time, did not vote in favor of the Merger and complied with certain procedures specified in the Merger Agreement (each, a "Dissenting Share"), will automatically be cancelled and the holder thereof will have the right to receive the Per Share Merger Consideration plus the amount of any excess of the appraised fair value as determined by the Supreme Court of Bermuda above the Per Share Merger Consideration; and (v) each common share, par value $0.000017727 per share, of Merger Sub issued and outstanding immediately prior to the Effective Time will remain outstanding and will constitute a fully paid and nonassesable common share of the Surviving Company. As a result of the Merger, Sumitovant will acquire Myovant and own all of the issued and outstanding shares of the Surviving Company.

In addition, immediately prior to the Effective Time, subject to specified exceptions applicable to certain restricted share units to be granted after the execution of the Merger Agreement or as otherwise agreed between the parties thereto, each Myovant equity award that is outstanding, whether vested or unvested, will be cancelled and thereafter only entitle the holder to the right to receive an amount (reduced by any applicable withholding tax) in cash equal to, as applicable: (i) the number of Common Shares subject to a Myovant stock option multiplied by the Per Share Merger Consideration, minus such stock option's exercise price; provided that each option with an exercise price per Common Share that is equal to or greater than the Per Share Merger Consideration will be cancelled without payment; (ii) the number of restricted share units of Myovant multiplied by the Per Share Merger Consideration; and (iii) the number of restricted share units of Myovant subject to performance-based vesting conditions (deeming performance goals as being satisfied), multiplied by the Per Share Merger Consideration.

Completion of the Merger is subject to the satisfaction of certain conditions, including: (i) the adoption of the Merger Agreement at a shareholder meeting to consider such matter by the requisite vote of Myovant's shareholders, including the approval by the holders of a majority of the outstanding Common Shares entitled to vote and voting at such meeting and by the holders of a majority of the outstanding Common Shares not held by Sumitovant or its affiliates, (ii) the expiration of applicable

waiting period of the Merger under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, (iii) the absence of any law, injunction, judgment or other legal restraint that prohibits the consummation of the Merger, (iv) the accuracy of each party's representations and warranties (subject to certain materiality and Company Material Adverse Effect (as defined in the Merger Agreement) qualifications), (v) each party's performance in all material respects of its obligations contained in the Merger Agreement and (vi) the absence of a Company Material Adverse Effect following the date of the Merger Agreement that is continuing.

Sumitovant and Myovant have each made customary representations, warranties and covenants in the Merger Agreement, including covenants: (i) in the case of Myovant, to cause a meeting of its shareholders to be duly called and held as soon as reasonably practicable following the clearance of a proxy statement and Statement on Schedule 13E-3 in connection with the Merger by the SEC for the purpose of voting on the adoption of the Merger Agreement and (ii) in the case of each party, to use its reasonable best efforts to promptly take, or cause to be taken, all actions and to do, or cause to be done, all things necessary, proper or advisable under the Merger Agreement and applicable laws to consummate and make effective as promptly as practicable the Merger, subject to certain limitations set forth in the Merger Agreement. Subject to certain exceptions, Myovant has agreed to conduct its business in the ordinary course consistent with past practice, including not taking certain specified actions, prior to the consummation of the Merger or the termination of the Merger Agreement pursuant to its terms.

Under the Merger Agreement, Myovant has agreed not to: (i) initiate, solicit, propose, knowingly encourage or knowingly facilitate any inquiry or the making of any proposal or offer that constitutes, or would reasonably be expected to lead to, an Alternative Proposal (as defined in the Merger Agreement); (ii) engage in, continue or otherwise participate in any discussions with or negotiations relating to any Alternative Proposal, subject to certain exceptions, or any inquiry, proposal or offer that would reasonably be expected to lead to an Alternative Proposal; (iii) provide any non-public information to any person in connection with any Alternative Proposal or any proposal or offer that would reasonably be expected to lead to an Alternative Proposal; (iv) otherwise knowingly facilitate any effort or attempt to make an Alternative Proposal; or (v) cause or permit the Company to enter into an Alternative Proposal. However, subject to the satisfaction of certain conditions, the Company Board (acting upon the recommendation of the Special Committee) or the Special Committee is permitted to take certain actions which may, as more fully described in the Merger Agreement, include, prior to adoption and approval of the Merger Agreement and the other transactions contemplated thereby, including the Merger, by the requisite vote of Myovant's shareholders, changing the Company Board's or the Special Committee's recommendation in response to a Superior Proposal or Intervening Event (each as defined in the Merger Agreement).

The Merger Agreement contains certain termination rights for each of Sumitovant and Myovant, including the right to terminate (i) by mutual written consent, (ii) by either the Company (acting at the recommendation of the Special Committee) or by Sumitovant under specific circumstances, (iii) if the Merger is not consummated on or before 5:00 p.m., Pacific Time, on May 31, 2023 or (iv) to enter into a definitive agreement related to a Superior Proposal. Additionally, the Merger Agreement provides that, upon termination of the Merger Agreement, under specified circumstances, Myovant will be required to pay Sumitovant a termination fee of $55.25 million.

No amounts have been paid to or received from Sumitovant under the Merger Agreement; however, the Company believes the Merger Agreement is material to its business and operations.

(B) Voting and Support Agreement

In connection with the entry into the Merger Agreement, on October 23, 2022, Sumitovant and Myovant entered into a Voting and Support Agreement (the "Voting and Support Agreement") whereby Sumitovant has agreed, among other things, that at any meeting of the shareholders of Myovant or in connection with any written consent of the shareholders of Myovant, Sumitovant will appear at such meeting or cause its Common Shares to be counted as present at such meeting for purposes of establishing a quorum and, so long as Sumitovant is not prohibited from doing so by applicable law, vote or consent all of its Common Shares in favor of the Merger and the adoption of the Merger Agreement.

No amounts have been paid to or received from Sumitovant under the Voting and Support Agreement; however, the Company believes the Voting and Support Agreement is material to its business and operations.

(C) Sumitomo Pharma Loan Agreement

On December 27, 2019, the Company and one of its subsidiaries, Myovant Sciences GmbH ("MSG"), entered into a Loan Agreement with Sumitomo Pharma (the "Sumitomo Pharma Loan Agreement"). Pursuant to the Sumitomo Pharma Loan Agreement, Sumitomo Pharma agreed to make revolving loans to the Company in an aggregate principal amount of up to $400.0 million. Funds may be drawn down by the Company once per calendar quarter, subject to certain terms and conditions, including consent of the Company's board of directors. The maturity date of the loans under the Sumitomo Pharma Loan Agreement is December 27, 2024 or the date the outstanding principal of the loans is declared due and payable due to an event

of default pursuant to the terms of the Sumitomo Pharma Loan Agreement. In addition, if Sumitomo Pharma fails to own at least a majority of the Company's outstanding common shares, it may become unlawful under Japanese law for Sumitomo Pharma to fund loans to the Company, and in which case the Company would not be able to continue to borrow under the Sumitomo Pharma Loan Agreement. Interest is due and payable quarterly, and the outstanding principal amounts are due and payable in full on the five-year anniversary of the closing date of the Sumitomo Pharma Loan Agreement. Loans under the Sumitomo Pharma Loan Agreement are prepayable at any time without premium or penalty upon 10 business days' prior written notice.

Loans under the Sumitomo Pharma Loan Agreement bear interest at a variable rate per annum equal to 3-month LIBOR plus a margin of 3% payable on the last day of each calendar quarter. Publication of 3-month LIBOR is currently expected to be discontinued on June 30, 2023. In the event that 3-month LIBOR becomes unavailable, the Company and Sumitomo Pharma will negotiate in good faith to select an alternative interest rate and, if applicable as a result of such alternative interest rate, margin adjustment that is consistent with industry accepted successor rates for determining a LIBOR replacement. The Company's obligations under the Sumitomo Pharma Loan Agreement are fully and unconditionally guaranteed by the Company and its subsidiaries. The loans and other obligations are senior unsecured obligations of the Company, MSG, and subsidiary guarantors. The Sumitomo Pharma Loan Agreement includes customary representations and warranties and affirmative and negative covenants.

The Sumitomo Pharma Loan Agreement also includes customary events of default, including payment defaults, breaches of representations and warranties, breaches of covenants following any applicable cure period, cross acceleration to certain other debt, failure to pay certain final judgments, certain events relating to bankruptcy or insolvency, failure of material provisions of the loan documents to remain in full force and effect or any contest thereto by the Company or any of its subsidiaries and certain breaches by the Company under the Investor Rights Agreement. Upon the occurrence of an event of default, a default interest rate of an additional 5.0% will apply to the outstanding principal amount of the loans, Sumitomo Pharma may terminate its obligations to make loans to the Company and declare the principal amount of loans to become immediately due and payable, and Sumitomo Pharma may take such other actions as set forth in the Sumitomo Pharma Loan Agreement. Upon the occurrence of certain bankruptcy and insolvency events, the obligations of Sumitomo Pharma to make loans to the Company would automatically terminate and the principal amount of the loans would automatically become due and payable. In addition, if it becomes unlawful for Sumitomo Pharma to maintain the loans under the Sumitomo Pharma Loan Agreement or within 30 days of a change of control with respect to the Company, the Company would be required to repay the outstanding principal amount of the Loans.

As of September 30, 2022, approximately $41.3 million of borrowing capacity remains available to the Company, subject to the terms of the Sumitomo Pharma Loan Agreement and the outstanding loan balance of $358.7 million is classified as a long-term liability on the unaudited condensed consolidated balance sheet under the caption long-term debt, less current maturities (related party). Interest expense under the Sumitomo Pharma Loan Agreement was $4.8 million and $8.4 million for the three and six months ended September 30, 2022, respectively, and $2.9 million and $5.8 million for the three and six months ended September 30, 2021, respectively, and is included in interest expense in the unaudited condensed consolidated statements of operations and comprehensive loss.

(D) Investor Rights Agreement

On December 27, 2019, the Company entered into an Investor Rights Agreement with Sumitomo Pharma and Sumitovant (the "Investor Rights Agreement"). Pursuant to the Investor Rights Agreement, among other things, the Company agreed, at the request of Sumitovant, to register for sale, under the Securities Act of 1933, common shares beneficially owned by Sumitovant, subject to specified conditions and limitations. In addition, the Company agreed to periodically provide Sumitovant (i) certain financial statements, projections, capitalization summaries and other information and (ii) access to the Company's books, records, facilities and employees during the Company's normal business hours as Sumitovant may reasonably request, subject to specified limitations.

The Investor Rights Agreement also contains certain protections for the Company's minority shareholders for so long as Sumitomo Pharma or certain of its affiliates beneficially owns more than 50% of the Company's common shares. These protections include: (i) a requirement that Sumitovant vote its shares for the election of independent directors in accordance with the recommendation of the Company's board of directors (the "board") or in the same proportion as the shareholders not affiliated with Sumitovant vote its shares; (ii) a requirement that the audit committee of the Company's board be composed solely of three independent directors; (iii) a requirement that any transaction proposed by Sumitomo Pharma or certain of its affiliates that would increase Sumitomo Pharma's beneficial ownership to over 60% of the outstanding voting power of the Company must be approved by the Company's audit committee (if occurring prior to December 27, 2022), and be conditioned on the approval of shareholders not affiliated with Sumitovant approving the transaction by a majority of the common shares

held by such shareholders; and a requirement that any related person transactions between Sumitomo Pharma or certain of its affiliates and the Company must be approved by the Company's audit committee.

Pursuant to the Investor Rights Agreement, the Company also agreed that at all times that Sumitomo Pharma beneficially owns more than 50% of the Company's common shares, Sumitomo Pharma, by purchasing common shares in the open market or from the Company in certain specified circumstances, will have the right to maintain its percentage ownership in the Company's common shares in the event of a financing event or acquisition event conducted by the Company, or specified other events, subject to specific conditions.

(E) Services and Information Sharing Agreement

In February 2022, the Company and two of its subsidiaries, MSG and Myovant Sciences, Inc. ("MSI"), entered into a services and information sharing agreement with Sumitovant Biopharma, Inc., a wholly-owned subsidiary of Sumitovant. Under the agreement, for so long as Sumitovant is a majority owner of the Company, the Company agrees to (1) subject to Sumitovant's reasonable request and on a timeline to be reasonably agreed by the parties, supply certain information summarizing material aspects of the Company's business to Sumitovant, and with reasonable advanced notice, give Sumitovant and its representatives the reasonable opportunity to discuss such information with the Company's senior management; and (2) subject to the oversight of the chairperson of the Company's Audit Committee, provide certain additional, more detailed information on business-essential matters in order to collaborate with Sumitovant or to enable the Company to leverage Sumitovant's expertise.

Under the agreement, Sumitovant also agrees to provide, upon the Company's election, various administrative and general business support services as well as research and development services to the Company and its subsidiaries, and the Company agrees to reimburse Sumitovant for expenses it, or third parties acting on its behalf, incurs for the Company. For any general and administrative and research and development activities performed by employees of Sumitovant, the agreement provides for Sumitovant to charge the Company based upon the relative percentage of time utilized on matters related to the Company by the respective employee and a mutually agreed upon mark-up on such expenses. Under the agreement, all other third-party pass-through costs are billed to the Company at cost. For both the three and six months ended September 30, 2022, the Company incurred less than $0.1 million, under this agreement.

(F) Market Access Services Agreement

On August 1, 2020, one of the Company's subsidiaries, entered into a Market Access Services Agreement, as amended ("Market Access Services Agreement"), with Sunovion. Pursuant to the Market Access Services Agreement, among other things, Sunovion agreed to provide certain market access services with respect to the distribution and sale of ORGOVYX ("Prostate Cancer Product") and MYFEMBREE ("Women's Health Product," and collectively with Prostate Cancer Product, the "Products", and each a "Product"), including, among other things: (i) adding the Products to Sunovion's agreements with its third party logistics providers; (ii) adding the Women's Health Product to certain of Sunovion's contracts with wholesalers, group purchasing organizations and integrated delivery networks and negotiating rates for the Products with certain market access customers; (iii) providing order-to-cash services; (iv) providing certain employees to provide market access account director services; (v) performing activities required in connection with supporting and maintaining contracts between the Company and market access customers for the coverage, purchase, or dispensing of the Products; (vi) managing the validation, processing and payment of rebates, chargebacks, and certain administrative, distribution and service fees related to the Products; (vii) providing the Company with price reporting metrics and other information required to allow the Company to comply with applicable government price reporting requirements; (viii) coordinating with the Company and any applicable wholesalers and distributors to address any recalls, investigations, or product holds; (ix) configuring, or causing to be configured, the appropriate software systems to enable Sunovion to perform its obligations under the Market Access Services Agreement; and (x) providing training and certain other ancillary support services to facilitate the foregoing. Pursuant to this agreement, Sunovion will also provide certain services to the Company to enable the Company to comply with its obligations under the State Transparency Laws.

The Company, in turn, appointed Sunovion as the exclusive distributor of the Women's Health Product and a non-exclusive distributor of the Prostate Cancer Product, each in the U.S., including all of its territories and possessions.

In order to facilitate Sunovion's provision of these services, the Company agreed, among other things, to: (i) grant Sunovion a non-exclusive license under all intellectual property owned or controlled by the Company, solely for Sunovion's use in connection with its performance of the contemplated services; (ii) provide Sunovion periodic reports of sales projections and estimated volume requirements, as well as such other information as Sunovion reasonably requests or may need to perform the services; (iii) comply with the provisions of any agreements between Sunovion and third parties pursuant to which the Products will be distributed or sold; (iv) cooperate with certain investigations related to orders and audits of the Company's quality systems solely related, as reasonably determined by Myovant, to Sunovion's performance of certain regulatory services, at Sunovion's costs; and (v) promptly notify Sunovion in the event relugolix is recalled.

As consideration for the services, the Company has paid and will continue to pay Sunovion an agreed-upon monthly service charge for each of the first two years of the Market Access Services Agreement term and any agreed regulatory and training service charges. After the second year of the Market Access Services Agreement term, the monthly service charges will be determined by the parties. In addition, the Company also agreed to (x) reimburse Sunovion for any pass-through expenses it incurs while providing the services, and (y) establish an escrow fund for use by Sunovion to manage payments for rebates, chargebacks and similar fees. For the three and six months ended September 30, 2022, the Company incurred $1.2 million and $2.4 million, respectively, under this agreement (inclusive of third-party pass-through costs billed to the Company) which are included in SG&A expenses, in the accompanying consolidated statements of operations and comprehensive loss. For the three and six months ended September 30, 2021, the Company incurred $1.2 million and $2.4 million of expense under this agreement (inclusive of third-party pass-through costs billed to the Company), which is included in SG&A expenses in the unaudited condensed consolidated statements of operations.

The Market Access Services Agreement also contains customary representations and warranties by the parties and customary provisions related to confidentiality, indemnification and insurance. The initial term of the Market Access Services Agreement is three years. Thereafter, the term will be automatically extended for one-year periods, unless either party provides notice of its intent not to renew the Market Access Services Agreement at least nine (9) months prior to the expiration of the applicable term. Either party may also terminate the Market Access Services Agreement prior to the end of its term in the event of an uncured material breach by the other party, if there are certain changes of law, or if such other party becomes insolvent or undergoes a change of control. The Company may also terminate the Market Access Services Agreement with respect to one or both Products if Sunovion fails to satisfy certain market access milestones or for convenience upon payment of a break-up fee.

Note 6—Income Taxes

The Company is not subject to taxation under the laws of Bermuda since it is organized as a Bermuda Exempted Limited Company, for which there is no current tax regime. It is subject to taxation under the laws of the U.K. by virtue of location of central management and control. The income tax expense of the Company and its affiliates currently is primarily attributable to U.S. federal, state and local taxes. The Company's effective tax rate for the three and six months ended September 30, 2022 was (21.63)% and (32.18)%, respectively. The Company's effective tax rate for the three and six months ended September 30, 2021 was 0.69% and (0.92)%, respectively. Key determinative factors of the Company's effective tax rate include the allocation of its earnings by jurisdiction and a valuation allowance that currently eliminates all of the Company's net deferred tax assets, including in respect of the R&D matter referred to below.

Effective for tax years beginning after December 31, 2021, the Tax Cuts and Jobs Act of 2017 ("TCJA") amendments to Internal Revenue Code Section 174 will no longer permit an immediate deduction for R&D expenditures in the tax year that such costs are incurred. For expenses that are incurred for R&D in the U.S., such amounts will be amortized over five years (this is currently approximately 90% of the Company's relevant spend), and expenses that are incurred for R&D expenditures outside the U.S. will be amortized over 15 years. The Company's effective tax rate for the three and six months ended September 30, 2022 was impacted accordingly. Although it is understood that Congress has been considering legislation that would extend the TCJA relief by one or more years, the possibility that this will happen is uncertain and the Company is required to calculate its income tax liabilities based on the provisions of current law.

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. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis. Factors reviewed include projections of pre-tax book income for the foreseeable future, determination of cumulative pre-tax book income after permanent differences, earnings history, and reliability of forecasting. Future factors may arise at subsequent balance sheet dates that would impact the assessment of the objective and subjective evidence of the Company. Any adjustment to the deferred tax asset valuation allowance would be recorded in the consolidated statement of operations and comprehensive loss for the period that the adjustment is determined to be required.

In response to the COVID-19 pandemic, many governments enacted measures to provide aid and economic stimulus. These measures included deferring the due dates of tax payments and other changes to income and non-income-based-tax laws as well as providing direct government assistance through grants and forgivable loans. On March 27, 2020, the U.S. Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was enacted in response to the COVID-19 pandemic and the negative impacts that it had on the global economy and U.S. companies. The CARES Act includes measures to assist companies, including temporary changes to income and non-income-based tax laws. The Company implemented certain provisions of the CARES Act, such as deferring employer payroll taxes through the end of calendar year 2020. As of September 30, 2022, the Company has $0.9 million of employer payroll taxes deferred under the CARES Act, which is included in accrued expenses and other current liabilities on the unaudited condensed consolidated balance sheet.

Note 7—Share-Based Compensation

The Company has two share-based compensation plans, the Myovant Sciences Ltd. 2016 Equity Incentive Plan ("Equity Incentive Plan") and the Myovant Sciences Ltd. 2020 Inducement Plan ("Inducement Plan") (collectively, the "Equity Plans"). As of September 30, 2022, there were approximately 2.7 million and 0.5 million common shares available for future issuance under the Equity Incentive Plan and the Inducement Plan, respectively. For additional information about the Company's Equity Plans, see Note 10, "Share-Based Compensation," to the Company's audited consolidated financial statements included in its Annual Report for the fiscal year ended March 31, 2022, filed with the SEC on May 11, 2022.

(A) Stock Options

Activity for stock options for the six months ended September 30, 2022 is included in the following table:

	Number of Options
Options outstanding at March 31, 2022	6,130,680
Granted	204,808
Exercised	(676,852)
Forfeited	(357,461)
Options outstanding at September 30, 2022	5,301,175
Options vested and expected to vest at September 30, 2022	5,301,175
Options exercisable at September 30, 2022	3,703,568

(B) Restricted Stock and Performance Stock Units

Activity for restricted stock units and performance stock units for the six months ended September 30, 2022 is included in the following table:

	Number of Shares
Unvested balance at March 31, 2022	4,532,619
Granted	5,391,581
Vested	(1,022,354)
Forfeited	(1,072,644)
Unvested balance at September 30, 2022	7,829,202

(C) Share-Based Compensation

Share-based compensation during the three and six months ended September 30, 2022 and 2021 was as follows (in thousands):

	Three Months Ended September 30,		Six Months Ended September 30,	
	2022	2021	2022	2021
Share-based compensation recognized as:				
SG&A expense	$ 7,744	$ 6,803	$ 13,716	$ 13,958
R&D expense	3,832	4,884	7,498	8,841
Cost of product revenue [1]	141	15	209	18
Share-based compensation expense	$ 11,717	$ 11,702	$ 21,423	$ 22,817
Share-based compensation capitalized into inventory	$ 325	$ 176	$ 688	$ 326

[1] Share-based compensation capitalized into inventory is recognized as cost of product revenue when the related product is sold.

SG&A expense for the three and six months ended September 30, 2021 includes $2.2 million and $3.6 million, respectively, of share-based compensation related to the separation of the Company's former Principal Executive Officer and Principal Financial Officer. There was no such expense during the three and six months ended September 30, 2022. Additional information is included in Note 10, "Share-Based Compensation," to the Company's audited consolidated financial statements

included in its Annual Report for the fiscal year ended March 31, 2022, filed with the SEC on May 11, 2022.

Total unrecognized share-based compensation was approximately $108.5 million as of September 30, 2022 and is expected to be recognized over a weighted-average period of approximately 2.78 years.

Note 8—Collaboration and License Agreements

(A) Pfizer Collaboration and License Agreement

On December 26, 2020, one of the Company's subsidiaries, MSG, and Pfizer, entered into a collaboration and license agreement (the "Pfizer Collaboration and License Agreement"), pursuant to which the Company and Pfizer collaborate to jointly develop and commercialize relugolix in oncology and women's health in the U.S. and Canada (the "Co-Promotion Territory"). On September 19, 2022, the Company and Pfizer entered into a letter agreement pursuant to which Pfizer's rights in Canada with respect to relugolix in oncology under the Pfizer Collaboration and License Agreement terminated. References to "Co-Promotion Territory" with respect to periods subsequent to September 19, 2022 exclude Canada with respect to relugolix in oncology. In addition, Pfizer also received an option to acquire exclusive commercialization and development rights to relugolix in oncology outside the Co-Promotion Territory, excluding certain Asian countries (the "Pfizer Territory"). Pfizer notified the Company on October 22, 2021 of its decision to decline this option.

In the Co-Promotion Territory, the Company and Pfizer equally share profits and certain expenses, including certain pre-launch inventory costs incurred by the Company prior to the effective date of the Pfizer Collaboration and License Agreement (the "Allowable Expenses"). The Company remains responsible for regulatory interactions and drug supply and continues to lead clinical development for MYFEMBREE in the women's health indications, while development for ORGOVYX is shared equally among the parties.

In the U.S., the Company is the principal on all sales transactions with third parties and recognizes 100% of product sales to third parties as revenue from contracts with customers. The Company concluded that based on the principal versus agent guidance in ASC 606, it has primary responsibility for fulfilling customer orders, controls inventory before it is sold to third party customers, assumes the risk of inventory loss, and maintains discretion in establishing product price.

Pursuant to the terms of the Pfizer Collaboration and License Agreement, the Company received an upfront payment of $650.0 million in December 2020, of which $150.0 million was Pfizer's advanced reimbursement for Pfizer's share of Allowable Expenses (the "cost share advance"), and is eligible to receive up to $3.8 billion of milestone payments, including two regulatory milestones of $100.0 million upon each FDA approval for MYFEMBREE in uterine fibroids and endometriosis ($200.0 million in the aggregate), and tiered sales milestones of up to $3.5 billion upon reaching certain thresholds of annual net sales for oncology and the combined women's health indications in the Co-Promotion Territory. In July 2021, the Company received the first $100.0 million regulatory milestone payment from Pfizer that was triggered upon the FDA approval of MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids on May 26, 2021. In September 2022, the Company received the second $100.0 million regulatory milestone payment from Pfizer that was triggered upon the FDA approval of MYFEMBREE for the management of moderate to severe pain associated with endometriosis on August 5, 2022.

Pursuant to the terms of the Pfizer Collaboration and License Agreement, the Company was required to bear Pfizer's share of Allowable Expenses, up to a maximum of $100.0 million for calendar year 2021 and up to a maximum of $50.0 million for calendar year 2022. Any unused portion was to carry over into the subsequent calendar years until the Company had assumed in aggregate $150.0 million of Pfizer's share of the Allowable Expenses. No amounts remained under the cost share advance from Pfizer as of September 30, 2022.

The term of the Pfizer Collaboration and License Agreement continues until no products are sold and all development activities have terminated in the Co-Promotion Territory. The Pfizer Collaboration and License Agreement may be terminated early by either party for the uncured material breach of the other party or for bankruptcy or other insolvency proceeding of the other party. In addition, Pfizer has certain other termination rights and may terminate the Pfizer Collaboration and License Agreement early upon providing written notice to the Company pursuant to the terms of the Pfizer Collaboration and License Agreement.

The Company assessed the Pfizer Collaboration and License Agreement and determined that it meets both criteria to be considered a collaborative agreement within the scope of ASC 808, *Collaborative Arrangements*: active participation by both parties and exposures to significant risks and rewards dependent on the commercial success of the activities. Although the Company is lead party and will perform many activities, both development and commercialization responsibilities are assigned between parties and both parties participate on joint steering and other committees overseeing the collaboration activities. Both parties are exposed to significant risks and rewards based on the economic outcomes of the collaboration through cost sharing and profit (loss) sharing provisions. Net payments to/from Pfizer for Pfizer's share of the net profits and Allowable Expenses

will be disaggregated and presented in the Company's consolidated statements of operations and comprehensive loss according to the nature of the expense (e.g., collaboration expense, R&D expenses, or SG&A expenses).

As discussed above, the Company received a $650.0 million upfront payment from Pfizer in December 2020, of which $150.0 million was Pfizer's advanced reimbursement for Pfizer's share of Allowable Expenses. The Company concluded that the prepayment by Pfizer of its share of Allowable Expenses represented a significant financing component since the Company received the cash flows at the outset of the arrangement, rather than over a two-year period. Accordingly, the Company reduced the amount of the advanced reimbursement by approximately $3.6 million, representing the implied financing costs, and recorded the discounted value of $146.4 million on the consolidated balance sheet as a deposit liability (cost share advance from Pfizer). The financing component was accreted to interest expense utilizing a method that approximated the effective yield method over the period in which the cost share advance was expected to be used. As of September 30, 2022, the financing component had been fully accreted to interest expense. The remainder of the upfront payment was recorded as deferred revenue and has been and will continue to be recognized as Pfizer collaboration revenue on a straight-line basis over the estimated term of the agreement of six years, which was estimated by the Company based upon the terms of the Pfizer Collaboration and License Agreement, including the termination provisions contained therein. The Company determined straight-line amortization to be appropriate because the upfront payment represents payment for Pfizer's right to participate in the collaboration activities, including both commercialization and development activities, which are expected to be realized evenly over this period.

The achievement of the regulatory milestones was outside of the Company's control and therefore was not deemed probable at contract inception. Amounts associated with the regulatory milestones were not initially recognized. Upon achievement of the related regulatory milestones, cumulative catch-up revenue was recorded as Pfizer collaboration revenue in the period in which the respective regulatory milestone was achieved, and the remainder will be recognized over the remaining contract term. The Company determined that, conceptually, the regulatory milestone payments represent payment for development activities that will continue to benefit the collaboration as the products move toward commercialization. Accordingly, the recognition of revenue associated with the regulatory milestones follows the same amortization model as the upfront payment described above.

Similar to the regulatory milestones, sales-based milestone payments will not initially be recognized due to the uncertainty associated with the future commercial outcomes of ORGOVYX and MYFEMBREE. Upon achievement, the sales-based milestones will be recognized as revenue immediately in the period when the annual sales thresholds are met as the payments represent consideration for past activities that are completed and culminated in the annual sales thresholds being met.

The amount due to Pfizer as of September 30, 2022, was approximately $38.9 million and consisted of $22.4 million payable to Pfizer for Pfizer's 50% share of net profits on sales of ORGOVYX and MYFEMBREE in the U.S. and approximately $16.5 million for 50% of Pfizer's reimbursement of Allowable Expenses. 100% of all expenses related to Pfizer under the Pfizer Collaboration and License Agreement are initially expensed and then the full pool of expenses incurred by both the Company and Pfizer are reduced through application of the cost sharing allowance. The amount due to Pfizer as of March 31, 2022 was approximately $32.6 million and consisted of $14.1 million payable to Pfizer for Pfizer's 50% share of net profits on sales of ORGOVYX and MYFEMBREE in the U.S. and approximately $18.5 million for 50% of Pfizer's reimbursement of Allowable Expenses.

(B) Richter Development and Commercialization Agreement

On March 30, 2020, one of the Company's subsidiaries, MSG, entered into an exclusive license agreement with Richter for Richter to commercialize relugolix combination tablet for uterine fibroids and endometriosis in Europe, the Commonwealth of Independent States including Russia, Latin America, Australia, and New Zealand (the "Richter Development and Commercialization Agreement"). Under the terms of the Richter Development and Commercialization Agreement, the Company received an upfront payment of $40.0 million on March 31, 2020, is eligible to receive up to $40.0 million in regulatory milestone payments (of which $25.3 million has been received), $107.5 million in sales-related milestones, and tiered royalties on net sales following regulatory approval.

The Company determined that the transaction price under the Richter Development and Commercialization Agreement totaled $50.0 million, consisting of the upfront payment of $40.0 million received on March 31, 2020 and a $10.0 million regulatory milestone payment received in April 2020. No other regulatory milestones, sales-related milestones, or royalties on net sales following regulatory approval were included in the transaction price given the substantial uncertainty related to their achievement. The Company concluded that Richter represented a customer and applied relevant guidance from ASC 606, *Revenue from Contracts with Customers*. The Company identified one material combined performance obligation to grant a license to Richter to certain of its intellectual property and to deliver certain clinical and regulatory data packages for relugolix combination tablet, the drug used for both potential indications of uterine fibroids and endometriosis. The Company determined that its grant of a license to Richter to certain of its intellectual property was not distinct from the delivery of certain clinical and regulatory data packages pertaining to relugolix combination tablet. In evaluating the appropriate measure for the Company's performance under the combined performance obligation, the Company determined that revenues should be recognized as data packages are delivered to Richter based on the relative value of the data packages delivered to date compared to the totality of the data packages it is obligated to deliver under the Richter Development and Commercialization Agreement. The Company evaluated the measure of progress each reporting period and, if necessary, adjusted the measure of performance and related revenue recognition. Based upon the Company's assessment of its progress toward delivering relugolix combination tablet clinical and regulatory data packages to Richter, the Company recognized the remaining $16.7 million of the transaction price as Richter license and milestone revenue upon the completion of the Company's delivery of the remaining substantive relugolix combination tablet data packages to Richter during the three and six months ended September 30, 2021.

On July 16, 2021, the EC approved RYEQO as the first and only long-term, once-daily oral treatment in Europe for moderate to severe symptoms of uterine fibroids in adult women of reproductive age. This approval triggered a $15.0 million regulatory milestone payment from Richter, which the Company recorded as Richter license and milestone revenue during the three and six months ended September 30, 2021. Richter license and milestone revenue for the three and six months ended September 30, 2022 consists of a $0.3 million regulatory milestone payment from Richter that was triggered upon the approval of RYEQO for the uterine fibroids indication in Australia.

Under the terms of the Richter Development and Commercialization Agreement, the Company continues to lead global development of relugolix combination tablet. The Company also agreed to assist Richter in transferring manufacturing technology from the Company's CMOs to Richter to enable Richter to manufacture relugolix combination tablet. The Company agreed to supply Richter with quantities of relugolix combination tablet for its territories pursuant to the Company's agreements with its CMOs. Richter is responsible for local clinical development, manufacturing, and all commercialization activities for its territories. The Company has also granted Richter an option to collaborate with the Company on relugolix combination tablet for future indications in women's health other than fertility.

The term of the Richter Development and Commercialization Agreement shall expire on a country-by-country basis upon expiry of the Royalty Term (as defined in the Richter Development and Commercialization Agreement) for the respective product in a country in Richter's Territory. The Richter Development and Commercialization Agreement may be terminated in its entirety or on a country-by-country basis by mutual consent of the parties, or by either party for the uncured material breach of the other party, for bankruptcy of the other party, and for certain other reasons in accordance with the terms of the Richter Development and Commercialization Agreement.

(C) Accord License Agreement

On May 5, 2022, one of the Company's subsidiaries, MSG, entered into an exclusive license agreement (the "Accord License Agreement") with Accord and Intas Pharmaceuticals, Ltd., parent entity of Accord, for Accord to commercialize relugolix for the treatment of advanced hormone-sensitive prostate cancer under the trade name ORGOVYX® (relugolix 120 mg) in the European Economic Area, U.K., Switzerland, and Turkey ("Accord's Territories"), with the right of first negotiation if the Company decides to enter into licensing arrangements in countries in the Middle East, Africa, and India. Under the terms of the Accord License Agreement, the Company received an upfront payment of $50.0 million in the three months ended June 30, 2022. As of September 30, 2022, the Company is also eligible to receive up to $90.5 million in commercial launch, sales-based,

and other milestone payments, as well as tiered royalties from the high-teens to mid-twenties on net sales of ORGOVYX in Accord's Territories.

Under the terms of the Accord License Agreement, the Company retains all rights to relugolix in the U.S. with its collaboration partner, Pfizer, as well as rights to relugolix in other therapeutic areas outside of prostate cancer, uterine fibroids, and endometriosis in Europe. The Company will continue to lead the global development of relugolix and may provide initial product supply to Accord, subject to the parties entering into a separate supply agreement. Accord will be responsible for certain local clinical development and all commercialization for its territories and has the option to manufacture relugolix in the future. In the event that Accord elects to exercise this option, the Company has agreed to assist Accord in transferring manufacturing technology from the Company's CMOs to Accord to enable Accord to manufacture its own product supply.

The term of the Accord License Agreement shall expire on a country-by-country basis upon expiry of the Royalty Term (as defined in the Accord License Agreement). The Accord License Agreement may be terminated in its entirety or on a country-by-country basis by either party for the uncured material breach or bankruptcy of the other party, and for certain other reasons in accordance with the terms of the Accord License Agreement.

The Company concluded that Accord represents a customer and evaluated the Accord License Agreement under ASC 606. Based on that evaluation, the Company identified a single performance obligation under the Accord License Agreement, consisting of the Company's promise to grant Accord a license to certain of the Company's intellectual property. The Company determined that the initial transaction price consisted solely of the non-refundable upfront payment of $50.0 million, which was recognized as revenue upon delivery of the license to Accord during the six months ended September 30, 2022.

The remaining forms of consideration are variable because they are dependent on the achievement of sales-based or other milestones. The Company evaluated the constraint on variable consideration and concluded that the milestone payments are dependent on regulatory approvals and actions of third parties, and thus are highly susceptible to factors outside the Company's influence. Therefore, at contract inception, the milestones are not included in the transaction price as it is not probable that a significant reversal of revenue would not occur. Furthermore, the sales-based milestones will be recognized as revenue immediately in the period when the related sales threshold is met. All other milestones will be recognized as revenue immediately in the period the underlying milestone is achieved. Any consideration related to sales-based royalties will be recognized when the related sales occur.

(D) Contract Balances

The following table presents changes in the Company's contract liabilities during the six months ended September 30, 2022 (in thousands):

	Balance at March 31, 2022	Additions	Imputed Interest	Deductions	Balance at September 30, 2022
Contract liabilities:					
Deferred revenue [1]	$ 476,270	$ 100,000	$ —	$ (79,718)	$ 496,552
Cost share advance from Pfizer [2]	$ 33,818	$ —	$ 568	$ (34,386)	$ —

[1] Includes $117.2 million and $379.3 million presented as current and non-current, respectively, on the unaudited condensed consolidated balance sheet as of September 30, 2022. Includes $100.6 million and $375.7 million presented as current and non-current, respectively, on the unaudited condensed consolidated balance sheet as of March 31, 2022.

[2] Includes $33.8 million presented as current on the unaudited condensed consolidated balance sheet as of March 31, 2022.

During the six months ended September 30, 2022, deferred revenue increased by $20.3 million. The net increase was a result of a $100.0 million regulatory milestone payment from Pfizer that was triggered upon the FDA approval of MYFEMBREE for the management of moderate to severe pain associated with endometriosis on August 5, 2022, partially offset by the recognition of $79.7 million of Pfizer collaboration revenue.

During the six months ended September 30, 2022, the cost share advance from Pfizer decreased by $33.8 million. The decrease was the net result of the application of 100% of shared Allowable Expenses incurred by the Company and 50% of reimbursement of Allowable Expenses incurred by Pfizer of approximately $34.4 million, partially offset by accretion of the implied financing component of $0.6 million. No amounts remained outstanding under the cost share advance from Pfizer as of September 30, 2022. See Note 8(A) for additional information about the cost share advance from Pfizer.

Note 9—Commitments and Contingencies

(A) Legal Contingencies

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. For cases in which 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. The Company is currently not involved in any material legal proceedings.

(B) Contract Service Providers

In the normal course of business, the Company enters into agreements with contract service providers to assist in the performance of its R&D and clinical and commercial manufacturing activities. 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 collaborative research, contract research, clinical and commercial manufacturing, and supplier agreements in the future, which may require upfront payments and long-term commitments of capital resources.

(C) Indemnification Agreements

The Company has agreed to indemnify its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director was serving at the Company's request in such capacity. The maximum amount of potential future indemnification liability is unlimited; however, the Company holds directors' and officers' liability insurance which limits the Company's exposure and may enable it to recover a portion of any future amounts paid. In the normal course of business, the Company also enters into contracts and agreements with service providers and other parties with which it conducts business that contain indemnification provisions pursuant to which the Company has agreed to indemnify the party against certain types of third-party claims. The Company has agreed to indemnify Sumitomo Pharma against certain losses, claims, liabilities and related expenses incurred by Sumitomo Pharma, subject to the terms of the Sumitomo Pharma Loan Agreement and the Investor Rights Agreement. The Company has also agreed to indemnify Sunovion against certain losses, claims, liabilities and related expenses incurred by Sunovion, subject to the terms of the Market Access Services Agreement, as amended. The Company has not experienced any material losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related accruals have been established.

(D) Takeda Agreements

On April 29, 2016, Takeda Pharmaceuticals International AG ("Takeda"), a subsidiary of Takeda Pharmaceutical Company Limited, the originator of relugolix, granted the Company a worldwide license to develop and commercialize relugolix (excluding Japan and certain other Asian countries) and an exclusive right to develop and commercialize MVT-602 in all countries worldwide. Pursuant to the license agreement (the "Takeda License Agreement"), Takeda granted to the Company an exclusive, royalty-bearing license under certain patents and other intellectual property controlled by Takeda to develop and commercialize relugolix and MVT-602, and products containing these compounds for all human diseases and conditions. Under the Takeda License Agreement, the Company will pay Takeda a fixed, high single-digit royalty on net sales of certain relugolix products, a low single-digit royalty on net sales of certain other relugolix products, and a high single-digit royalty on net sales of MVT-602 products in the Company's territory, all subject to certain agreed reductions. The Company recorded royalty expense to Takeda of $3.8 million and $6.9 million for the three and six months ended September 30, 2022, respectively, and $1.5 million and $2.4 million for the three and six months ended September 30, 2021, respectively, and is included in cost of product revenue on the unaudited condensed consolidated statements of operations and comprehensive loss. As of September 30, 2022 and March 31, 2022, the Company recorded royalties payable to Takeda of $3.8 million and $2.5 million, respectively, which are included in accrued expenses and other current liabilities on the unaudited condensed consolidated balance sheets. Takeda will pay the Company a high single-digit royalty on net sales of relugolix products for prostate cancer in the Takeda Territory, subject to certain agreed reductions. Royalties are required to be paid, on a product-by-product and country-by-country basis, until the latest to occur of the expiration of the last to expire valid claim of a licensed patent covering such product in such country, the expiration of regulatory exclusivity for such product in such country, or 10 years after the first commercial sale of such product in such country. Under the Takeda License Agreement, there was no upfront payment and there are no payments upon the achievement of clinical development or marketing approval milestones.

If the Takeda License Agreement is terminated in its entirety or with respect to relugolix for prostate cancer, other than for safety reasons or by the Company for Takeda's uncured material breach, prior to receipt of the first regulatory approval of relugolix for prostate cancer in Japan, then the Company must either reimburse Takeda for its out of pocket costs and expenses directly incurred in connection with Takeda's completion of the relugolix development for prostate cancer, up to an agreed upon cap, or complete by itself the conduct of any clinical studies of relugolix for prostate cancer that are ongoing as of the effective date of such termination, at its cost and expense.

In May 2018, the Company entered into a Commercial Manufacturing and Supply Agreement with Takeda (the "Takeda Commercial Supply Agreement") pursuant to which Takeda agreed to supply the Company and the Company agreed to obtain from Takeda certain quantities of relugolix drug substance according to agreed-upon quality specifications. 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 will automatically renew 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 will remain in effect and be binding on both parties. The Takeda Commercial Supply Agreement, including any then-open purchase orders thereunder, will terminate immediately upon the termination of the Takeda License Agreement in accordance with its terms.

Note 10—Subsequent Events

On October 23, 2022, Myovant, Sumitovant, Merger Sub, and, solely with respect to Article IX and Annex A of the Merger Agreement, Sumitomo Pharma, entered into the Merger Agreement (see Note 5(A)). In addition, on October 23, 2022, Myovant and Sumitovant entered into a Voting and Support Agreement (see Note 5(B)).

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

Objective

The purpose of the following discussion and analysis is to provide material information relevant to an assessment of our financial condition and results of operations from management's perspective, including to describe and explain key trends, events, and other factors that impacted our reported results for the periods presented and that are reasonably likely to impact our future performance.

The discussion and analysis below is organized as follows:

- executive summary, including a description of our business and recent events that are important to understand our results of operations and financial condition;
- a description of the components of our results of operations and a discussion of our results of operations, including an explanation of significant changes between the periods presented in the specific line items of our condensed consolidated statements of operations and comprehensive loss;
- financial condition addressing our liquidity position, sources and uses of cash, capital resources and requirements, and commitments; and
- critical accounting policies and significant judgments and use of estimates which are most important to our financial condition and results of operations.

As you read this discussion and analysis, refer to our unaudited condensed consolidated financial statements and footnotes included in Part 1. Item 1. of this Quarterly Report on Form 10-Q ("Quarterly Report"). Also refer to our Annual Report on Form 10-K ("Annual Report") for the year ended March 31, 2022, filed with the United States Securities and Exchange Commission ("SEC") on May 11, 2022, which is available free of charge on the SEC's website at www.sec.gov and our investor relations website at investors.myovant.com. This discussion and analysis contains forward looking statements and should also be read in conjunction with the cautionary statement set forth in the section below titled, "Information Relating to Forward-Looking Statements."

Dollar amounts reported in millions within this Quarterly Report are computed based on the amounts in thousands, and therefore, the sum of components may not equal the total amount reported in millions due to rounding.

Information Relating to Forward-Looking Statements

This Quarterly Report contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended, (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 include, but are not limited to, statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things:

- the effects that our entry into the Merger Agreement (as such term is defined below) may have on our business prior to the closing of the Merger (as such term is defined below), or if the Merger does not close;
- our and our collaboration and commercialization partners' ability to successfully plan for and commercialize ORGOVYX®, MYFEMBREE®, and RYEQO®, as well as any product candidates, if approved;
- the success and anticipated timing of our clinical studies for our product candidates;
- the anticipated start dates, durations and completion dates of our ongoing and future nonclinical and clinical studies;
- the anticipated designs of our future clinical studies;
- the anticipated future regulatory submissions and the timing of, and our ability to, obtain and maintain, regulatory approvals for our product candidates, including any decision the United States ("U.S.") Food and Drug Administration ("FDA") may make regarding our supplemental New Drug Application ("sNDA") that proposes updates to MYFEMBREE's United States Prescribing Information ("USPI") based on safety and efficacy data from the Phase 3 LIBERTY randomized withdrawal study of MYFEMBREE in premenopausal women with heavy menstrual bleeding associated with uterine fibroids for up to two years;
- our ability to procure sufficient quantities of commercial relugolix drug substance and drug product from approved third party commercial manufacturing organizations ("CMOs");
- our ability to achieve commercial sales of any approved products, whether alone or in collaboration with others;
- our ability to obtain and maintain reimbursement and coverage from government and private payers for our products if 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 and third-party logistics providers;
- our ability to quickly and efficiently identify and develop new product candidates;
- the impact of pandemics, epidemics or outbreaks of infectious diseases, including the effect that the COVID-19 pandemic and related public health measures will have on our business operations, financial condition and results of operations;
- the impact of various social, political, economic, industry, inflationary, global supply chain, or other market conditions in the U.S. and around the world (including wars and other forms of conflict such as the conflict in Ukraine);
- our ability to hire and retain our management and other key personnel;
- our ability to obtain, maintain and enforce intellectual property rights for our products and 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, cash equivalents, and marketable securities currently on hand, including our expectations for how long these capital resources will enable us to fund our operations;

- our expectations regarding potential future payments that we are eligible to receive from Pfizer Inc. ("Pfizer") under the Pfizer Collaboration and License Agreement, Gedeon Richter Plc. ("Richter") under the Richter Development and Commercialization Agreement, and Accord Healthcare, Ltd. ("Accord") under the Accord License Agreement;
- our ability to borrow under the Sumitomo Pharma Co., Ltd. ("Sumitomo Pharma") Loan Agreement;
- third party collaboration or commercialization partners' abilities to perform their obligations under our agreements with them;
- our ability to raise additional capital if needed, on acceptable terms to us;
- 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, particularly in the section titled "Risk Factors" set forth in Part II. Item 1A. of this Quarterly Report, 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, 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 biopharmaceutical company that aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. Founded in 2016, we have executed multiple successful Phase 3 clinical trials across oncology and women's health leading to three regulatory approvals by the FDA: (1) ORGOVYX® (relugolix 120 mg), which was approved in the U.S. in December 2020 as the first and only oral gonadotropin-releasing hormone ("GnRH") receptor antagonist for the treatment of adult patients with advanced prostate cancer; (2) MYFEMBREE® (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg), which was approved in the U.S. in May 2021 as the first and only once-daily oral GnRH treatment for the management of heavy menstrual bleeding associated with uterine fibroids; and (3) MYFEMBREE which was approved in August 2022 for the management of moderate to severe pain associated with endometriosis, establishing MYFEMBREE as the first and only once-daily oral GnRH treatment approved for both uterine fibroids and endometriosis.

In July 2021, the European Commission ("EC"), and in August 2021, the United Kingdom ("U.K.") Medicines and Healthcare products Regulatory Agency ("MHRA"), approved RYEQO® (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) as the first and only long-term, once-daily oral treatment in the European Union ("EU") and U.K., respectively, for moderate to severe symptoms of uterine fibroids in adult women of reproductive age. In April 2022, the EC, and in June 2022, the MHRA, approved ORGOVYX (relugolix 120 mg) as the first and only oral androgen deprivation therapy for advanced hormone-sensitive prostate cancer in the EU and U.K., respectively.

In June 2022, the FDA accepted for review our supplemental New Drug Application ("sNDA") that proposes updates to the U.S. Prescribing Information based on the safety and efficacy data from the Phase 3 LIBERTY randomized withdrawal study ("RWS") of MYFEMBREE in premenopausal women with heavy menstrual bleeding due to uterine fibroids for up to two years. The FDA set a Prescription Drug User Fee Act ("PDUFA") goal date of January 29, 2023 for this sNDA. MYFEMBREE is also being evaluated for contraceptive efficacy in women with heavy menstrual bleeding associated with uterine fibroids or endometriosis-associated pain who are 18 to 50 years of age and at risk for pregnancy. We are also developing MVT-602, an investigational oligopeptide kisspeptin-1 receptor agonist, which has completed a Phase 2a study for the treatment of female infertility as a part of assisted reproduction.

Since our inception, we have funded our operations primarily from the issuance and sale of our common shares, from debt financing arrangements, and more recently from the upfront and milestone payments we have received from our collaboration and commercialization partners, as well as net revenues generated from sales of ORGOVYX and MYFEMBREE in the U.S.

Our majority shareholder is Sumitovant Biopharma Ltd. ("Sumitovant"), a wholly-owned subsidiary of Sumitomo Pharma, the name of which prior to April 1, 2022 was Sumitomo Dainippon Pharma Co., Ltd. As of September 30, 2022, Sumitovant directly, and Sumitomo Pharma indirectly, beneficially own 50,041,181, or approximately 51.8%, of our outstanding common shares.

On October 23, 2022, Myovant, Sumitovant, Zeus Sciences Ltd., a wholly owned subsidiary of Sumitovant ("Merger Sub"), and, solely with respect to Article IX and Annex A of the Merger Agreement, Sumitomo Pharma, entered into an Agreement and Plan of Merger (the "Merger Agreement") providing for the merger of Merger Sub with and into Myovant (the "Merger"), with Myovant continuing as the surviving company following the Merger as a wholly owned subsidiary of Sumitovant (the "Surviving Company"). Subject to the terms and conditions set forth in Merger Agreement, in the event the Merger is consummated, holders of our common shares (other than Excluded Shares, Parent Owned Shares and Dissenting Shares (as each such term is defined in the Merger Agreement)) will be entitled to receive $27.00 per share in cash, without interest and less any applicable withholding taxes (the "Per Share Merger Consideration"). See Note 5(A) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

In connection with the entry into the Merger Agreement, on October 23, 2022, Sumitovant and Myovant entered into a Voting and Support Agreement (the "Voting and Support Agreement") whereby Sumitovant has agreed, among other things, that at any meeting of the shareholders of Myovant or in connection with any written consent of the shareholders of Myovant, Sumitovant will appear at such meeting or cause the common shares of Myovant it holds to be counted as present at such meeting for purposes of establishing a quorum and, so long as Sumitovant is not prohibited from doing so by applicable law, vote or consent all of its Common Shares in favor of the Merger and the adoption of the Merger Agreement. See Note 5(B) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

Second Fiscal Quarter Ended September 30, 2022 Financial Highlights and Recent Business Updates

In this section, we summarize certain of our second fiscal quarter ended September 30, 2022 financial highlights and recent regulatory, clinical and business updates. Additional information about our business is included in Part I, Item 1., "Business," of our Annual Report, filed with the SEC on May 11, 2022.

Financial Highlights

- Total revenues for the three months ended September 30, 2022, were $104.8 million, compared to $77.9 million for the three months ended September 30, 2021.
- Product revenue, net for the three months ended September 30, 2022, was $49.9 million, compared to $21.1 million for the three months ended September 30, 2021. Net revenue from sales of ORGOVYX and MYFEMBREE in the U.S.

were $43.3 million and $6.4 million, respectively, for the three months ended September 30, 2022, compared to $18.7 million and $0.6 million, respectively, for the three months ended September 30, 2021.

- Pfizer collaboration revenue for the three months ended September 30, 2022, was $54.6 million, compared to $25.2 million for the three months ended September 30, 2021.
- Total operating costs and expenses for the three months ended September 30, 2022, were $138.5 million , compared to $96.2 million for the three months ended September 30, 2021.
- Net loss for the three months ended September 30, 2022, was $45.6 million, or $0.47 per common share, compared to a net loss of $21.6 million, or $0.23 per common share for the three months ended September 30, 2021.
- Cash, cash equivalents, and marketable securities were $371.3 million at September 30, 2022, compared to $434.2 million at March 31, 2022.

See “Results of Operations” below for a discussion of our results of operations for the three and six months ended September 30, 2022, as compared to the three and six months ended September 30, 2021.

Recent Business Updates

Corporate

- On October 23, 2022, we announced that Myovant entered into the Merger Agreement with Sumitovant, Zeus Sciences Ltd., a wholly owned subsidiary of Sumitovant, and, solely with respect to Article IX and Annex A of the Merger Agreement, Sumitomo Pharma, under which Sumitovant has agreed to acquire the remaining shares of Myovant that Sumitovant does not currently hold. Subject to the terms and conditions set forth in the Merger Agreement, in the event the Merger is consummated, holders of our common shares (other than Excluded Shares, Parent Owned Shares and Dissenting Shares) will be entitled to receive $27.00 per share in cash. See Note 5(A) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

Regulatory

- On August 5, 2022, the FDA approved MYFEMBREE for the management of moderate to severe pain associated with endometriosis, establishing it as the first and only once-daily oral GnRH treatment approved for both uterine fibroids and endometriosis. MYFEMBREE was launched in the U.S. for this indication by us and Pfizer in August 2022. Pursuant to the terms of the Pfizer Collaboration and License Agreement, this approval triggered a $100.0 million regulatory milestone payment from Pfizer, which we received in September 2022.
- In September 2022 and October 2022, we and Pfizer completed New Drug Submissions to Health Canada seeking marketing approval in Canada for MYFEMBREE for heavy menstrual bleeding associated with uterine fibroids and MYFEMBREE for the treatment of endometriosis-associated pain, respectively.
- In September 2022, our commercialization partner, Richter submitted a Type II variation application to the MHRA seeking approval for RYEQO for moderate to severe pain associated with endometriosis in adult women of reproductive age with a history of previous medical or surgical treatment for their endometriosis.
- In October 2022, Richter, submitted a Type II variation application to the European Medicines Agency (“EMA”) seeking approval for RYEQO for the treatment of moderate to severe pain associated with endometriosis in adult women of reproductive age with a history of previous medical or surgical treatment for their endometriosis. The acceptance of the Type II variation submission is pending validation by the EMA. Pursuant to the Richter Development and Commercialization Agreement, the acceptance of the Type II variation application by the EMA would trigger a $4.0 million milestone payment due from Richter.

Clinical

- We and Pfizer are initiating a new Phase 3 randomized open label clinical study, the REPLACE-CV study, to assess the risk of major adverse cardiovascular events (“MACE”) associated with ORGOVYX compared with leuprolide. The REPLACE-CV study is designed to enroll 2,250 men 18 years of age or older with prostate cancer who require treatment with androgen deprivation therapy (“ADT”) for at least one year. The primary efficacy endpoint will be the time to first adjudicated MACE, with MACE defined as a non-fatal myocardial infarction, non-fatal stroke, or a

cardiovascular death. Reported events will be adjudicated by a blinded adjudication committee. The study will be considered complete once 237 men have had an adjudicated MACE.

- The REPLACE-CV study design was agreed upon with the FDA. The study could further differentiate ORGOVYX by potentially adding additional data to the prescribing information concerning MACE events versus leuprolide, if approved by the FDA.

Ex-U.S. Commercial

- In October 2022, our commercialization partner, Accord, launched ORGOVYX for the treatment of advanced hormone-sensitive prostate cancer in Europe. Pursuant to the Accord License Agreement, the first commercial sale of ORGOVYX in Europe triggered a $5.0 million milestone payment due from Accord.

Expected Upcoming Milestones

The following is a summary of certain of our expected upcoming milestones.

- We expect to submit a New Drug Submission to Health Canada seeking marketing approval for ORGOVYX for advanced prostate cancer by the end of calendar year 2022.
- We expect the FDA decision for the MYFEMBREE sNDA proposing updates to MYFEMBREE's USPI based on the safety and efficacy data from the Phase 3 LIBERTY RWS of MYFEMBREE in premenopausal women with heavy menstrual bleeding associated with uterine fibroids for up to two years by the January 29, 2023 PDUFA goal date.
- We expect to submit an sNDA to the FDA for the SPIRIT 2-year long-term extension study for MYFEMBREE in women for the management of pain associated with endometriosis in the first half of calendar year 2023.

Effects of the COVID-19 Pandemic on our Business

While the COVID-19 pandemic has created certain operational complexities, we have thus far been successful at devising solutions to mitigate its impact on our business operations. To date, we do not believe that the COVID-19 pandemic has disproportionately impacted us relative to other commercial stage oncology and women's health biopharmaceutical companies with which we compete. We will continue to monitor developments with respect to COVID-19 that could pose additional risks for us, including the spread of the Omicron variant and its subvariants in the U.S. and other countries, and the potential emergence of new SARS-CoV-2 variants that may prove especially contagious or virulent.

Despite our COVID-19 pandemic mitigation efforts, we may experience delays or an inability to execute our business plans, reduced revenues, or other adverse impacts to our business. Refer to the risk factor titled "Business interruptions resulting from effects of pandemics or epidemics, such as the COVID-19 pandemic, may materially and adversely affect our business and financial condition," as well as other risk factors included in the section titled "Risk Factors" set forth in Part II. Item 1A of this Quarterly Report.

Effects of the Russian Federation-Ukraine Conflict on our Business

The uncertain nature, magnitude, and duration of hostilities stemming from the conflict in Ukraine, including the potential effects of sanctions, retaliatory cyber-attacks on the world economy and markets, and potential shipping delays, have contributed to increased market volatility and uncertainty, which could have an adverse impact on macroeconomic factors that affect our business. As a result of the conflict in Ukraine, the U.S., U.K., and the EU governments, among others, have developed and coordinated economic and financial sanctions. As the conflict in Ukraine continues, there is no certainty regarding whether such governments or other governments will impose additional sanctions, or other economic or military measures against the Russian Federation.

The impact of the conflict in Ukraine, including economic sanctions or additional war or military conflict, as well as potential responses to them by the Russian Federation, is currently unknown and they could adversely affect our business, supply chain, clinical studies, suppliers or customers. In addition, the continuation of the conflict in Ukraine by the Russian Federation could lead to other disruptions, instability and volatility in global markets and industries that could negatively impact our operations. It is not possible to predict the broader consequences of this conflict, which could include further sanctions, embargoes, regional instability, geopolitical shifts and adverse effects on macroeconomic conditions, the availability and cost of raw materials and fuel, supplies, freight and labor, inflation, and fluctuations in currency exchange rates, all of which could impact our business, financial condition and results of operations.

Refer to the risk factor titled "The conflict between the Russian Federation and Ukraine and other government policies and actions could negatively affect our clinical trial sites in Ukraine. We and/or our collaboration or commercialization partners may not be able to launch our commercial products in the Russian Federation, Ukraine or other regions which may negatively affect our financial results. The uncertain nature, magnitude, and duration of hostilities stemming from such conflict may result in changes in the world's macroeconomic conditions which negatively affect our business operations."

Certain Components of our Results of Operations

Revenues

We record product revenue from sales of ORGOVYX and MYFEMBREE in the U.S. net of estimated discounts, chargebacks, rebates, product returns, and other gross-to-net revenue deductions. For the three and six months ended September 30, 2022, the gross-to-net deduction for ORGOVYX was approximately 43.2%, and 43.8%, respectively, and we expect it to be in the low-to-mid 40%'s for the remainder of fiscal year 2022. Product revenue, net also includes revenues related to product supply to Richter as well as royalties on net sales of RYEQO in Richter's Territory.

Our Pfizer collaboration revenue consists of the partial recognition of the upfront payment and the regulatory milestone payments from Pfizer that were triggered upon the FDA approval of MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids and for the management of moderate to severe pain associated with endometriosis.

Our Accord license revenue consists of the recognition of the upfront payment we received from Accord in May 2022 pursuant to the Accord License Agreement. We recognized the upfront payment as revenue upon delivery of the license to Accord during the three months ended June 30, 2022.

Our Richter license and milestone revenue consists of the recognition of the upfront payment we received from Richter, as well as regulatory milestone payments from Richter that were triggered upon approvals of RYEQO.

See Note 8 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for additional information regarding the Pfizer Collaboration and License Agreement, the Richter Development and Commercialization Agreement, and the Accord License Agreement.

Cost of Product Revenue

Our cost of product revenue is composed of the cost of goods sold and royalty expense payable to Takeda. Our cost of goods sold consists of raw materials, third-party manufacturing costs to manufacture the raw materials into finished product, freight, and indirect overhead costs associated with sales of ORGOVYX and MYFEMBREE in the U.S. and sales of product supply to Richter. The cost of inventories written down as a result of excess, obsolescence, or other reasons is also charged to cost of goods sold. Our royalty expense consists of royalties on net sales of relugolix payable to Takeda pursuant to the terms of the Takeda License Agreement (see Note 9(D) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report).

Collaboration Expense to Pfizer

Our collaboration expense to Pfizer consists of Pfizer's 50% share of net profits from sales of ORGOVYX and MYFEMBREE arising in the U.S. (see Note 8(A) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report).

Selling, General and Administrative Expenses

SG&A expenses consist primarily of personnel costs, including salaries, sales incentive compensation, bonuses, fringe benefits, and share-based compensation for our executive, finance, human resources, legal, information technology, commercial operations, marketing, market access, sales, and other administrative functions. Our SG&A expenses also include marketing programs, patient assistance and support programs for qualified uninsured and underinsured patients, promotion and advertising, conferences, congresses, travel expenses, professional fees for legal, business development, accounting, auditing and tax services, and costs related to rent and facilities, insurance, information technology, commercial operations, and general overhead. Our SG&A expenses also include related party expenses pursuant to our agreements with Sunovion and Sumitovant (see Note 5 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report).

Without consideration of additional costs that may arise due to the Merger Agreement (see Note 5(A) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report), SG&A expenses in the remaining quarters of fiscal year 2022 are expected to be similar to the second quarter of fiscal year 2022 driven largely by marketing and promotional expenses to support the ongoing commercialization of ORGOVYX and MYFEMBREE in the U.S., including

annualization of the MYFEMBREE marketing and promotional spend and targeted patient activation primarily for MYFEMBREE. The timing and magnitude of our SG&A expenses are primarily dependent on our commercial success and sales growth of ORGOVYX and MYFEMBREE, as well as the timing of any new indications or product launches and other potential business and operational activities. SG&A expenses are presented net of cost sharing of certain expenses arising in respect of the Co-Promotion Territory with Pfizer (see Note 8(A) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report). We are unable to estimate the amount of additional expenses that may arise due to the Merger Agreement.

Research and Development Expenses

R&D activities have been, and will continue to be, central to our business model. Our R&D expenses to date have been primarily attributable to the clinical development of our product candidates including the conduct of multiple Phase 3 and earlier clinical studies, the expansion of our team, and the initiation of activities in preparation for our anticipated commercial launches such as the establishment of our medical affairs function, as well as regulatory and certain manufacturing activities. Our R&D expenses include program-specific costs, as well as costs that are not allocated to a specific program.

Our program-specific costs primarily include third-party costs, which include expenses incurred under agreements with CROs and 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 and clinical studies, as well as costs related to pre-commercial manufacturing activities and regulatory submissions, and other third-party expenses directly attributable to the development of our product candidates.

Our unallocated R&D costs primarily include employee-related expenses, such as salaries, share-based compensation, fringe benefits and travel for employees engaged in R&D activities including clinical operations, biostatistics, regulatory, and medical affairs, and the cost of contractors and consultants who assist with R&D activities not specific to a program, and costs associated with nonclinical studies.

The duration, costs and timing of clinical studies and development of our product candidates will depend on a variety of factors that include, but are not limited to: the number of studies required for approval; the per patient study costs; the number of patients who participate in the studies; the number of sites included in the studies; the countries in which the studies 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 drug doses that patients receive; the drop-out or discontinuation rates of patients; the potential additional safety monitoring or other studies requested by regulatory agencies; the duration of patient follow-up; the timing and receipt of regulatory approvals; the costs of clinical study materials; and the efficacy and safety profile of the product candidate.

In addition, the probability of commercial success for ORGOVYX, MYFEMBREE, or for any of our current or potential future product candidates, if approved, will depend on numerous factors, including competition, manufacturing capability and commercial viability. Our R&D activities may be subject to change from time to time as we evaluate our priorities and available resources.

Without consideration of additional costs that may arise due to the Merger Agreement (see Note 5(A) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report), R&D expenses in the remaining quarters of fiscal year 2022 are expected to be higher than the second quarter of fiscal year 2022, driven largely by spending on relugolix lifecycle opportunities, such as the SERENE study and the REPLACE-CV study, as well as on post-marketing requirements as agreed upon with the FDA. R&D expenses are presented net of cost sharing of certain expenses arising in respect of the Co-Promotion Territory with Pfizer (see Note 8(A) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report). We are unable to estimate the amount of additional expenses that may arise due to the Merger Agreement.

Interest Expense

Our interest expense consists of related party interest expense pursuant to the Sumitomo Pharma Loan Agreement, which bears interest at a variable rate per annum equal to 3-month London Interbank Offered Rate ("LIBOR") plus a margin of 3% payable on the last day of each calendar quarter (see Note 5(C)to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report), and the accretion of the financing component of the cost share advance from Pfizer (see Note 8(A) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report). Fluctuations in 3-month LIBOR could negatively impact our financial results.

Interest Income

Our interest income consists primarily of interest earned and the accretion of discounts to maturity for cash equivalents and marketable securities.

Income Tax Expense (Benefit)

Our income tax expense (benefit) currently is primarily attributable to U.S. federal, state and local taxes. For the three and six months ended September 30, 2022, our income tax expense is significantly affected by the changed requirement under Internal Revenue Code Section 174 to capitalize and subsequently amortize over five years R&D expenditures, pursuant to changes made to Internal Revenue Code Section 174 effective for years beginning after December 31, 2021, under the Tax Cuts and Jobs Act of 2017 ("TCJA"). Previously, Section 174 allowed for immediate expensing for accounting periods beginning before December 31, 2021. Although it is understood that Congress has been considering legislation that would extend the TCJA relief by one or more years, the possibility that this will happen is uncertain and we are required to calculate our income tax liabilities based on the provisions of current law. Without consideration of additional costs that may arise due to the Merger Agreement (see Note 5(A) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report), we currently estimate our total tax expense for fiscal year 2022 to be approximately $28.0 million to $32.0 million. This estimate is subject to assumptions in relation to matters that are variable and difficult to predict, such as assumptions related to our common share price at the time equity awards vest or are exercised, as well as option exercise behavior of participants in our equity plans. Actual results could differ from our estimates and assumptions. We are unable to estimate the amount of additional expenses that may arise due to the Merger Agreement.

Results of Operations

The following table summarizes our results of operations for the three and six months ended September 30, 2022 and 2021 (in thousands):

	Three Months Ended September 30,		Six Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
Product revenue, net	$ 49,947	$ 21,063	$ 91,298	$ 32,617
Pfizer collaboration revenue	54,577	25,172	79,718	54,681
Accord license revenue	—	—	50,000	—
Richter license and milestone revenue	300	31,667	300	31,667
Total revenues	104,824	77,902	221,316	118,965
Operating costs and expenses:				
Cost of product revenue	4,942	2,622	9,857	3,654
Collaboration expense to Pfizer	22,418	8,565	40,434	13,826
Selling, general and administrative	84,259	58,781	163,291	119,993
Research and development	26,916	26,280	50,806	57,160
Total operating costs and expenses	138,535	96,248	264,388	194,633
Loss from operations	(33,711)	(18,346)	(43,072)	(75,668)
Interest expense	4,813	3,494	9,013	6,999
Interest income	(1,018)	(100)	(1,504)	(178)
Loss before income taxes	(37,506)	(21,740)	(50,581)	(82,489)
Income tax expense (benefit)	8,113	(149)	16,277	762
Net loss	$ (45,619)	$ (21,591)	$ (66,858)	$ (83,251)

Revenues

The following table provides information about our revenues for the three and six months ended September 30, 2022 and 2021 (in thousands):

	Three Months Ended September 30,		Six Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
Product revenue, net:				
ORGOVYX	$ 43,319	$ 18,663	$ 79,353	$ 29,142
MYFEMBREE	6,403	629	10,402	1,704
Richter product supply and royalties	225	1,771	1,543	1,771
Total product revenue, net	49,947	21,063	91,298	32,617
Pfizer collaboration revenue:				
Amortization of upfront payment	20,974	20,974	41,948	41,948
Amortization of regulatory milestones	33,603	4,198	37,770	12,733
Total Pfizer collaboration revenue	54,577	25,172	79,718	54,681
Accord license revenue	—	—	50,000	—
Richter license and milestone revenue	300	31,667	300	31,667
Total revenues	$ 104,824	$ 77,902	$ 221,316	$ 118,965

Product Revenue, net

We generate product revenue from sales of ORGOVYX and MYFEMBREE in the U.S. We record product revenue net of estimated discounts, chargebacks, rebates, product returns, and other gross-to-net revenue deductions.

For the six months ended September 30, 2022, product revenue, net, also includes revenues related to product supply to Richter of $1.1 million, and for the three and six months ended September 30, 2022, product revenue, net, also includes royalties on net sales of RYEQO in Richter's Territory of $0.2 million and $0.4 million, respectively. There was no revenue related to product supply to Richter for the three months ended September 30, 2022. For the three and six months ended September 30, 2021, product revenue, net, also includes revenues related to product supply to Richter of $1.7 million, as well as royalties on net sales of RYEQO in Richter's Territory of less than $0.1 million.

Pfizer Collaboration Revenue

Pfizer collaboration revenue for the three and six months ended September 30, 2022 and 2021 consists of the partial recognition of the upfront payment we received from Pfizer in December 2020 and of the $100.0 million regulatory milestone payment we received from Pfizer that was triggered upon the FDA approval of MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids on May 26, 2021. Pfizer collaboration revenue for the three and six months ended September 30, 2022 also includes the partial recognition of the $100.0 million regulatory milestone payment we received from Pfizer that was triggered upon the FDA approval of MYFEMBREE for the management of moderate to severe pain associated with endometriosis on August 5, 2022.

Accord License Revenue

We recognized $50.0 million of Accord license revenue for the six months ended September 30, 2022, which consists of an upfront payment we received from Accord in May 2022 pursuant to the Accord License Agreement. There was no Accord license revenue for the three months ended September 30, 2022, or for the three and six months ended September 30, 2021.

Richter License and Milestone Revenue

We recognized $31.7 million of Richter license and milestone revenue for the three and six months ended September 30, 2021, which consists of a $15.0 million regulatory milestone payment that was triggered upon the EC approval of RYEQO for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age and $16.7 million of previously deferred revenue that was recognized upon the completion of our delivery of the remaining substantive relugolix combination tablet data packages to Richter. Richter license and milestone revenue for the three and six months ended September 30, 2022 consists of a $0.3 million regulatory milestone payment that was triggered upon the approval of RYEQO for the uterine fibroids indication in Australia.

Cost of Product Revenue

For the three and six months ended September 30, 2022, our cost of product revenue was $4.9 million and $9.9 million, respectively, which includes the cost of goods sold of $1.2 million and $3.0 million, respectively, and royalty expense payable to Takeda of $3.8 million and $6.9 million, respectively.

For the three and six months ended September 30, 2021, our cost of product revenue was $2.6 million and $3.7 million, respectively, which includes the cost of goods sold of $1.1 million and $1.3 million, respectively, and royalty expense payable to Takeda of $1.5 million and $2.4 million, respectively.

The $2.3 million and $6.2 million increase in our cost of product revenue for the three and six months ended September 30, 2022, respectively, compared to the year ago periods, was due to increases in cost of goods sold and royalty expense payable to Takeda primarily as a result of higher sales of ORGOVYX and MYFEMBREE in the U.S. during the three and six months ended September 30, 2022.

Collaboration Expense to Pfizer

For the three and six months ended September 30, 2022, our collaboration expense to Pfizer was $22.4 million and $40.4 million, respectively. For the three and six months ended September 30, 2021, our collaboration expense to Pfizer was $8.6 million and $13.8 million, respectively.

Collaboration expense to Pfizer increased $13.9 million and $26.6 million for the three and six months ended September 30, 2022, compared to the year ago periods, primarily due to an increase in net profits generated from sales of ORGOVYX and MYFEMBREE in the U.S.

Selling, General and Administrative Expenses

SG&A expenses increased by $25.5 million, to $84.3 million, in the three months ended September 30, 2022 compared to $58.8 million in the year ago period.

The most significant components of the $25.5 million net increase in SG&A expenses include the following:

- $20.2 million increase in commercialization expenses, net of cost sharing of certain expenses arising in respect of the Co-Promotion Territory with Pfizer, to support our U.S. commercialization activities for ORGOVYX and MYFEMBREE;
- $4.2 million increase in personnel expenses, including personnel expenses related to our U.S. oncology and women's health sales forces;
- $3.8 million decrease in general overhead, administrative, information technology, and other expenses; and
- $3.5 million increase in legal and professional fees.

SG&A expenses increased by $43.3 million, to $163.3 million, in the six months ended September 30, 2022 compared to $120.0 million in the year ago period.

The most significant components of the $43.3 million net increase in SG&A expenses include the following:

- $28.2 million increase in commercialization expenses, net of cost sharing of certain expenses arising in respect of the Co-Promotion Territory with Pfizer, to support our U.S. commercialization activities for ORGOVYX and MYFEMBREE;
- $10.6 million increase in personnel expenses, including personnel expenses related to our U.S. oncology and women's health sales forces; and
- $4.1 million increase in legal and professional fees.

Research and Development Expenses

For the three months ended September 30, 2022 and 2021, our R&D expenses consisted of the following (in thousands):

	Three Months Ended September 30,		
	2022	2021	Change
Program-specific costs:			
Relugolix	$ 2,715	$ 5,524	$ (2,809)
MVT-602	14	50	(36)
Unallocated costs:			
Personnel expense	16,692	13,733	2,959
Share-based compensation	3,832	5,060	(1,228)
Other expense	3,663	1,913	1,750
Total R&D expenses	$ 26,916	$ 26,280	$ 636

For the six months ended September 30, 2022 and 2021, our R&D expenses consisted of the following (in thousands):

	Six Months Ended September 30,		
	2022	2021	Change
Program-specific costs:			
Relugolix	$ 3,558	$ 12,715	$ (9,157)
MVT-602	39	113	(74)
Unallocated costs:			
Personnel expense	33,342	28,497	4,845
Share-based compensation	7,498	9,167	(1,669)
Other expense	6,369	6,668	(299)
Total R&D expenses	$ 50,806	$ 57,160	$ (6,354)

R&D expenses increased by $0.6 million, to $26.9 million, in the three months ended September 30, 2022 compared to $26.3 million in the three months ended September 30, 2021. The increase in R&D expenses in the three months ended September 30, 2022 was primarily driven by higher personnel expenses and other expenses, partially offset by a reduction in relugolix clinical study costs due to the completion and wind down of our Phase 3 clinical trials. R&D expenses decreased by $6.4 million, to $50.8 million, in the six months ended September 30, 2022 compared to $57.2 million in the six months ended September 30, 2021. The decrease in R&D expenses in the six months ended September 30, 2022 was primarily driven by a reduction in relugolix clinical study costs due to the completion and wind down of our Phase 3 clinical trials, partially offset by lower personnel expenses.

Interest Expense

Interest expense was $4.8 million and $9.0 million for the three and six months ended September 30, 2022, respectively, compared to $3.5 million and $7.0 million for the three and six months ended September 30, 2021, respectively.

Interest expense associated with the Sumitomo Pharma Loan Agreement increased $1.9 million to $4.8 million in the three months ended September 30, 2022 compared to $2.9 million in the year ago period, and increased $2.7 million to $8.4 million in the six months ended September 30, 2022 compared to $5.8 million in the year ago period, as a result of an increase in 3-month LIBOR as compared to the year ago periods.

Accretion of the financing component of the cost share advance from Pfizer was $0.6 million for six months ended September 30, 2022, and $0.6 million and $1.2 million for the three and six months ended September 30, 2021, respectively. There was no accretion for the three months ended September 30, 2022.

Interest Income

Interest income was $1.0 million and $1.5 million for the three and six months ended September 30, 2022, respectively. Interest income was $0.1 million and $0.2 million for the three and six months ended September 30, 2021, respectively. Interest income was derived from our investments in marketable securities and cash equivalents. The increase in interest income in the three and six months ended September 30, 2022 compared to the year ago periods was primarily due to higher interest rates.

Income Tax Expense (Benefit)

Our income tax expense was $8.1 million and $16.3 million for the three and six months ended September 30, 2022, respectively. Our income tax (benefit) expense was $(0.1) million and $0.8 million for the three and six months ended September 30, 2021, respectively. Our effective tax rate for the three and six months ended September 30, 2022 was (21.63)% and (32.18)%, respectively, and for the three and six months ended September 30, 2021 was 0.69% and (0.92)%, respectively. Our tax expense currently relates principally to profits earned in the U.S. Key determinative factors of our effective tax rate include the allocation of our earnings by jurisdiction and a valuation allowance that currently eliminates all of our net deferred tax assets.

The increase in our effective tax rate for the three and six months ended September 30, 2022, compared to the corresponding prior year periods, was driven principally by the changed requirement under Internal Revenue Code Section 174, effective for years beginning after December 31, 2021, to capitalize and subsequently amortize R&D expenditures, pursuant to changes enacted in the Tax Cuts and Jobs Act of 2017. For periods beginning prior to December 31, 2021, R&D expenses were allowed to be expensed as incurred. See Note 6 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

Liquidity and Capital Resources

We have incurred losses since our inception and have an accumulated deficit of $1.32 billion as of September 30, 2022, compared to $1.25 billion as of March 31, 2022.

Sources of Liquidity

Since our inception, we have funded our operations primarily from the issuance and sale of our common shares, from debt financing arrangements, and more recently from upfront and milestone payments we have received from our collaboration and commercialization partners, as well as net revenues generated from sales of ORGOVYX and MYFEMBREE in the U.S.

As of September 30, 2022, we had cash, cash equivalents, marketable securities, and amounts available to us under the Sumitomo Pharma Loan Agreement of $412.6 million, consisting of $371.3 million of cash, cash equivalents, and marketable securities and $41.3 million of borrowing capacity available to us under the Sumitomo Pharma Loan Agreement. Cash, cash equivalents, marketable securities, and amounts available to us under the Sumitomo Pharma Loan Agreement as of March 31, 2022 was $475.5 million, consisting of $434.2 million of cash, cash equivalents, and marketable securities and $41.3 million of borrowing capacity available to us under the Sumitomo Pharma Loan Agreement. Additional funds under the Sumitomo Pharma Loan Agreement may be drawn down by us no more than once per calendar quarter, subject to certain terms and conditions, including consent of our board of directors.

As of September 30, 2022, we are eligible to earn additional payments from our collaboration and commercialization partners, including:

- up to $3.5 billion of tiered sales milestones from Pfizer upon reaching certain thresholds of annual net sales for oncology and the combined women's health indications in the Co-Promotion Territory. We and Pfizer equally share profits and certain expenses arising in respect of the Co-Promotion Territory;
- up to $122.2 million of milestone payments from Richter, including regulatory milestones of up to $14.7 million and tiered sales milestones of up to $107.5 million upon reaching certain thresholds of annual net sales in Richter's Territory, and tiered royalties on net sales in Richter's Territory; and
- up to $90.5 million of commercial launch, sales-based, and other milestones and tiered royalties from the high-teens to mid-twenties on net sales of ORGOVYX in Accord's territories.

Funding Requirements

We believe that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our anticipated operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of this

Quarterly Report. This estimate is based on our current assumptions, including assumptions related to our ability to manage our spend, that might prove to be wrong, and we could use our available capital resources sooner than we currently expect. In future periods, if our cash, cash equivalents, marketable securities, and amounts that we expect to generate from product sales and/or third-party collaboration payments, are not sufficient to enable us to fund our operations, we may need to raise additional funds in the form of equity, debt, or from other sources. In addition, we may choose to raise additional funds in the form of equity, debt, or from other sources due to market conditions or strategic considerations even if we believe we have sufficient funds for our current and future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our common shareholders' ownership interest may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect our common shareholders' rights. The Sumitomo Pharma Loan Agreement involves, 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, raising capital through equity offerings, making capital expenditures or declaring dividends.

Additionally, we are subject to a variety of specified liquidity and capitalization restrictions under the Merger Agreement. Unless we obtain Sumitovant's prior written consent (which consent may not be unreasonably withheld, delayed or conditioned) and except (i) as required or expressly contemplated by the Merger Agreement, (ii) as required by applicable laws or terms of contracts in effect as of October 23, 2022 or (iii) as set forth in the confidential disclosure schedule we delivered to Sumitovant, we may not, among other things and subject to certain exceptions and aggregate limitations, incur additional indebtedness, issue additional shares of our common shares, repurchase shares of our common stock, pay dividends, acquire or dispose of material assets or property, amend, modify or enter into material contracts or make certain additional capital expenditures. See Note 5(A) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report. We do not believe that these restrictions will prevent us from meeting our ongoing costs of operations, working capital needs, or capital expenditure requirements.

We expect our operating expenses, net of costs that are expected to be shared with Pfizer pursuant to the Pfizer Collaboration and License Agreement, to increase as we continue to commercialize ORGOVYX and MYFEMBREE in the U.S., prepare for additional potential regulatory approvals, initiate life cycle management activities as well as conduct post-marketing requirements as agreed upon with the FDA for our relugolix franchise, and potentially further develop our product candidates and expand our pipeline. However, while we expect our future capital requirements and operating expenses to continue to be significant, we expect our net cash burn to gradually decrease as our net product revenues increase. Our operating expenses and operating cash flows may fluctuate significantly from quarter-to-quarter and year-to-year and our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the price, level of demand and net product revenues generated from commercial sales of our drug products and from any product candidates that may receive marketing approval in the future;
- the achievement of regulatory milestones, commercial launch milestones, sales milestones, or other milestones, and/or royalties that we are eligible to earn pursuant to our collaboration or commercialization agreements;
- the timing, shared costs, and level of investment in our and our collaboration and commercialization partners' activities related to sales, marketing, market access, manufacturing, and distribution for our drug products and for any product candidates that may receive marketing approval in the future;
- the timing, shared costs, and level of investment in our and our collaboration partners' research and development activities involving ORGOVYX, MYFEMBREE, RYEQO, and any product candidates;
- costs, timing, and outcomes of regulatory submissions and regulatory reviews of our product candidates;
- costs to expand our chemistry, manufacturing, and control and other manufacturing related activities;
- costs to identify, acquire, develop, and commercialize additional product candidates;
- costs to integrate acquired technologies into a comprehensive regulatory and product development strategy;
- costs to maintain, expand, and protect our patent claims and other intellectual property rights;
- costs to hire additional commercial operations, sales and marketing, scientific, clinical, regulatory, quality, and other personnel to support our commercialization, sales and marketing, regulatory, and clinical development efforts;
- costs to implement or enhance operational, accounting, finance, quality, commercial, and management information systems;
- costs to service our debt obligations and associated interest payments;

- economic factors over which we have no control, including changes in inflation, interest rates, foreign currency rates, and the potential effect of such factors on revenues and expenses;
- costs to operate as a public company; and
- costs that may arise due to the Merger Agreement (see Note 5(A) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report).

Until such time, if ever, as we can generate positive cash flows as a result of increased sales of ORGOVYX, MYFEMBREE, or any product candidate, we expect to fund our operations through a combination of cash, cash equivalents, and marketable securities currently on hand and amounts available to us under the Sumitomo Pharma Loan Agreement, subject to the consent of our board of directors, as well as potential payments we are eligible to receive from Pfizer, Richter, and Accord pursuant to the terms of our agreements with them.

Cash Flows

The following table sets forth a summary of our cash flows for the six months ended September 30, 2022 and 2021 (in thousands):

	Six Months Ended September 30,	
	2022	2021
Net cash used in operating activities	$ (66,885)	$ (76,578)
Net cash used in investing activities	$ (2,233)	$ (87,774)
Net cash provided by financing activities	$ 5,142	$ 15,135

Operating Activities

Net cash used in operating activities was $66.9 million for the six months ended September 30, 2022 and consisted of our net loss of $66.9 million (see "Results of Operations" above) and changes in operating assets and liabilities of $23.6 million, (see below), offset by adjustments for non-cash operating items of $23.6 million. The non-cash operating items included share-based compensation of $21.4 million, amortization of operating lease right of use asset of $0.9 million, depreciation expense of $0.7 million, and accretion of the implied financing component of the cost share advance from Pfizer of $0.6 million.

The changes in operating assets and liabilities included the following:

- $34.4 million decrease in cost share advance from Pfizer due to the application of shared Allowable Expenses (see Note 8(A) and Note 8(D) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report);
- $20.3 million net increase in deferred revenue due to a $100.0 million regulatory milestone payment from Pfizer, partially offset by the recognition of $79.7 million of Pfizer collaboration revenue (see Note 8 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report);
- $15.5 million increase in accrued expenses and other current liabilities, primarily driven by increases in accrued discounts, rebates, and allowances, and royalties payable to Takeda due to an increase in product revenue, net, accrued professional fees, and accrued income tax payable (see Note 6 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report), partially offset by a decrease in accrued compensation-related expenses as a result of the payment of annual corporate bonuses in April 2022.
- $15.0 million increase in inventories, due to an increase in raw materials and work in process inventories, partially offset by a decrease in finished goods inventories;
- $10.5 million increase in accounts receivable, net as a result of an increase in net product revenues related to sales of ORGOVYX and MYFEMBREE in the U.S.;
- $6.4 million increase in amounts due to Pfizer as a result of an increase in profit share and reimbursement of Allowable Expenses incurred by Pfizer (see Note 8(A) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report);
- $4.1 million decrease in accounts payable, primarily driven by the timing of vendor invoice payments; and

- $1.8 million net change in other operating assets and liabilities.

Net cash used in operating activities was $76.6 million for the six months ended September 30, 2021, and consisted of our net loss of $83.3 million and changes in operating assets and liabilities of $19.2 million, partially offset by adjustments for non-cash operating items of $25.9 million. The non-cash operating items included share-based compensation of $23.1 million, accretion of the implied financing component of the cost share advance from Pfizer of $1.2 million, amortization of operating lease right of use asset of $0.8 million, and depreciation expense of $0.7 million.

The changes in operating assets and liabilities included the following:

- $38.3 million decrease in cost share advance from Pfizer due to the application of shared Allowable Expenses (see Note 8(A) and Note 8(D) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report);
- $28.7 million net increase in deferred revenue due to a $100.0 million regulatory milestone payment from Pfizer, partially offset by the recognition of $54.7 million of Pfizer collaboration revenue and $16.7 million of Richter license and milestone revenue (see Note 8 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report);
- $18.0 million increase in amounts due to Pfizer as a result of an increase in profit share and reimbursement of Allowable Expenses incurred by Pfizer (see Note 8(A) to our unaudited condensed consolidated financial statement included elsewhere in this Quarterly Report);
- $10.8 million increase in accounts receivable, net as a result of an increase in net product revenues, mainly driven by sales of ORGOVYX in the U.S.;
- $9.5 million decrease in accounts payable, primarily driven by the timing of vendor invoice payments;
- $3.5 million increase in inventories, driven by the capitalization of inventory manufactured or purchased after FDA approval of ORGOVYX (on December 18, 2020) and MYFEMBREE (on May 26, 2021); and
- $3.7 million net change in other operating assets and liabilities.

Investing Activities

For the six months ended September 30, 2022, we used $2.2 million of cash in investing activities, which was primarily for the purchase of marketable securities, net of maturities.

For the six months ended September 30, 2021, we used $87.8 million of cash in investing activities, which was primarily for the purchase of marketable securities, net of maturities.

Financing Activities

For the six months ended September 30, 2022, $5.1 million of cash was provided by financing activities, which was from proceeds from the exercise of stock options.

For the six months ended September 30, 2021, $15.1 million of cash was provided by financing activities, which was from proceeds from the exercise of stock options.

Contractual Obligations and Other Cash Needs

During the six months ended September 30, 2022, there have been no material changes outside the ordinary course of business to our contractual obligations and other cash needs as described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report for the year ended March 31, 2022.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of our unaudited condensed consolidated financial statements and related notes requires us to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and disclosures of contingent liabilities. We have based our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Management periodically reviews our estimates and makes adjustments when facts and circumstances dictate. To the extent there are material differences between these estimates and actual results, our financial

condition or results of operations will be affected. Changes in estimates and assumptions are reflected in reported results in the period in which they become known.

An accounting policy is considered to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and if different estimates that reasonably could have been used, or changes in the accounting estimates that are reasonably likely to occur periodically, could materially impact the consolidated financial statements.

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 for the fiscal year ended March 31, 2022, filed with the SEC on May 11, 2022. We believe there have been no material changes to our critical accounting policies and use of estimates as disclosed in our Annual Report.

Recent Accounting Pronouncements

For information regarding the impact of recently adopted accounting pronouncements and the expected impact of recently issued accounting pronouncements not yet adopted on our consolidated financial statements, see Note 1 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our activities can expose us to market risks which include interest rate risk, inflation risk, and credit risk. Risk management is carried out by our management under policies approved by our Board of Directors, with oversight provided by the Audit Committee of our Board of Directors. Our overall risk management program seeks to minimize adverse effects on our financial performance.

Interest Rate Risk

We are exposed to interest rate risk with respect to our variable rate debt. As of September 30, 2022, we had an outstanding loan balance of $358.7 million under the Sumitomo Pharma Loan Agreement that bears interest at a variable rate per annum equal to 3-month LIBOR plus a margin of 3%. We currently do not engage in any hedging activities against changes in interest rates. A hypothetical 100 basis point increase in 3-month LIBOR would result in a $0.9 million quarterly increase in interest expense, based on the outstanding balance under the Sumitomo Pharma Loan Agreement as of September 30, 2022.

The U.K Financial Conduct Authority (the authority that regulates LIBOR) has announced that 3-month LIBOR will cease publication after June 30, 2023. When the publication of 3-month LIBOR is discontinued, we will need to agree with Sumitomo Pharma on a new method of calculating the interest rate under the Sumitomo Pharma Loan Agreement. Changes in the method of calculating LIBOR, or the replacement of LIBOR with an alternative rate or benchmark, may adversely affect interest rates and result in higher borrowing costs. This could adversely affect our results of operations, cash flows and liquidity. We cannot predict the effect of the 3-month LIBOR replacement benchmark rate at this time.

Inflation Risk

In recent months, inflation has continued to increase significantly in the U.S. and overseas resulting in rising transportation, wages, and other costs. Inflation may generally affect us by increasing our cost of labor, commercial support, manufacturing and clinical trial expenditures. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, if our costs become subject to significant inflationary pressures, we may not be able to fully offset such higher costs with increased revenues. Our inability or failure to do so could harm our business, financial condition, and results of operations.

Credit Risk

Financial instruments that potentially subject us to concentrations of credit risk include cash, cash equivalents, and marketable securities. We are exposed to credit risk in the event of default by the financial institutions holding our cash and the issuers of our cash equivalents and marketable securities. We maintain our cash deposits and cash equivalents in highly-rated, federally-insured financial institutions in excess of federally insured limits. We have established guidelines relative to diversification and maturities of investments to maintain safety and liquidity. We have not historically experienced any significant credit losses related to these financial instruments and do not believe that we are exposed to any significant credit risk related to these instruments.

We are also subject to credit risk from accounts receivable from product sales to customers, amount due from our related party, and amounts due from our collaboration and commercialization partners. We monitor the financial performance and creditworthiness of these parties so we can properly assess and respond to changes in their credit profile and our exposure. We record a reserve against uncollectible amounts as necessary. No significant reserves were recorded as of September 30, 2022.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act, and the rules and regulations thereunder, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information 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. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) promulgated under the Securities Exchange Act of 1934 as amended) as of the end of the period covered by this Quarterly Report, have concluded that, based on such evaluation, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended September 30, 2022 that have materially affected, or are 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 ("Quarterly Report"), including the section of this Quarterly 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 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.

Risks Related to the Proposed Acquisition of Myovant by Sumitovant

The conditions to the proposed Merger as set forth in the Merger Agreement may not be satisfied or waived in a timely manner or at all, or the Merger Agreement may be terminated in accordance with its terms, which could negatively impact our business, financial condition, results of operations, and the price of our common shares.

On October 23, 2022, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with Sumitovant Biopharma Ltd. ("Sumitovant"), Zeus Sciences Ltd. ("Merger Sub"), and Sumitomo Pharma Co. Ltd. ("Sumitomo Pharma"). Pursuant to the Merger Agreement, and subject to the terms and conditions set forth therein, Merger Sub would be merged with and into Myovant (the "Merger"), with Myovant continuing as the surviving company in the Merger. Completion of the Merger is subject to the satisfaction certain conditions, including: (i) the adoption of the Merger Agreement at a meeting of our shareholders to consider such matter by the requisite vote of our shareholders, including the approval by holders of a majority of our outstanding common shares entitled to vote and voting at such meeting (the "Company Shareholder Approval") and by the holders of a majority of our outstanding common shares not held by Sumitovant or its affiliates (the "Minority Shareholder Approval"), (ii) the expiration of applicable waiting period of the Merger under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, (iii) the absence of any law, injunction, judgment or other legal restraint that prohibits the consummation of the Merger, (iv) the accuracy of each party's representations and warranties (subject to certain materiality and Company Material Adverse Effect (as defined in the Merger Agreement) qualifications), (v) each party's performance in all material respects of its obligations contained in the Merger Agreement and (vi) the absence of a Company Material Adverse Effect following the date of the Merger Agreement that is continuing.

If the Merger is not consummated on or before May 31, 2023, because any of the conditions set forth above have not been satisfied or waived or due any other impediment, then either we or Sumitovant will be able to terminate the Merger Agreement (to the extent the terminating party's breach of any provision of the Merger Agreement did not directly or indirectly cause the failure to consummate the Merger). Similarly, if we do not obtain the Minority Shareholder Approval at a special meeting of our shareholders at which a vote on the Merger was taken, then either we or Sumitovant will be able to terminate the Merger Agreement. In addition, both we and Sumitovant have the right to terminate the Merger Agreement if because of any breach of the Merger Agreement by the other party, the closing conditions regarding the accuracy of such party's representations and warranties or the performance of such party's obligations could not be satisfied as of the anticipated closing date, subject to a specified cure period. These terms and conditions, and other circumstances under which the Merger Agreement may be terminated in accordance with its terms, are described in more detail in the Merger Agreement, which we filed as an exhibit to the Current Report on Form 8-K with the SEC on October 24, 2022.

We intend to pursue the satisfaction or waiver, as applicable, of each condition to the completion of the Merger, including the receipt of the Company Shareholder Approval and the Minority Shareholder Approval. However, no assurance can be given that the required approvals will be obtained and, even if all such approvals are obtained, no assurance can be given as to the terms, conditions and timing of the approvals or that they will satisfy the terms of the Merger Agreement.

If the Merger is not completed in a timely manner or at all, the share price of our common shares may change to the extent that the current market price of our common shares reflects an assumption that the Merger will be completed. The failure of the parties to consummate the Merger could also result in negative publicity for us or negative impressions of us in the investment community or business community generally. In addition, certain costs related to the Merger, including the fees and/or expenses of our legal and financial advisors, may be required to be paid even if the Merger is not completed.

The announcement of the proposed Merger could negatively impact our business, financial condition, or results of operations.

Our announcement of having entered into the Merger Agreement could cause a material disruption to our business and there can be no assurance that the conditions to the completion of the Merger will be satisfied. We are subject to several risks as a result of the announcement of the Merger Agreement, including, but not limited to, the following:

- pursuant to the Merger Agreement, we are subject to certain restrictions on the conduct of our business prior to the completion of the Merger, which restrictions could adversely affect our ability to realize certain of our business strategies or take advantage of certain business opportunities;
- uncertainty as to whether the transactions will be completed may affect our ability to recruit prospective employees or to retain and motivate existing employees, and we may be unable to retain certain key employees who may seek and obtain different employment in anticipation of the completion of the Merger; and
- uncertainty as to our future could adversely affect our business and our relationship with collaborators, vendors, suppliers, regulators and other business partners, and third parties may determine to delay or defer purchase decisions

or contractual arrangements or terminate and/or attempt to renegotiate their relationships with us as a result of the Merger, whether pursuant to the terms of their existing agreements with us or otherwise.

In addition to these risks, the announcement of our entry into the Merger Agreement could attract lawsuits from litigious parties that frequently target mergers of publicly-traded companies. There may be shareholder class action complaints and other complaints filed against us, our board of directors, Sumitovant, Sumitovant's board of directors, and others in connection with the transactions contemplated by the Merger Agreement. The outcome of litigation is uncertain, and we may not be successful in defending against any such future claims. Lawsuits that may be filed against us, our board of directors, Sumitovant, or Sumitovant's board of directors could delay or prevent the consummation of the Merger, divert the time and attention of our management away from our business operations, and otherwise adversely affect us financially.

The Merger Agreement contains provisions that may discourage a third party from acquiring us prior to the completion of the Merger.

The Merger Agreement contains restrictions on our ability to seek or accept a third-party proposal to acquire us. These provisions include our agreement not to initiate, solicit, propose, knowingly encourage or knowingly facilitate any inquiry or the making of any proposal or offer that constitutes, or would reasonably be expected to lead to, or engage in, continue or otherwise participate in any discussion with or negotiations relating to, an alternative proposal to acquire us, as well as restrictions on our ability to respond to such proposals. Under certain circumstances set forth in the Merger Agreement, we are permitted to terminate the Merger Agreement to accept a superior proposal from a third party to acquire us; however, we would be required to pay Sumitovant a termination fee equal to $55.25 million in connection with such termination.

These provisions might discourage an otherwise-interested third party from considering or proposing an acquisition of our company, including proposals that may be deemed to offer a greater value to our shareholders than the $27.00 per share merger consideration. Furthermore, even if a third party elects to propose an acquisition, the requirement that we must pay a termination fee to accept any such proposal may cause that third party to offer a lower price to our shareholders than such third party might otherwise have offered.

In addition, Sumitovant communicated in its September 30, 2022 proposal letter that Sumitovant, in its capacity as a majority shareholder of the Company, is interested only in acquiring common shares of the Company not already owned by Sumitovant and that in such capacity, Sumitovant has no interest in selling any of our common shares it owns, nor would Sumitovant support any alternative sale, merger or similar transaction involving Myovant, which could also discourage the making of an acquisition proposal by a third party.

Attending to matters related to the proposed Merger could divert our management's focus from our ongoing business operations.

Our management will need to take a number of actions in connection with the proposed Merger, including, among other things, holding a special meeting of our shareholders for the purposes of considering and voting on the adoption and approval of the Merger Agreement, filing a proxy statement, in preliminary and definitive form, in connection with its solicitation of proxies from our shareholders for the special meeting, responding to questions from our shareholders, employees, suppliers, counterparties and other interested stakeholders regarding the proposed Merger, addressing litigation brought against us and our directors in connection with the proposed Merger, ensuring that we comply with the various restrictions on the conduct of our business set forth in the Merger Agreement, and working with Sumitovant to ensure the various conditions to closing the Merger are satisfied or waived.

These tasks could divert our management's focus away from our ongoing business operations or reduce the time or resources management could otherwise direct towards the commercialization of our approved products and the development, regulatory approval and commercialization of our product candidates. If management is not able to devote sufficient time to these significant commercialization and development efforts, our business and the results of our operations could be materially impaired.

We have incurred, and will continue to incur, direct and indirect costs as a result of the transactions relating to the Merger Agreement.

We have incurred, and will continue to incur, direct and indirect costs and expenses, including fees for professional services and other transaction costs, in connection with the Merger, for which we may receive little or no benefit if the Merger is not completed. Many of these fees and costs will be payable by us even if the Merger is not completed and may relate to activities that we would not have undertaken other than to complete the Merger. There are a number of factors beyond our control that could affect the total amount or the timing of these costs and expenses, any of which could materially and adversely affect our

business, prospects, financial condition and results of operations. Many of the expenses that will be incurred, by their nature, are difficult to estimate accurately.

Risks Related to Commercialization of Our Drug Products

Our success depends in part on the successful commercialization of our drug products. To the extent our drug products are not commercially successful, our business, financial condition and results of operations will be materially harmed.

We received approval for ORGOVYX® (relugolix 120 mg) in December 2020 from the United States ("U.S.") Food and Drug Administration ("FDA") for the treatment of adult patients with advanced prostate cancer, and received approval for MYFEMBREE® (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) in May 2021 for the management of heavy menstrual bleeding associated with uterine fibroids, and in August 2022 for the management of moderate to severe pain associated with endometriosis. We continue to invest a significant portion of our efforts and financial resources in the commercialization of these drug products in the U.S. The ability for us and/or our collaboration partner, Pfizer Inc. ("Pfizer"), to generate net product revenues from our drug products will depend upon the size of the markets, the number of competitors in such markets and numerous other factors, including:

- successfully establishing and maintaining effective sales, marketing, and distribution systems in jurisdictions in which our drug products are approved for sale;
- successfully establishing and maintaining commercial third-party manufacturers and having adequate commercial quantities of our drug products manufactured at acceptable cost and quality levels, including maintaining current good manufacturing practice ("cGMP") and quality systems regulation standards required by various regulatory agencies;
- broad acceptance of our drug products by physicians, patients and the healthcare community;
- the acceptance of pricing and placement of our drug products on payers' formularies and the associated tiers;
- effectively competing with other approved or used medicines and future compounds in development;
- continued demonstration of safety and efficacy of our drug products in comparison to competing products, including through differentiated approved product labeling; and
- obtaining, maintaining, enforcing, and defending intellectual property rights and claims.

Further, in July 2021, the European Commission ("EC"), and in August 2021, the United Kingdom ("U.K.") Medicines and Healthcare products Regulatory Agency ("MHRA"), approved RYEQO® (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) as the first and only long-term, once-daily oral treatment in the European Union ("EU") and the U.K., respectively, for moderate to severe symptoms of uterine fibroids in adult women of reproductive age, with no limitation for duration of use. Since RYEQO's approvals in the EU and U.K., our commercialization partner, Gedeon Richter Plc. ("Richter") has launched RYEQO in a number of countries in Europe. In April 2022, the EC approved ORGOVYX as the first and only oral androgen deprivation therapy for advanced hormone-sensitive prostate cancer in Europe. Our commercialization partner, Accord Healthcare, Ltd. ("Accord"), has launched ORGOVYX in Europe. The success of Richter in generating net revenue from RYEQO and the success of Accord in generating net revenue from ORGOVYX are also subject to many of the factors described above. If we and/or our partners do not achieve one or more of these factors in a timely manner or at all, we and/or our partners could experience significant delays or an inability to successfully commercialize any of our drug products, which would materially harm our business.

Our drug products may fail to achieve the degree of market acceptance by physicians, patients, third-party payers or others in the medical community necessary for commercial success, which would negatively impact our business.

Our drug products may fail to gain sufficient market acceptance by physicians, patients, third-party payers, or others in the medical community. If any of our drug products do not achieve an adequate level of acceptance, we may not generate significant net product revenue or become profitable. The degree of market acceptance of our drug products is dependent on a number of factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments, including the convenience and ease or duration of administration;
- the prevalence and severity of any side effects;

- the acceptability of the price of our drug products relative to other treatments;
- the content of the approved product labels and our ability to make compelling product claims;
- the effectiveness and adequacy of our and our collaboration or commercialization partners' sales and marketing efforts;
- the patients' out-of-pocket costs in relation to alternative treatments;
- the willingness of potential patient population to try new therapies and of healthcare providers to prescribe these therapies;
- the breadth and cost of distribution support;
- the effectiveness of our patient assistance and support programs;
- the availability of third-party payer coverage and adequate reimbursement;
- whether diagnosis and treatment rates change in advanced prostate cancer, heavy menstrual bleeding associated with uterine fibroids, moderate to severe pain associated with endometriosis, or other indications for which our drug products were approved; and
- any restrictions on the use of our drug products together with other medications.

The degree of market acceptance of ORGOVYX will also depend on the acceptance and degree of adoption by institutional treatment pathways and institutional, local, and national clinical guidelines such as the National Comprehensive Cancer Networks® Clinical Practice Guidelines in Oncology, the American Urological Association guidelines, American Society of Clinical Oncology Clinical Practice Guidelines, or other country-specific guidelines. This could also be the case for MYFEMBREE in terms of inclusion in practice guidelines such as those from the American College of Gynecology, American Society for Reproductive Medicine, American Association of Gynecologic Laparoscopists, or other country-specific guidelines. In the U.S., healthcare providers may refer to these guidelines with respect to patient treatment decisions. To the extent that our current or any future approved products are not included or positioned favorably in such treatment guidelines and pathways, the full utilization potential of our products may not be reached, which may harm our ability to successfully commercialize our current or any future approved products.

If we and our collaboration or commercialization partners are unable to effectively market and sell our drug products, the commercialization of our drug products will not be successful and our business will be harmed.

To market our drug products successfully, we must continue to develop and maintain our capabilities in sales, market access, marketing, distribution, and other commercial functions, either on our own or with our third-party partners. We have made arrangements regarding some of these functions in certain markets with third-party partners. For example, on August 1, 2020, we entered into a Market Access Services Agreement, as amended, with Sunovion Pharmaceuticals Inc. ("Sunovion") pursuant to which, among other things, Sunovion agreed to provide to us certain market access services with respect to the distribution and sale of ORGOVYX and MYFEMBREE in the U.S. On December 26, 2020, we entered into the Pfizer Collaboration and License Agreement, pursuant to which we and Pfizer agreed to collaborate to jointly develop and commercialize relugolix in oncology and women's health in the U.S. and Canada (the "Co-Promotion Territory" which, with respect to the periods subsequent to September 19, 2022, excludes Canada with respect to relugolix in oncology). On March 30, 2020, we entered into the Richter Development and Commercialization Agreement pursuant to which Richter agreed to commercialize relugolix combination tablet for uterine fibroids and endometriosis (if approved) in Europe, the Commonwealth of Independent States including Russia, Latin America, Australia, and New Zealand. On May 5, 2022, we entered into the Accord License Agreement pursuant to which Accord agreed to commercialize ORGOVYX in the European Economic Area, U.K., Switzerland, and Turkey, with the right of first negotiation if we decide to enter into licensing arrangements in countries in the Middle East, Africa and India. If Sunovion, Pfizer, Richter, Accord or any other collaboration or commercialization partners we may engage in the future, fail to perform or satisfy its obligations under their respective agreements with us or terminate their relationship with us, the sales, market access, marketing and/or distribution of our drug products would be delayed or may not occur. In addition to the third-party collaboration and commercialization arrangements described above, we continue to develop and maintain our own sales, market access, marketing, distribution and other commercial capabilities. There are significant expenses and risks involved with maintaining our own sales, market access, marketing, distribution, and other commercial capabilities, including: (i) our ability to recruit, train, and retain adequate numbers of qualified and effective sales, market access and marketing personnel; (ii) our ability to attain access to adequate numbers of healthcare professionals to prescribe any approved drugs; (iii) our ability to negotiate coverage and reimbursement for our products with payers at reasonable rebate or discount levels; (iv) our ability to negotiate competitive provider contracts to ensure access in in-office dispensing pharmacies;

and (v) unforeseen costs and expenses associated with establishing and maintaining our own sales, market access, marketing, distribution, and other commercial capabilities. The COVID-19 pandemic may negatively impact our and our collaboration and commercialization partners' ability to maintain commercial capabilities and may negatively impact our ability to rapidly and effectively educate potential prescribers and, if significant delays result, to commercialize our drug products.

We and our collaboration partner, Pfizer, launched ORGOVYX for the treatment of adult patients with advanced prostate cancer in the U.S. in January 2021 and MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids in the U.S. in June 2021. We and Pfizer launched MYFEMBREE in the U.S. for an additional indication, for the management of moderate to severe pain associated with endometriosis, in August 2022. Further, our commercialization partner, Richter, has launched RYEQO in Europe, and Accord has launched ORGOVYX in Europe. We and/or our collaboration and commercialization partners continue to expend significant time and resources to market, sell, seek reimbursement, and distribute these drug products to physicians and the medical community in a credible, persuasive, and compliant manner consistent with applicable laws. There is no guarantee that the strategies, tactics, marketing messages, or the distribution and reimbursement capabilities that we or our collaboration or commercialization partners have developed will be successful. Specifically, for distribution of these drug products, we are heavily dependent on third-party logistics, pharmacy and distribution partners. If we or our collaboration or commercialization partners are unable to perform effectively, our ability to realize sales targets and the return on our investment in developing these drug products will suffer.

Failure to successfully obtain coverage and reimbursement for ORGOVYX and MYFEMBREE in the United States, or the availability of coverage only at limited levels, would diminish our ability to generate net product revenue.

Our and Pfizer's ability to commercialize ORGOVYX and MYFEMBREE successfully in the U.S. will depend in part on the extent to which coverage and reimbursement for ORGOVYX and MYFEMBREE will be available from third-party payers, including government health administration authorities (such as the Department of Veterans Affairs, and the Department of Defense and state Medicaid programs), Medicare Part D plan sponsors, and private health insurers, such as pharmacy benefit managers, health plans, and self-insured organizations. In the U.S., no uniform policy for coverage for products exists among third-party payers. Third-party payers decide which drugs they will pay for, what steps prescribers must take to obtain authorization for patients to fill their prescriptions, and how much patients must pay out of their own pocket. Payer decisions regarding the extent of coverage to be provided for any of our product candidates that obtain marketing approval will be made on a plan-by-plan basis. Additionally, a third-party payer's decision to provide coverage for a drug does not imply that an affordable out-of-pocket cost for patients will be established. Each third-party payer determines whether or not it will provide coverage for a drug, what amount it will reimburse for the drug, on what tier of its formulary the drug will be placed, and whether to require step therapy or prior authorizations. The position of a drug on a formulary generally determines out-of-pocket costs that a patient will pay 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, providers prescribing such therapies and pharmacies that dispense drugs generally rely on third-party payers to reimburse all or part of the associated healthcare and drug costs. Coverage from both governmental healthcare programs, such as Medicare Part D and Medicaid, and coverage by private commercial payers are critical to ORGOVYX's and MYFEMBREE's commercial success. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Providers may also participate in shared savings programs with government or commercial payers that may also create barriers to use for innovative drugs. Further, coverage policies and third-party reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

Additionally, there have been a number of legislative and regulatory proposals to change the healthcare system that may impact drug pricing, drug price increase penalties, drug coverage, reimbursement for drugs, and patient out-of-pocket costs in the U.S. that could affect our ability to successfully commercialize ORGOVYX and MYFEMBREE. These legislative and regulatory changes may negatively impact the coverage, reimbursement, and patient out-of-pocket costs for ORGOVYX, MYFEMBREE and any future drugs, if approved.

We face substantial competition in the commercialization of our approved drug products and our operating results will suffer if we fail to compete effectively.

The commercialization of new pharmaceutical products is highly competitive, and we face substantial competition with respect to our approved drug products. For example, although ORGOVYX is the first and only oral GnRH receptor antagonist for adult patients with advanced prostate cancer approved by the FDA in the U.S., we may face competition from various drugs approved for the treatment of prostate cancer, such as Lupron Depot® (AbbVie Inc.), Eligard® (Tolmar Pharmaceuticals), Firmagon® (Ferring Pharmaceuticals), and Camcevi™ (Accord BioPharma (U.S.)). MYFEMBREE is the first and only once-daily oral GnRH treatment for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women approved by the FDA in the U.S. MYFEMBREE competes with ORIAHNN®, an oral GnRH receptor antagonist combination

therapy (one capsule (elagolix 300 mg, estradiol 1 mg, norethindrone acetate 0.5 mg) in the morning and one capsule (elagolix 300 mg) in the evening), which was approved by the FDA and launched by AbbVie in June 2020 for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. In addition, although ObsEva's NDA for linzagolix, an oral GnRH receptor antagonist, for the treatment of uterine fibroids for use with and without add-back therapy that ObsEva licensed from Kissei Pharmaceutical, was withdrawn in August 2022 after the FDA identified deficiencies in ObsEva's submission, linzagolix remains a potential competitor to MYFEMBREE because linzagolix received marketing authorization in the EU in June 2022 but the commercial availability of linzagolix in the U.S. is uncertain. MYFEMBREE is also approved by the FDA in the U.S. for the management of moderate to severe pain associated with endometriosis in premenopausal women, establishing it as the first and only once-daily oral GnRH treatment approved for both uterine fibroids and endometriosis. MYFEMBREE's most direct competitor for the treatment of pain associated with endometriosis is ORILISSA™ (elagolix), an oral GnRH receptor antagonist, which was approved as monotherapy (150 mg once a day or 200 mg twice a day) by the FDA and launched by AbbVie in August 2018 for the management of moderate-to-severe pain associated with endometriosis.

Many of our current and potential future competitors may have significantly more resources that they can deploy to commercialize drugs and may succeed in developing, acquiring or licensing, on an exclusive basis, drugs that are more effective or less costly than our drug products or any product candidate that we may obtain approval or develop. 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. The availability and pricing of our competitors' products could limit the demand, lead to competitors having preferential payer coverage and limit the price we are able to charge for our drug products or any product candidate that we may obtain approval for or develop. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a smaller number of our competitors.

The inability to compete with existing or subsequently introduced drugs would have an adverse impact on our business, financial condition, and prospects.

If manufacturers obtain approval for generic versions of ORGOVYX, MYFEMBREE, or of products with which they compete, our business may suffer.

Under the U.S. Food, Drug and Cosmetic Act ("FDCA"), the FDA can approve an Abbreviated New Drug Application ("ANDA"), for a generic version of a branded drug without the ANDA applicant undertaking the clinical testing necessary to obtain approval to market a new drug. Generally, in place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its product has the same active ingredient(s), strength, dosage form, route of administration and that it is bioequivalent to the branded product.

The FDCA requires that an applicant seeking approval of a generic form of a branded drug certify either that its generic product does not infringe any of the patents listed by the owner of the branded drug in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book, or that those patents are not enforceable. This process is known as a paragraph IV challenge. Upon notice of a paragraph IV challenge, a patent owner has 45 days to bring a patent infringement suit in federal district court against the company seeking ANDA approval of a product covered by one of the owner's patents. If this type of suit is commenced, the FDCA provides a 30-month stay on the FDA's approval of the competitor's application. If the litigation is resolved in favor of the ANDA applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA may thereafter approve the application based on the standards for approval of ANDAs. Once an ANDA is approved by the FDA, the generic manufacturer may market and sell the generic form of the branded drug in competition with the branded medicine.

The ANDA process can result in generic competition if the patents at issue are not upheld or if the generic competitor is found not to infringe the owner's patents. If this were to occur with respect to ORGOVYX, MYFEMBREE, or products with which they compete, our business would be materially harmed.

If patient safety issues were to arise for any of our drug products, our future sales of our drug products may be reduced, adversely affecting our results of operations.

The data supporting the marketing approvals in the U.S. for ORGOVYX and MYFEMBREE and forming the basis for our product labels for ORGOVYX and MYFEMBREE were obtained in controlled clinical studies of limited duration. As ORGOVYX and MYFEMBREE are used over longer periods of time by patients, including those taking other medicines, we may continue to identify new issues such as safety concerns, drug resistance or interactions of these drug products, which may require us to provide additional warnings or contraindications on our product labels or narrow the approved indications, each of which could reduce the market acceptance of our drug products.

Regulatory authorities have been moving towards more active and transparent pharmacovigilance and are making greater amounts of stand-alone safety information directly available to the public through websites and other means, e.g., periodic safety update report summaries, risk management plan summaries and various adverse event data. Safety information, without the appropriate context and expertise, may be misinterpreted and lead to misperception or legal action which may potentially negatively impact sales of our drug products. Further, if serious safety, drug resistance or interaction issues arise with any of our drug products, sales could be limited or halted by us or by regulatory authorities and our results of operations would be adversely affected. In addition, problems with other drugs marketed by third parties that utilize the same therapeutic target or that belong to the same therapeutic class as any of our drug products could adversely affect commercialization of our drug products.

If a safety issue emerges post-approval, we may become subject to costly product liability litigation by our customers, patients or payers. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by our insurance. If we cannot successfully defend ourselves against claims that our drug products caused injuries, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our drug products;
- the inability to commercialize our drug products;
- injury to our reputation and significant negative media attention;
- withdrawal of patients from clinical studies or cancellation of clinical studies of our product candidates;
- significant costs to defend the related litigation;
- substantial monetary awards to patients; and
- loss of net product revenue.

Our product liability insurance coverage may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to obtain insurance coverage at a reasonable cost or in amounts adequate to satisfy any liability or associated costs that may arise in the future. These events could harm our business and results of operations and cause our common share price to decline.

If we or our collaboration or commercialization partners are found to have improperly promoted unapproved uses of our drug products, we may be subject to restrictions on the sale or marketing of our drug products and significant fines, penalties, sanctions and product liability claims, and our image and reputation within the industry and marketplace could be harmed.

The FDA and other regulatory agencies, including regulatory authorities outside the U.S., strictly regulate the marketing and promotional claims that are made about drug products, such as ORGOVYX and MYFEMBREE. In particular, promotion for a product must be consistent with its labeling approved by the FDA or by regulatory agencies in other countries. For example, in the case of ORGOVYX and MYFEMBREE, physicians may prescribe ORGOVYX or MYFEMBREE for indications or uses that are inconsistent with the approved label while we and our collaboration partner, Pfizer, may not market or promote such off-label uses. If we or our collaboration or commercialization partners are found to have promoted such unapproved uses, we may, among other consequences, receive untitled or warning letters and become subject to significant liability, which would materially harm our business. Furthermore, the use of our products for indications other than those approved by the FDA or regulatory authorities outside the U.S. may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. Both the U.S. federal government and foreign regulatory authorities have levied significant civil and criminal fines against companies and individuals for alleged improper promotion and have entered into settlement agreements with pharmaceutical companies to limit inappropriate promotional activities. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our reputation could be damaged.

Physicians' prescribing our products for unapproved uses may also subject us to product liability claims, to the extent such uses lead to adverse events, side effects, or injuries. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. Any of these events could harm our business and results of operations and cause our common share price to decline.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the U.S., we could be subject to additional reimbursement requirements, fines, sanctions and exposure under other laws which could have a material adverse effect on our business, results of operations and financial condition.

We participate in the Medicaid Drug Rebate Program, as administered by the Centers for Medicare and Medicaid Services ("CMS") and other federal and state government pricing programs in the U.S., and we may participate in additional government pricing programs in the future. These programs generally require us to pay rebates or otherwise provide discounts to government payers in connection with drugs that are dispensed to beneficiaries/recipients of these programs. Pricing requirements and rebate/discount calculations are complex, vary among products and programs, and are often subject to interpretation by governmental or regulatory agencies and the courts. Thus, there can be no assurance that we will be able to identify all factors that may cause our discount and rebate payment obligations to vary from period to period, and our actual results may differ significantly from our estimated allowances for discounts and rebates. Changes in estimates and assumptions may have a material adverse effect on our business, results of operations and financial condition.

In addition, the Office of Inspector General of the Department of Health and Human Services and other Congressional enforcement and administrative bodies have increased their focus on pricing requirements for products, including, but not limited to the methodologies used by manufacturers to calculate average manufacturer price ("AMP"), and best price ("BP"), for compliance with reporting requirements under the Medicaid Drug Rebate Program. We are liable for errors associated with our submission of pricing data and for any overcharging of government payers. For example, failure to submit monthly/quarterly AMP and BP data on a timely basis could result in significant civil monetary penalties for each day the submission is late beyond the due date. Failure to make necessary disclosures and/or to identify overpayments could result in allegations against us under the Federal False Claims Act and other laws and regulations. Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operations and financial condition. In addition, in the event that CMS were to terminate our rebate agreement, no federal payments would be available under Medicaid or Medicare for our covered outpatient drugs.

Our drug products are complex to manufacture, and manufacturing disruptions may occur that could cause us to experience disruptions in the supply of our drug products.

Our drug products are complex to manufacture. Notwithstanding the fact that our third-party manufacturers have validated our processes, manufacturing disruptions may occur. Such problems may prevent the production of lots that meet the specifications required for sale of the product and may be difficult and expensive to resolve. If any such issues were to arise with respect to our drug products or any future products, our business, financial results, or common share price could be adversely affected. Also, see the Risk Factor titled, "We do not have our own manufacturing capabilities and rely on third parties to produce clinical and commercial supplies of drug substance and drug product. If these third parties do not perform as we expect, do not maintain their regulatory approvals, or become subject to other negative circumstances, it may result in a delay in our ability to develop and commercialize our products."

Risks Related to Commercialization of our Drug Products Outside the U.S. and for our Product Candidates

Our success relies on the successful commercialization of drug products outside the U.S. and the development or commercialization of our product candidates. If we are successful in obtaining regulatory approval for drug products in jurisdictions outside the U.S. or for our product candidates, we will be subject to the same or similar commercialization risks as described above for our approved drug products.

We expect to seek other regulatory approvals for our drug products in jurisdictions outside the U.S. and for our product candidates in the U.S. If we receive regulatory approval for any drug products in jurisdictions outside the U.S. or for our product candidates in the U.S., we will be subject to the same or similar risks we currently face with the commercialization of ORGOVYX and MYFEMBREE, as described under "Risks Related to Commercialization of Our Drug Products" above. For example, in July 2021, the EC, and in August 2021, the MHRA, approved RYEQO as the first and only long-term, once-daily oral treatment in the EU and the U.K., respectively, for moderate to severe symptoms of uterine fibroids in adult women of reproductive age, with no limitation for duration of use. Our commercialization partner, Richter, has launched RYEQO in a number of countries in Europe since these regulatory approvals. In April 2022, the EC approved ORGOVYX as the first and only oral androgen deprivation therapy for advanced hormone-sensitive prostate cancer in Europe. Our commercialization partner, Accord, has launched ORGOVYX in Europe. Sufficient coverage and reimbursement are important for Richter and Accord to successfully commercialize RYEQO and ORGOVYX, respectively, in Europe, but healthcare reimbursement models and reimbursement requirements vary from country to country in Europe. Although RYEQO and ORGOVYX have been approved in the EU, many countries have not decided on pricing and reimbursement models. Some European countries may choose not to reimburse RYEQO and/or ORGOVYX at all or only reimburse RYEQO and/or ORGOVYX at a comparatively low price. The commercialization opportunities of RYEQO and ORGOVYX in Europe may be limited if either product fails to obtain sufficient coverage or reimbursement in certain countries.

Risks Related to Our Financial Position and Capital Requirements

If we do not have adequate funds to cover our development and commercialization activities, we may have to raise additional capital or curtail or cease operations. We may not be able to obtain funding through public or private offerings of our capital shares, debt financings, collaboration or licensing arrangements, or other sources.

In the U.S., we began to commercialize ORGOVYX for the treatment of adult patients with advanced prostate cancer in January 2021, MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids in June 2021, and MYFEMBREE for the management of moderate to severe pain associated with endometriosis in August 2022. We also seek to advance additional product candidates through research and clinical development to regulatory approval and commercialization. These activities will require substantial financial resources.

As of September 30, 2022, we had cash, cash equivalents and marketable securities of $371.3 million. Based on our current operating plan, we believe that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of this Quarterly Report. 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. In future periods, if our cash, cash equivalents, marketable securities, and amounts that we expect to generate from product sales and/or third-party collaboration payments are not sufficient to enable us to fund our operations, we may need to raise additional funds in the form of equity, debt, or from other sources. In addition, we may choose to raise additional funds in the form of equity, debt, or from other sources due to market conditions or strategic considerations even if we believe we have sufficient funds for our current and future operating plans.

We expect our operating expenses, net of costs that are expected to be shared with Pfizer pursuant to the Pfizer Collaboration and License Agreement, to increase and our future capital requirements are expected to be significant. Our operating expenses and operating cash flows may fluctuate significantly from quarter-to-quarter and year-to-year and our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the price, level of demand and net product revenues generated from commercial sales of our drug products, and for any product candidates that may receive marketing approval in the future;
- the achievement of regulatory milestones, commercial launch milestones, sales milestones, and/or royalties that we are eligible to earn pursuant to our collaboration or commercialization agreements;
- the timing, shared costs, and level of investment in our and our collaboration and commercialization partners' activities related to sales, marketing, market access, manufacturing, and distribution for our drug products and for any product candidates that may receive marketing approval;

- the timing, shared costs, and level of investment in our and our collaboration partners' research and development activities involving ORGOVYX, MYFEMBREE, RYEQO, and any product candidates;
- the initiation, progress, timing, costs, and results of our planned and ongoing clinical studies for our product candidates;
- the outcome, timing, and cost of meeting regulatory requirements established by the FDA and comparable foreign regulatory authorities;
- the cost to maintain, expand, and protect our patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the cost of raw materials and manufacture of our drug products, including packaging;
- the costs to hire additional commercial operations, sales and marketing, scientific, clinical, regulatory, quality, and other personnel to support our commercialization, sales and marketing, regulatory, and clinical development efforts;
- the costs to implement or enhance operational, accounting, finance, quality, commercial, and management information systems; and
- economic factors over which we have no control, including changes in inflation, interest rates, foreign currency rates, and the potential effect of such factors on revenues and expenses.

Under the terms of the Sumitomo Pharma Loan Agreement, we may not raise additional capital without obtaining the consent of Sumitomo Pharma Co. Ltd. ("Sumitomo Pharma"). If we do not have sufficient funds to complete the development of, seek regulatory approvals for our product candidates and commercialize our drug products and, if approved, our product candidates, we may be required to delay, limit, reduce, or terminate our drug development programs, commercialization efforts, and/or limit or cease our operations if we are unable to obtain additional capital to support our current operating plan. 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 and commercialization efforts.

We are required to meet certain terms and conditions to draw down funds under the Sumitomo Pharma Loan Agreement. If we are unable to meet such terms and conditions, we may not be able to access funding from the Sumitomo Pharma Loan Agreement. Further, we may be obligated to repay the loans prior to their scheduled maturity date under certain circumstances.

On December 27, 2019, we, one of our subsidiaries, and Sumitomo Pharma entered into the Sumitomo Pharma Loan Agreement, pursuant to which Sumitomo Pharma agreed to make revolving loans to us in an aggregate principal amount up to $400.0 million. As of September 30, 2022, approximately $41.3 million of borrowing capacity remained available to us under the Sumitomo Pharma Loan Agreement. We may draw down additional funds under the Sumitomo Pharma Loan Agreement once per calendar quarter, subject to certain terms and conditions, including the consent of our board of directors and no change of control having occurred with respect to us. We may not be able to meet such terms and conditions in the future and may not be able to secure additional funds. The maturity date of the loans under the Sumitomo Pharma Loan Agreement is December 27, 2024 or the date the outstanding principal of the loans is declared due and payable due to an event of default pursuant to the terms of the agreement. In addition, if Sumitomo Pharma fails to own at least a majority of the outstanding common shares of Myovant, it may become unlawful under Japanese law for Sumitomo Pharma to fund loans to us, and in which case we would not be able to continue to borrow under the Sumitomo Pharma Loan Agreement. Furthermore, within 30 days of a change of control having occurred with respect to us, we will be obligated to repay the outstanding amount of loans and accrued interest under the Sumitomo Pharma Loan Agreement.

We 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 may fail to gain regulatory approval or fail to become commercially viable. Since inception, we have incurred significant operating losses. We expect to continue to incur significant operating expenses as we continue commercialization of ORGOVYX and MYFEMBREE in the U.S., continue to develop our product candidates, and prepare for potential regulatory approval and commercialization of our drug products in the U.S. and other jurisdictions. The timing and magnitude of our net income (loss) will depend on the commercial success of our drug products, as well as the timing and commercial success of any product launches, as well as other potential business and operational activities. Likewise, any potential future milestone or royalty payments that we are eligible to earn under our collaboration and

commercialization agreements will depend on the regulatory and commercial success of our drug products and product candidates, if approved. As a result, we may never achieve or maintain profitability.

Risks Related to Our Business Operations

The terms of the Sumitomo Pharma Loan Agreement place restrictions on our operating and financial flexibility.

Our obligations under the Sumitomo Pharma Loan Agreement are senior unsecured obligations that are guaranteed on a full and unconditional basis by all our subsidiaries.

The Sumitomo Pharma Loan Agreement also includes customary representations and warranties as well as affirmative and negative covenants. The negative covenants include limitations on additional indebtedness, liens, certain corporate changes, certain restricted payments, investment transactions with affiliates, entry into certain restrictive agreements, change in the nature of business, and use of proceeds. 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 Sumitomo Pharma Loan Agreement also includes customary events of default, including payment defaults, breaches of representations and warranties and certain covenants following any applicable cure period, cross acceleration to certain debt, other failure to pay certain final judgments, certain events relating to bankruptcy or insolvency, certain breaches by us under our Investor Rights Agreement with Sumitovant Biopharma Ltd. ("Sumitovant") and Sumitomo Pharma, dated December 27, 2019, and failure of material provisions of the loan documents to remain in full force and effect or any contest thereto by us or any of our subsidiaries. Upon the occurrence of an event of default, a default interest rate of an additional 5.0% will apply to the outstanding principal amount of the loans, Sumitomo Pharma may terminate its obligations to make loans to us and declare the principal amount of all outstanding loans and other obligations under the Sumitomo Pharma Loan Agreement to become immediately due and payable, and Sumitomo Pharma may take such other actions as set forth in the Sumitomo Pharma Loan Agreement. Upon the occurrence of certain bankruptcy and insolvency events, the obligations of Sumitomo Pharma to make loans to us would automatically terminate and the principal amount of all outstanding loans and other obligations due under the Sumitomo Pharma Loan Agreement would automatically become due and payable. In addition, if it becomes unlawful for Sumitomo Pharma to maintain the loans under the Sumitomo Pharma Loan Agreement, we would be required to repay the outstanding principal amount of the loans and if a change of control occurs with respect to us, we would be required to repay the outstanding principal amount of the loans within 30 days of such change of control. We may not have enough available funds 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. 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, which may limit our growth potential.

Part of our strategy involves 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 novel product candidates may prove to be unsuccessful and may not be effective in treating their targeted diseases.

In addition, time and resources spent searching for, identifying, acquiring, and developing potential product candidates may distract management's attention from our primary business. 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 for future growth.

We do not have our own manufacturing capabilities and rely on third parties to produce clinical and commercial supplies of drug substance and drug product. If these third parties do not perform as we expect, do not maintain their regulatory approvals, or become subject to other negative circumstances, it may result in a delay in our ability to develop and commercialize our products.

We do not own or operate, and we do not expect to own or operate, facilities for drug substance and drug product manufacturing, storage and distribution, or testing and are subject to the risk that our contract manufacturers become subject to negative circumstances. For example, in June 2016, we and one of Takeda's affiliates, Takeda Pharmaceutical Company Limited ("Takeda Limited") entered into an agreement for the manufacture and clinical supply of relugolix pursuant to which Takeda Limited supplied us with, and we obtained from Takeda, all of our requirements for relugolix drug substance and drug product that were used under our development plans. In May 2018, we entered into a Commercial Manufacturing and Supply Agreement with Takeda pursuant to which Takeda agreed to manufacture and supply us with certain commercial relugolix drug substance quantities. In addition, in April 2019, we entered into a Commercial Manufacturing and Supply Agreement with Excella GmbH & Co. KG ("Excella"), which was amended and restated in April 2021 and pursuant to which Excella agreed to manufacture and supply us with certain commercial relugolix drug substance quantities.

Takeda is no longer developing MVT-602. Additional process development and manufacturing will be required for us to complete further Phase 2 and Phase 3 clinical studies for MVT-602. Any third-party vendor that we retain for MVT-602 process and formulation development and manufacturing will need certain specialized capabilities required for MVT-602.

If we need to replace a third-party manufacturer, or if any of our third-party manufacturers experience adverse developments, including with respect to adverse findings during regulatory inspections, delays in regulatory approvals and/or the COVID-19 pandemic, we could experience a significant delay in the supply of a product candidate, which could result in a considerable delay in completing our clinical studies, product testing, and potential regulatory approval of our product candidates. In addition, the commercial launch of our product candidates could be delayed and there could be a shortage in supply, which would impair our ability to generate revenue from the sale of our product candidates.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the regulatory authorities pursuant to inspections that may be conducted after we submit our regulatory applications to such regulatory authorities. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP requirements and other regulations and laws for the manufacture of relugolix drug substance and drug product. 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 may not be able to secure or maintain regulatory approvals for their manufacturing facilities and any applications that we submit to the FDA or other regulatory authorities that list those manufacturing facilities may be negatively affected. Our third-party contract manufacturing facilities must also be in an acceptable state of cGMP compliance and not be subject to a cGMP-related regulatory or enforcement action that limits their ability to manufacture drug substance or drug product. If any of the drug substance or drug product supplied by a contract manufacturing partner cannot be utilized due to quality or cGMP concerns, adverse findings during regulatory inspections or other reasons, our development plans and commercialization of relugolix could be significantly delayed or otherwise adversely affected. The FDA or other regulatory authority may withhold approval of any pending regulatory applications or supplements in which non-complaint manufacturing facilities are listed.

For example, in June 2020, Takeda received a warning letter from the FDA which indicated that the FDA was not satisfied with Takeda's response to an FDA Form 483 issued to Takeda following its routine inspection of aseptic finished pharmaceuticals manufacturing at Takeda's manufacturing facility located at Takeda 4720, Mitsui, Hikari, Yamaguchi, Japan ("Hikari Facility"). Although this matter was resolved in October 2021, this warning letter required us to remove the Hikari Facility as a manufacturing site from our NDA submissions and to rely on the alternate contract manufacturing organization ("CMO") listed in the NDA (i.e. Excella) to a greater extent than we had originally planned. We also face the risk that our CMOs may face adverse developments, including with respect to adverse findings during regulatory inspections, delays in regulatory approval and/or the COVID-19 pandemic. If our CMOs fail to fulfill their obligations to manufacture and supply relugolix drug substance and drug product needed for any of our approved drug products and any of our product candidates, or if any of the materials cannot be utilized due to quality or cGMP concerns, adverse findings during regulatory inspections, process validation delays, or other reasons, our development plans and commercialization of any of our approved drug products and any of our product candidates could be significantly delayed or otherwise adversely affected.

Our product candidates contain highly potent compounds 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.

Further, our reliance on third-party manufacturers entails various risks, including:

- delay or inability to manufacture our drug products;
- failure of the drug substance transferred from a CMO to meet our product specifications and quality requirements;
- 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 cGMP and similar foreign standards;
- deficient or improper record-keeping;
- inability to negotiate manufacturing and quality 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 our drug products or product candidates (if approved) 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;
- adverse inspection findings by the FDA or other regulatory authorities at third-party manufacturing facilities and/or failure to remediate such findings;
- cGMP regulatory or enforcement action at our third-party manufacturing facilities that limit their ability to manufacture drug substance or drug product for commercial use;
- 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 study 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 the FDA or other regulatory authority action, including injunction, recall, seizure, or total or partial suspension of production.

Our or our affiliates' employees, independent contractors, advisers, third-party manufacturers, principal investigators, consultants, commercialization partners, collaboration partners, service providers, and other vendors, 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, independent contractors, advisers, third-party manufacturers, principal investigators, consultants, commercialization partners, collaboration partners, 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 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 payers, and customers will be subject to applicable healthcare regulatory laws, which could expose us to

penalties," and "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., which could interrupt our business operations and harm our future international expansion and, consequently, negatively impact our financial condition, results of operations, and cash flows." These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commissions, 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 studies, creating fraudulent data in our nonclinical or clinical studies 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.

Business interruptions resulting from effects of pandemics or epidemics, such as the COVID-19 pandemic, may materially and adversely affect our business and financial condition.

While the COVID-19 pandemic has created certain operational complexities, we have thus far been successful at devising solutions to mitigate its impact on our business operations. To date, we do not believe that the COVID-19 pandemic has disproportionately impacted us relative to other commercial-stage oncology and women's health biopharmaceutical companies with which we compete.

We believe that the COVID-19 pandemic continues to have an impact on our commercialization activities that is consistent with other oncology and women's health biopharmaceutical companies. As a result of the COVID-19 pandemic, there have been changes in the practice of medical care and medical education. For example, the ability of commercial and medical affairs field teams to call on healthcare providers has been restricted or converted to virtual access. We and our collaboration partner, Pfizer, launched ORGOVYX in the U.S. in January 2021 and MYFEMBREE in the U.S. in June 2021. We and Pfizer launched MYFEMBREE in the U.S. for an additional indication in August 2022. Richter has launched RYEQO in a number of countries in Europe and Accord has launched ORGOVYX in Europe. We and our collaboration and commercialization partners may launch other approved products or indications in the COVID-19 environment. While restrictions have eased in many countries and certain regions in the U.S. in recent months, future development in the pandemic could lead to a return to stricter restrictions that may make it more difficult for us and our collaboration and commercialization partners, such as Sunovion, Pfizer, Richter, and Accord, to maximize the effectiveness of third-party market access, marketing, sales, and distribution capabilities.

In addition, we rely on third parties in the U.S. and in various parts of the world to assist in the conduct of our clinical studies and to supply us with sufficient drug supplies. Our ability to ensure continuous clinical drug supply to patients and our ability to ensure continuous patient follow up and data monitoring for our ongoing clinical studies may be adversely impacted. Likewise, while we currently expect that the drug supply we have on hand or expect to procure will be sufficient to support our ongoing clinical studies, our and our collaboration and commercialization partners' commercial sales for our approved drug products, our supply chain for raw materials, drug substance and drug product is worldwide, and the duration of the COVID-19 pandemic and its impact on the ability of our suppliers to operate could negatively impact our manufacturing supply chain for our approved drug products and for our product candidates that may receive regulatory approval, or for clinical study materials. If disruptions to our supply chain persist for an extended period of time, our clinical study timelines, our financial condition and our results of operations may be negatively impacted. In addition, due to COVID-19 and its various variants, the FDA's review process and timing of potential approval of our product candidates may be delayed. Regulatory agency pre-approval inspections continue to be limited due to COVID-19 backlog, and it is not clear if virtual inspections will be required and acceptable.

Despite our COVID-19 pandemic mitigation efforts, we may experience delays or an inability to execute our business plans, reduced revenues, or other adverse impacts to our business. We will continue to monitor developments with respect to COVID-19 that could pose additional risks for us, including the spread of the Omicron variant and its subvariants in the U.S. and other countries, and the potential emergence of new SARS-CoV-2 variants that may prove especially contagious or virulent. Additionally, even after normalcy resumes, we may continue to experience adverse impacts to our business as a result of the COVID-19 pandemic's global economic impact, including any economic downturn or recession that has occurred or may occur in the future. The impact of COVID-19 pandemic may also exacerbate other risks and uncertainties described elsewhere in this "Risk Factors" section. As such, it is uncertain as to the full magnitude that any pandemic or epidemic, such as the COVID-19 pandemic, may have on our financial condition, liquidity, and future 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., which could interrupt our business operations and harm our future international expansion and, consequently, negatively impact our financial condition, results of operations, and cash flows.

Part of our business strategy involves international expansion, including establishing and maintaining operations outside of the U.S., and establishing and maintaining relationships with healthcare providers, payers, government officials, distributors, manufacturers and other third parties globally.

Conducting business internationally involves a number of risks, including:

- the increased complexity, difficulties and costs inherent in staffing and managing international operations and business practices in different jurisdictions;
- multiple conflicting and changing laws and regulations such as tax laws, trade protection measures, export and import restrictions, employment, immigration and labor laws, privacy and cybersecurity laws, anti-bribery and anti-corruption laws, regulatory requirements and other governmental approvals, permits and licenses;
- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- possible failure by us or our distributors to obtain and maintain appropriate licenses or regulatory approvals for the sale or use of our product candidates, if approved, in various countries;
- complexities associated with managing multiple payer-reimbursement, pricing and insurance 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 or no protection over intellectual property rights;
- business interruptions resulting from geopolitical actions, economic instability, or natural disasters, including, but not limited to, wars (such as the conflict between the Russian Federation and Ukraine) and terrorism, economic weakness, inflation, political instability in particular foreign economies and markets, boycotts, curtailment of trade, sanctions, labor disputes, unexpected changes in tariffs, and other business restrictions, outbreak of disease (such as the COVID-19 pandemic), fires, earthquakes, hurricane, tornado, severe storm, power outage, system failure, typhoons or floods;
- 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 EU General Data Protection Regulation (the "GDPR") which introduced strict requirements for processing personal data of individuals within the EU;
- 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;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

Any of these risks, if encountered, could interrupt our business operations and harm our future international expansion and, consequently, negatively impact our financial condition, results of operations, and cash flows. We have no prior experience in certain countries, and many healthcare companies have found the process of marketing their products in foreign countries to be very challenging.

The withdrawal of the U.K. from the EU, commonly referred to as "Brexit," may adversely impact our ability to obtain regulatory approvals of our product candidates in the EU, result in restrictions or imposition of taxes and duties for importing our product candidates into the EU, and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the EU.

Following the result of a referendum in 2016, the U.K. left the EU on January 31, 2020, commonly referred to as Brexit. A trade and cooperation agreement (the "Trade and Cooperation Agreement") that outlines the future trading relationship between the U.K. and the EU was agreed to in December 2020. Since a significant proportion of the regulatory framework in the U.K. applicable to our business and certain of our product candidates are derived from EU directives and regulations, Brexit has had,

and may continue to have, a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the U.K. or the EU. For example, the U.K is no longer covered by the centralized procedures for obtaining EU-wide marketing authorization from the European Medicines Agency (the "EMA"), and a separate marketing authorization will be required to market our product candidates in the U.K. Until January 2023, it is possible for the MHRA to rely on a decision taken by the EC on the approval of a new marketing authorization via the centralized procedure. However, it is unclear whether the MHRA in the U.K. is sufficiently prepared to handle the increased volume of marketing authorization applications that it is likely to receive after such time. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us and our collaboration and commercialization partners from commercializing our product candidates in the U.K. or the EU and restrict our ability to generate revenue and achieve and sustain profitability.

While the Trade and Cooperation Agreement provides for the tariff-free trade of medicinal products between the U.K. and the EU, there may be additional non-tariff costs to such trade which did not exist before. Further, should the U.K. diverge from the EU from a regulatory perspective in relation to medicinal products, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the U.K. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU.

Our internal computer systems, and those of 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 our contract research organizations ("CROs"), CMOs, third-party logistics providers, third-party collaboration and commercialization partners, and other contractors, consultants, and law and accounting firms, may sustain damage or data leakage from computer viruses, unauthorized access or disclosure, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war, and telecommunication and electrical failures. We rely on our third-party providers to implement effective security and data recovery measures and identify and correct for any such failures, deficiencies or breaches. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of the commercialization of our drug products and our drug development programs. For example, the loss of commercialization information, nonclinical or clinical study data from completed, ongoing or planned clinical studies could result in delays in our commercialization, 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, access or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability, suffer reputational damage, and the further development of any current or future product candidate could be delayed.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. This information includes, among other things, our intellectual property and proprietary information, commercialization activities, and non-clinical or clinical data from completed, ongoing, or planned clinical studies, and the personally identifiable information of our employees. It is important to our operations and business strategy that this electronic information remains secure and is perceived to be secure. The size and complexity of our information technology systems, and those of third parties whom we conduct business with, and the volume of data we retain, make such systems potentially vulnerable to breakdown, malicious intrusion, security breaches, ransomware attacks, social engineering attacks, supply-chain attacks, and other cyber-attacks. Ransomware attacks are becoming increasingly prevalent and severe. These threats may come from a wide variety of actors, including traditional hackers, employees, sophisticated nation-states, and state-sponsored actors.

Similarly, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties in our supply chain have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems and infrastructure or the information technology systems and infrastructure of third parties that support our operations. Furthermore, because of the COVID-19 pandemic, we have adopted a remote workforce model, which increases the risk that our information technology systems and data could be compromised as more of our employees work from home, utilizing network connections outside our premises. As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities. Although to our knowledge, we have not experienced any material incident or disruption to date, we cannot be certain that we, or third parties with which we conduct business, will not be the target of cybersecurity incidents. While we have implemented security measures to data security and information technology systems, such measures may not prevent such events. Significant disruptions of our information technology systems or breaches of data security could have a material adverse effect on our business, financial condition and results of operations.

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, California enacted the California Consumer Privacy Act (“CCPA”), which became effective 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 study data, and Health Insurance Portability and Accountability Act (“HIPAA”) protected health information, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. The CCPA has prompted a number of proposals for new federal and state privacy legislation that, if passed, 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 studies 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 has 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 and guidance issued by different EU member states 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 also 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 U.K. In particular, it is unclear whether, post Brexit, the U.K. will enact data

protection legislation equivalent to the GDPR and how data transfers to and from the U.K. 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.

The failure to successfully expand and maintain our enterprise resource planning ("ERP") system and other information technology systems could adversely affect our business and results of operations or the effectiveness of internal control over financial reporting.

We have a company-wide ERP system pertaining to certain business, operational, and finance processes. We have continued to optimize and expand this ERP system and have implemented and continue to optimize other systems as a part of our ongoing technology and process improvement initiatives. ERP and other information technology system implementations are complex, expensive and time consuming projects that require transformations of business, operational, and finance processes. Any such transformation involves risk inherent in the conversion to a new system, including loss of information and potential disruption to normal operations.

Any disruptions, delays, or deficiencies in the design or the ongoing maintenance and optimization of the ERP system and other information technology systems could adversely affect our ability to accurately maintain our books and records, provide accurate, timely and reliable reports on our financial and operating results, or otherwise operate our business. Additionally, if the ERP system and other information technology systems do not operate as intended, the effectiveness of our internal control over financial reporting could be adversely affected and could cause us to fail to comply with SEC obligations related to our internal control over financial reporting. In addition, if we experience interruptions in service or operational difficulties and are unable to effectively manage our business following the implementation or optimization of the ERP system or other information technology systems, our business and results of operations could be harmed.

The phase-out of the London Interbank Offered Rate ("LIBOR"), or the replacement of LIBOR with an alternative reference rate, may adversely affect interest rates on our outstanding variable rate indebtedness with Sumitomo Pharma.

On July 27, 2017, the U.K.'s Financial Conduct Authority (the authority that regulates LIBOR) announced that after 2021, it would no longer compel banks to submit the rates required to calculate LIBOR. The administrator for LIBOR and other inter-bank offered rates, ICE Benchmark Administration ("IBA"), confirmed on March 5, 2021 its previously announced dates for LIBOR cessation. The 1-week and 2-week USD LIBOR have ceased publication and the 3-month, 6-month and 1-year USD LIBOR are currently scheduled to cease publication after June 30, 2023. The interest rate under the Sumitomo Pharma Loan Agreement is calculated based on 3-month LIBOR and, when the publication of 3-month LIBOR is discontinued, we will need to agree with Sumitomo Pharma on a new method of calculating the interest rate under the Sumitomo Pharma Loan Agreement. Changes in the method of calculating LIBOR, or the replacement of LIBOR with an alternative rate or benchmark, may adversely affect interest rates and result in higher borrowing costs. This could adversely affect our results of operations, cash flows and liquidity. We cannot predict the effect of the 3-month LIBOR replacement benchmark rate at this time.

In addition, the Federal Reserve and other regulating bodies around the world have raised, and may continue to raise, or may announce intentions to raise, interest rates. These developments, along with global economic uncertainties and market volatility, inflation, the impacts of COVID-19, and the conflict between the Russian Federation and Ukraine, could cause interest rates,

including the 3-month LIBOR and any replacement benchmark rate, to be volatile.

The conflict between the Russian Federation and Ukraine and other government policies and actions could negatively affect our clinical trial sites in Ukraine. We and/or our collaboration and commercialization partners may not be able to launch our commercial products in the Russian Federation, Ukraine or other regions which may negatively affect our financial results. The uncertain nature, magnitude, and duration of hostilities stemming from such conflict may result in changes in the world's macroeconomic conditions which negatively affect our business operations.

The conflict between the Russian Federation and Ukraine may have a material adverse effect on our ability to adequately conduct certain clinical trial procedures and maintain compliance with the clinical trial protocol in Ukraine, due to the prioritization of hospital resources away from clinical trials, reallocation or evacuation of site staff and clinical trial participants, or as a result of government-imposed curfews, warfare, violence or other governmental action or events that restrict movement. Some patients may not be able to comply with clinical trial protocols if the conflict impedes patient movement or interrupts healthcare services. We may not be able to access sites for monitoring in regions affected by economic, political or social disruptions in Ukraine and we may not be able to obtain data from affected sites going forward. Our collaboration partners could experience disruptions in their supply chains in regions affected by such rising conflict that may have a negative impact on us. If our access to our clinical trial sites and data were to experience significant disruption due to these risks or for other reasons, it could have an adverse effect on the timing of our clinical trials. The ability of the FDA to conduct pre-approval inspections in Ukraine or other disrupted areas could also be adversely affected. In addition, the U.S., the E.U., and the U.K. have adopted comprehensive sanctions, which restrict a wide range of trade and financial dealings with the Russian Federation and Russian persons, as well as certain regions in Ukraine, including by imposing stricter export controls, prohibiting dealings with major Russian banks and credit institutions, and prohibiting trade with the Donetsk and Luhansk regions of Ukraine. These sanctions could also extend to Russian allies, such as Belarus. We, or our collaboration and commercialization partners, may not be able to launch our commercial products in Russia, Ukraine or certain regions that are subject to such trade sanctions which may negatively affect our financial results.

The uncertain nature, magnitude, and duration of hostilities stemming from the conflict between the Russian Federation and Ukraine and potential further sanctions against the Russian Federation, embargoes, regional instability, and geopolitical shifts could have a material negative impact on the world's macroeconomic conditions which may result in potential shipping delays, increased market volatility and uncertainty, and increased cost or unavailability of raw materials and fuel, supplies, freight and labor, inflation, and fluctuations in currency exchange rates. These macroeconomic factors could adversely affect our business, supply chain, clinical studies, results of operations, suppliers or customers. It is not possible for us to predict the broader consequences of this conflict at this time and we continue to monitor this situation and the impact to our business.

Risks Related to Clinical Development and Regulatory Approval

Clinical studies are very expensive, time consuming, difficult to design and implement, and involve uncertain outcomes. Clinical study failures can occur at any stage of clinical studies, and we could encounter problems that cause us to suspend, abandon or repeat clinical studies. We cannot predict with any certainty the timing for commencement or completion of current or future clinical studies.

Any product candidate 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. Human clinical studies are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The FDA or other regulatory authorities may not agree with our proposed plans for any clinical studies of our product candidates, or any other potential future product candidates, which may delay or prevent the approval of an NDA or similar application. For example, on May 18, 2021, the FDA informed us by teleconference that it placed a partial clinical hold on our Phase 3 SERENE study (MVT-601-050) evaluating relugolix combination tablet for the prevention of pregnancy pending amendment of the study protocol. In August 2021, the FDA informed us that the partial clinical hold on such study was lifted following study protocol amendments.

The clinical study process is also very time consuming. The commencement and completion of clinical studies may be delayed or prevented by several factors, including:

- failure to obtain regulatory approval to commence a study or regulatory actions requiring a hold on any of our clinical studies;
- unforeseen safety issues;
- lack of effectiveness during clinical studies;

- identification of dosing issues;
- inability to reach agreement on acceptable terms with prospective CROs and/or clinical study sites, the terms of which can be subject to extensive negotiations and may vary significantly among different CROs and clinical study sites;
- our determination that the cost of completing the clinical trial and obtaining regulatory approval does not warrant the expense and investment of time by management and our other personnel;
- slower than expected rates of patient recruitment and enrollment or failure to recruit suitable patients to participate in a study;
- failure to open a sufficient number of clinical study sites;
- unanticipated impact from changes in or modifications to clinical study design;
- inability or unwillingness of clinical investigators or study participants to follow our clinical and other applicable protocols; for example, missed assessments or impeded access to clinical study sites due to the COVID-19 pandemic or the conflict between the Russian Federation and Ukraine;
- premature discontinuation of study participants from clinical studies 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 studies;
- inability to monitor patients adequately during or after treatment; or
- inappropriate unblinding of study patients or study results.

Clinical study failures can occur at any stage of clinical studies, and we could encounter problems that cause us to suspend, abandon or repeat clinical studies. We, the FDA or an institutional review board or other regulatory authority may suspend our clinical studies at any time if it appears that we or our collaborators are failing to conduct a clinical study in accordance with regulatory requirements, including, the FDA's current Good Clinical Practices ("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 other submissions or the manner in which the clinical studies are conducted. In addition, product candidates in later stages of clinical development may fail to show the desired safety and efficacy outcomes despite having progressed successfully through prior stages of preclinical and clinical testing. Results from clinical studies may require further evaluation, delaying the next stage of clinical development or submission of an NDA or other similar application for regulatory approval. Further, we may determine to terminate a clinical trial if we determine that the cost and time of management and our other personnel does not warrant further investment in the clinical trial. Therefore, we cannot predict with any certainty the timing for commencement or completion of current or future clinical studies. If we experience delays in the commencement or completion of our clinical studies, or if we terminate a clinical study prior to completion, the commercial prospects of any product candidates could be harmed, and our ability to generate net product revenue from any product candidates may be delayed. In addition, any delays in our clinical studies could increase our costs, cause a decline in our common share price, slow down the regulatory approval process, and jeopardize our ability to commence product sales and generate net product 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 studies may also ultimately lead to the denial of regulatory approval of our product candidates.

Moreover, principal investigators for our clinical studies 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 study site and the utility of the clinical study itself may be jeopardized. Clinical study sites, CROs, and manufacturing sites may be inspected for compliance with cGCP or cGMP. Any questions about data integrity or significant quality issues 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.

We are dependent on the research and development of relugolix and MVT-602 previously conducted by Takeda. If Takeda did not conduct this research and development in compliance with applicable requirements, it could result in increased costs and delays in our development of these product candidates.

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 relugolix or MVT-602. We are dependent on Takeda having conducted such research and development in accordance with the applicable protocols and legal, regulatory, and scientific standards, having accurately reported the results of all clinical studies 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 studies 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 any of such nonclinical or clinical work 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 studies 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 studies on our current timelines, or at all, and even once enrolled, we may be unable to retain a sufficient number of patients to satisfactorily complete any of our clinical studies. Enrollment in our clinical studies may be slower than we anticipated, leading to delays in our development timelines. Patient enrollment and retention in clinical studies depends on many factors, including the size of the patient population, the nature of the study protocol, our ability to recruit clinical study 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 studies of competing drugs for the same indication, the proximity of patients to clinical trial sites, the eligibility criteria for the study and the proportion of patients screened that meet those criteria, our ability to obtain and maintain patient consents, and the risk that patients enrolled in clinical studies will not comply with the protocol or will drop out of the studies before completion. In addition, unforeseen global instability, including political instability, such as the ongoing conflict between the Russian Federation and Ukraine, or instability from an outbreak of pandemic or contagious disease, such as the COVID-19 pandemic, in or around the countries in which we conduct our clinical studies, could delay the commencement or rate of completion of our clinical studies. Furthermore, any negative results we or a collaboration partner may report from clinical studies of our product candidates may make it difficult or impossible to recruit, enroll, and retain patients in other clinical studies of that same product candidate. Similarly, negative or positive results reported by our competitors about their products or product candidates may negatively affect patient recruitment, enrollment, or retention in our clinical studies. 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 studies, delaying or potentially preventing us from completing clinical studies. Delays or failures in planned patient recruitment, enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates, or could render further development impossible.

The results of our clinical studies may not support our proposed claims for our product candidates. The results of previous clinical studies may not be predictive of future results, and interim or top-line data may be subject to change or qualification based on the complete analysis of data.

Even if our clinical studies are completed as planned, we cannot be certain that their results will support the efficacy or safety of our product candidates. For example, product candidates may not meet the criteria for success for their 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 study. Success in nonclinical testing and early clinical studies does not ensure that later clinical studies will be successful, and we cannot be sure that the results of later clinical studies will replicate the results of prior clinical studies and nonclinical testing. Likewise, promising results in interim analyses or other preliminary analyses do not ensure that the clinical study as a whole will be successful. In addition, the FDA may not agree that clinical study results are sufficient for approval for any product candidate, or even if approved, may not support a label that is capable of competing with existing treatments. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical studies, even after having achieved 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. Positive results from any of our clinical studies may not be predictive of the results of any of our other ongoing and potential future clinical studies, and there can be no assurance that the results of studies conducted by third parties will be viewed favorably or are indicative of our own future study results. We may publicly disclose top-line or interim data from time to time, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review, audit,

and verification of the data related to the particular study. We make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated.

A future failure of a clinical study to meet its primary endpoints would likely cause us to abandon a product candidate and may delay development of a product candidate. Any delay in, or termination of, our clinical studies will delay the submission of our NDAs to the FDA or other similar applications to other foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates and generate net product revenue.

Reported data or other clinical development announcements by Takeda, its partners or sublicensees, or by our collaboration and commercialization partners, including Pfizer, Richter, or Accord may adversely affect our commercialization of our drug products and our clinical development plans.

Takeda, its partners and sublicensees, and our collaboration and commercialization partners, Pfizer, Richter, and Accord may be involved in the further clinical development of relugolix. Favorable announcements by Takeda, Pfizer, Richter, or Accord do not guarantee that the results of our clinical studies will also be favorable as the designs of our clinical studies may differ from those of Takeda, Pfizer, Richter, or Accord. Further, if clinical study or post-marketing adverse events regarding relugolix are reported, or subsequent announcements by our partners regarding relugolix are unfavorable, it could negatively impact our commercialization of drug products, and our clinical development plans for or opinions of the FDA or other regulatory authorities with respect to relugolix. For example, Takeda has developed 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 studies in Japan in women with uterine fibroids and has obtained market authorization in Japan from the Ministry of Health, Labor and Welfare for Relumina® tablets 40 mg (generic name: relugolix) for the improvement of symptoms of uterine fibroids, including heavy menstrual bleeding, lower abdominal pain, lower back pain, and anemia. We cannot provide assurance that the FDA or other health authorities will allow us to use the data from Takeda's clinical studies in support of any NDA or marketing authorization application that we may submit, and such data may be interpreted differently by the regulatory authorities and provide contradictory evidence in support of the evaluation by the FDA or other regulatory authority. If the FDA or other regulatory authorities do not allow us to use the data from Takeda's clinical studies, we may be required to perform additional clinical studies.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, and inherently unpredictable. If we are not able to obtain required regulatory approvals for our product candidates, our ability to generate net product revenue will be materially impaired.

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. 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 and our collaboration and commercialization partners are not permitted to market our product candidates in the U.S. until we receive approval of NDAs or sNDAs or in any foreign country until we receive the requisite approvals from the appropriate regulatory authorities in such countries. Obtaining approval of an NDA, an sNDA or similar foreign 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 our product candidates. The time required to obtain approval of an NDA or an sNDA by the FDA or similar regulatory authorities outside of the U.S. is unpredictable but typically takes many years following the commencement of clinical studies and depends upon numerous factors, including the substantial discretion of the regulatory authority. 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. Obtaining approval of an NDA or an sNDA from the FDA or a regulatory approval from a regulatory authority outside the U.S. is an expensive process. The submission of NDAs and sNDAs is subject to a substantial application user fee, and the manufacturer and/or sponsor under approved NDAs and sNDAs are also subject to annual program user fees. We may incur additional costs in the future for our anticipated regulatory submissions, including the fees associated with NDAs, sNDAs and foreign equivalent submissions.

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 our product candidates for the specified indication. The process of responding to the FDA or other regulatory authorities' information requests in the review process, potentially preparing for and appearing at a public advisory committee or oral hearing, and preparing our manufacturers and investigators to successfully complete inspections by the FDA or other regulatory authorities during the approval process requires significant human and financial resources. If the information from our completed clinical studies is insufficient to support regulatory approvals, we may have to complete ongoing or additional clinical studies.

We rely on third-party CROs and consultants to assist us in submitting 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 approvals 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 net product revenue. Despite efforts at compliance, from time to time, we or our partners may receive notices of manufacturing, quality-related, or other observations following inspections by regulatory authorities, as well as official agency correspondence regarding compliance. We also face the risk that our CMOs may face adverse developments, including with respect to adverse findings during regulatory inspections, delays in regulatory approval and/or the COVID-19 pandemic. If Excella or our other CMOs fail to fulfill their obligations to manufacture and supply relugolix drug substance and drug product needed for our commercialization, or if any of the materials cannot be utilized due to quality or cGMP concerns, adverse findings during regulatory inspections, process validation, or other reasons, our development plans and commercialization of our product candidates could be significantly delayed or otherwise adversely affected.

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 product candidates' full market potential.

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 for a product candidate by the FDA in the U.S. does not ensure approval by regulatory authorities in any other country or jurisdiction. In addition, clinical studies 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 studies 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. For example, we are reliant, in part, upon the regulatory expertise of Richter and Accord to gain approval for certain drug products in the licensed territories and are completely reliant on Richter and Accord to generate net product revenue in the territories licensed to them. In July 2021, the EC, and in August 2021, the MHRA, approved RYEQO as the first and only long-term, once-daily oral treatment in the EU and the U.K., respectively, for moderate to severe symptoms of uterine fibroids in adult women of reproductive age, with no limitation for duration of use. In addition, in April 2022, the EC approved ORGOVYX for the treatment of advanced hormone-sensitive prostate cancer. We rely on Richter and Accord to successfully commercialize our approved drug products in Europe. If we or our collaboration or commercialization partners 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 adversely affected.

Adverse events associated with our product candidates could cause us, regulatory authorities, other reviewing entities or clinical study sites to interrupt, delay, request modification of, or halt clinical studies and could result in the denial of regulatory approval.

Adverse events associated with our product candidates could cause us, regulatory authorities, or other reviewing entities or clinical study sites to interrupt, delay, request modification of, or halt clinical studies and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events are reported in our clinical studies for our product candidates, our ability to obtain regulatory approval or a desirable label 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 study 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.

We are required to monitor the safety and efficacy of ORGOVYX, MYFEMBREE and RYEQO and any other product candidates that are approved by the FDA or other regulatory authorities. We are subject to ongoing regulatory requirements to submit safety and other post-marketing information and reports, including adverse event reporting. Post-marketing adverse events related to our approved products could negatively impact our commercialization plans for these products and could negatively impact the clinical development of our product candidates.

If any of our approved drug products cause, or 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 (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 studies;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications or limit the duration of use;
- we may be required to change the way the product is administered or to conduct additional clinical studies;
- we may be required to repeat a nonclinical or clinical study or terminate a program, even if other studies or studies 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 our approved products and any of our product candidates, if approved.

Even though we have obtained regulatory approval for ORGOVYX and MYFEMBREE in the U.S., and RYEQO and ORGOVYX in Europe, or even if we obtain regulatory approval for any of our product candidates, we face or will still face extensive regulatory requirements and our products may face future development risks and regulatory difficulties.

Our drug products and 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, are and 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 studies 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. Even if any product candidate receives marketing approval, if the indication approved by regulatory authorities is narrower than we expect or the accompanying label limits the approved use of our product, our sales of products could be limited, and we may not generate significant revenue from sales of our products.

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. The FDA does not regulate the behavior of physicians in their choice of treatments and physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. However, regulatory authorities, including the FDA, impose stringent restrictions on manufacturers' communications regarding off-label use of their products, 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 those discussed

in the Risk Factor titled, "Adverse events associated with our product candidates could cause us, regulatory authorities, other reviewing entities or clinical study sites to interrupt, delay, request modification of, or halt clinical studies and could result in the denial of regulatory approval."

Our current and future relationships with investigators, healthcare professionals, consultants, third-party payers, 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 payers, patient support service providers, 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, the federal false claims laws, HIPAA, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, the federal Physician Payments Sunshine Act, and analogous state fraud and abuse, data privacy, and transparency laws.

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, imprisonment, possible exclusion from participation in Medicare Part D, 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.

Changes in legislation may increase the difficulty and cost for us to obtain marketing approval for and commercialize our drug products or product candidates 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 our drug products in other jurisdictions or product candidates in the U.S. and other jurisdictions, restrict or regulate post-approval activities, and affect our ability to profitably sell any products for which we obtain marketing approval.

In addition, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. In the U.S., such scrutiny has resulted in several Presidential executive orders, 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. Congress is considering additional health reform measures. For example, in August 2022, the Inflation Reduction Act of 2022 (the "IRA") was passed by the U.S. Congress and signed into law by President Biden. The IRA includes provisions that will, among others: (i) direct CMS to negotiate the price of certain single-source prescription drugs reimbursed under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law; (ii) impose requirements on drug manufacturers to provide rebates to CMS under Medicare Part B and Medicare Part D as a penalty for price increases that outpace inflation; and (iii) cap Medicare beneficiaries' annual out-of-pocket drug expenses. The IRA also extends enhanced subsidies for individuals purchasing coverage in a health insurance marketplace through plan year 2025. The effect of the IRA on our business and the healthcare industry in general is not yet known.

At the state level, individual states in the U.S. have increasingly passed legislation and implemented 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.

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 or other agency regulations, guidance or interpretations will be changed, or what the impact of such changes on our current and future operations, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic.

Risks Related to Our Dependence on Third Parties

We are dependent upon our relationships with collaboration and commercialization partners to further develop, fund, manufacture, and commercialize our drug products and our product candidates. If such relationships are unsuccessful, or if a collaboration or commercialization partner terminates its collaboration or commercialization agreement with us, it could negatively impact our ability to conduct our business and generate net product revenue. Failure by a collaboration or commercialization partner to perform its duties under its collaboration or commercialization agreement with us (e.g. financial reporting or internal control compliance) may negatively affect us.

On December 26, 2020, we entered into the Pfizer Collaboration and License Agreement, pursuant to which we and Pfizer collaborate to jointly develop and commercialize relugolix in oncology and women's health in the Co-Promotion Territory. In addition to the Pfizer Collaboration and License Agreement, we have entered into collaboration arrangements with other collaboration and commercialization partners. On August 1, 2020, we entered into a Market Access Services Agreement, as amended, with Sunovion pursuant to which, among other things, Sunovion agreed to provide to us certain market access services with respect to the distribution and sale of ORGOVYX and MYFEMBREE in the U.S. On March 30, 2020, we entered into the Richter Development and Commercialization Agreement pursuant to which, among other things, Richter agreed to be responsible for all commercialization activities for RYEQO for the treatment of women with uterine fibroids and relugolix combination tablet for endometriosis (if approved) in certain territories outside of the U.S. On May 5, 2022, we entered into the Accord License Agreement pursuant to which, among other things, Accord agreed to be responsible for all commercialization activities of ORGOVYX in the European Economic Area, U.K., Switzerland, and Turkey, with the right of first negotiation if we decide to enter into licensing arrangements in countries in the Middle East, Africa and India.

We are subject to a number of risks associated with our dependence on our relationships with our collaboration and commercialization partners, including:

- our collaboration and commercialization partners may terminate their collaboration or commercialization agreements with us for reasons specified in the collaboration or commercialization agreements, including our breach;
- the need for us to identify and secure on commercially reasonable terms the services of third parties to perform key activities, including development and commercialization activities, currently performed by our collaboration or commercialization partners in the event that a collaboration or commercialization partner was to terminate its agreement with us;
- adverse decisions by a collaboration or commercialization partner regarding the amount and timing of resource expenditures for the commercialization, distribution, and sale of our drug products;
- failure by a collaboration or commercialization partner to perform its duties under its agreement with us (e.g., its failure to comply with regulatory requirements which may disrupt its performance of its obligations under the agreement with us);
- failure by a collaboration or commercialization partner to timely deliver accurate and complete financial information to us or to maintain adequate and effective internal control over its financial reporting may negatively affect our ability to meet our financial reporting obligations as required by the SEC;
- collaboration or commercialization partners' and their affiliates' development and commercialization of products that compete directly or indirectly with our products or product candidates; for example, Accord is our commercialization partner responsible for the commercialization of ORGOVYX in Europe and one of its affiliates, Accord BioPharma (U.S.) sells Camcevi™, a competitive drug to ORGOVYX, in our U.S. market;

- decisions by a collaboration or commercialization partner to prioritize other of its current or future products more highly than our drug products or our product candidates when it performs its duties;
- possible disagreements with a collaboration or commercialization partner as to the timing, nature, and extent of our development plans or distribution and sales and marketing plans; and
- the financial returns to us, if any, under our collaboration agreements with Pfizer, Richter, and Accord depend in large part on the achievement of milestones and generation of product sales, and if Pfizer, Richter, or Accord fail to perform or satisfy their obligations under the collaboration agreements, the development and commercialization of our drug products could be delayed, hindered or may not occur and our business and prospects could be materially and adversely affected.

Due to these factors and other possible disagreements with our collaboration and commercialization partners, we may be delayed or prevented from further developing, manufacturing or commercializing our drug products or our product candidates or we may become involved in litigation or arbitration, which would be time consuming and expensive.

If any collaboration or commercialization partner were to terminate our relationship with it unilaterally, we would need to undertake development, commercialization or distribution or sale activities for our drug products and product candidates solely at our own expense, and/or seek one or more other partners for some or all of these activities in the U.S. or worldwide. If we pursued these activities on our own, it would significantly increase our capital and infrastructure requirements, might limit the indications we are able to pursue for our drug products and our product candidates, and could prevent us from effectively commercializing our drug products and our product candidates. If we sought to find one or more other pharmaceutical company partners for some or all of these activities, we may not be successful in such efforts, or they may result in collaborations that have us expending greater funds and efforts than our relationships with our current collaboration and commercialization partners.

Regulatory requirements or manufacturing disruptions may make it difficult for us to be able to obtain materials or supplies necessary to conduct clinical studies or to manufacture and sell any of our product candidates, if approved.

To sustain our business, we need access to sufficient quantities of our product candidates to satisfy our clinical study needs and, if approved, to maintain sufficient commercial inventories of our products. 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 those suppliers are not approved or the qualification of a new supplier is required. If these third parties do not perform as we expect, do not maintain their regulatory approvals or become subject to other negative circumstances, it may result in a delay in our ability to obtain approvals from the FDA or other regulatory authorities. 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 cGMP. Manufacturers are subject to regular, periodic inspections by the regulatory authorities both prior to and 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, issue import restrictions or take other cGMP or regulatory action that could affect our ability to obtain materials from such supplier. If the manufacturing operations of any single suppliers for any of our products are adversely affected or 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 studies. 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 or a pandemic, equipment failure or other difficulty, may negatively impact our development and commercialization efforts. If we were to encounter any of these difficulties, our ability to provide our products, if approved, and product candidates to patients would be jeopardized.

We are reliant on third parties to conduct, manage, and monitor our clinical studies, 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 (“GLP”) requirements. We rely substantially on CROs and clinical study sites to ensure the proper and timely conduct of our clinical studies, 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 clinical study sponsors, CROs, and clinical study sites. Although we rely on CROs to conduct our GLP-compliant nonclinical studies and GCP-compliant clinical studies, we remain responsible for ensuring that each of our nonclinical studies and clinical studies 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, our CROs or clinical study sites fail to comply with current GCP requirements, the clinical data generated in our clinical studies may be deemed unreliable and the FDA or comparable foreign regulatory authorities may reject our marketing applications or require us to perform additional clinical studies 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 studies, 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 studies, 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 studies 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.

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, products, 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 patent applications that we own or have in-licensed 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, products, 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 (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 products and 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. Our collaborations with Pfizer, Richter, and Accord also contain provisions for the assignment of, or a license to us for, intellectual property rights arising out of those agreements.

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 of our product candidates and commercialization of our drug products 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 products, 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.

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 products or 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 products or product candidates may infringe.

In addition, third parties may obtain patent rights in the future and claim that use of our technologies infringes upon such rights. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our products or 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 products or product candidates 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 products or product candidates 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 products or 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 products or product candidates, and we may do 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 products or 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 products 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, enablement, written description, or patentable 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 products, or 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, 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.

In addition, the ongoing conflict in Ukraine and related sanctions could significantly devalue our patents and patent applications in Ukraine, the Russian Federation and certain other countries and regions, such as Belarus and Eurasia. The ongoing conflict in Ukraine, the recent Russian decrees and other countries' sanctions against the Russian Federation may also significantly limit our ability to enforce our patents in Ukraine, the Russian Federation, and certain other countries. We cannot predict when or how this situation will change.

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 rely on third parties to manufacture our drug products and other clinical study materials, and any future product candidates, and we expect to collaborate with third parties on the development of relugolix, MVT-602, and any future product candidates, we must, at times, share trade secrets with them. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our partnerships, market access, distribution 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.

Risks Related to Our Being a Controlled Company

We have agreements with Sumitovant, our majority shareholder, and with Sumitovant's parent, Sumitomo Pharma, and their affiliates, including Sunovion, that may be perceived to create conflicts of interest which, if other investors perceive that Sumitovant or Sumitomo Pharma will not act in the best interests of all of our shareholders, may affect the price of our common shares and have other effects on our company.

There are a number of relationships that may give rise to certain conflicts of interest between Sumitovant and Sumitomo Pharma, and their affiliates, on the one hand, and the other investors of our common shares and us, on the other hand. We are party to the Merger Agreement, pursuant to which Sumitovant is to acquire us, and the Voting and Support Agreement, pursuant to which Sumitovant has agreed, among other things, so long as Sumitovant is not prohibited from doing so by applicable law, vote or consent all of our common shares it holds in favor of the Merger and the adoption of the Merger Agreement. We are also party to the Sumitomo Pharma Loan Agreement that creates restrictions, including limiting or restricting our ability to take specific actions, such as raising additional capital, incurring additional debt, making capital expenditures, or declaring dividends. In addition, we are party to an Investor Rights Agreement with Sumitovant and Sumitomo Pharma that, although designed in part to provide protections for our minority shareholders, also provides rights to Sumitovant and Sumitomo Pharma, such as the ability of Sumitomo Pharma to appoint directors on our board, to maintain their share ownership percentage in our company, and together with an information sharing agreement we have with Sumitovant, to provide Sumitovant with certain information and give them access to certain of our records. Further, we are a party to a Market Access Services Agreement with Sunovion, a subsidiary of Sumitomo Pharma, pursuant to which Sunovion provides certain market access services with respect to the distribution and sale of ORGOVYX and MYFEMBREE in the U.S. We may enter into additional agreements with Sumitovant or Sumitomo Pharma or their affiliates in the future. Sumitovant and Sumitomo Pharma and its affiliates may have interests which differ from our interests or those of the minority holders of our common shares. Any material transaction between us and Sumitomo Pharma and its affiliates is subject to our related party transaction policy and the Investor Rights Agreement, which requires prior approval of such transaction by our Audit Committee composed of three independent directors. 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 conduct business with us, all of which could have an adverse effect on our business, financial condition, results of operations, and cash flows, and on the market price of our common shares. Further, our agreements with Sumitovant, Sumitomo Pharma and Sunovion may result in unanticipated risks or other unintended consequences on our business and on investor perception that could have a significant impact on the market price of our common shares.

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

We are currently a "controlled company" within the meaning of the NYSE corporate governance requirements. Under these rules, a "controlled company" 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.

Risks Related to Us and Our Shareholders Related to Our Being a Foreign Corporation

We are an exempted company limited by shares incorporated under the laws of Bermuda and it may be difficult for our shareholders to enforce judgments against us or our directors and executive officers.

We are an exempted company limited by shares incorporated under the laws of Bermuda. 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, (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 in which 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, in which 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 ("BMA") must approve all issues and transfers of shares of a Bermuda exempted company. However, the BMA 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 BMA 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 without 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.

Legislation enacted in Bermuda as to economic substance may affect our operations.

Pursuant to the Economic Substance Act 2018 of Bermuda, as amended (the "Economic Substance Act") that came into force on January 1, 2019, a registered entity other than an entity which is resident for tax purposes in certain jurisdictions outside Bermuda (a "non-resident entity") that carries on as a business any one or more of the "relevant activities" referred to in the Economic Substance Act must comply with economic substance requirements. The Economic Substance Act may require in-scope Bermuda entities which are engaged in such "relevant activities" to be directed and managed in Bermuda, have an adequate level of qualified employees in Bermuda, incur an adequate level of annual expenditure in Bermuda, maintain physical offices and premises in Bermuda or perform core income-generating activities in Bermuda. The list of "relevant activities" includes carrying on any one or more of: banking, insurance, fund management, financing, leasing, headquarters, shipping, distribution and service centre, intellectual property and holding entities.

Based on the Economic Substance Act currently, for so long as we are a non-resident entity, we are not required to satisfy any such economic substance requirements other than providing the Bermuda Registrar of Companies annually information on the jurisdiction in which it claims to be resident for tax purposes together with sufficient evidence to support that tax residence. We currently do not anticipate material impact on our business or operations from the Economic Substance Act. However, since such legislation is new and remains subject to further clarification and interpretation, it is not currently possible to ascertain the precise impact of the Economic Substance Act on us. If we ceased to be a non-resident entity, we may be unable to comply with the Economic Substance Act or may have to restructure our business to comply with the Economic Substance Act, either of which may have a material adverse effect on our business.

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

We (Myovant Sciences Ltd.) are incorporated under the laws of Bermuda, where we are not subject to any income or withholding taxes. However, we are centrally managed and controlled in the U.K., and under U.K. tax law, a company which is centrally managed and controlled in the U.K. is regarded as resident in the U.K. for taxation purposes. Accordingly, we expect to be subject to U.K. taxation on our income and gains, and subject to U.K.'s controlled foreign company rules, in respect of which a tax liability could arise on certain profits of controlled companies to which no exemption applies.

We may be treated as a dual resident company for U.K. tax purposes. This could have the effect of denying us the right to claim certain reliefs from U.K. tax, although we do not anticipate any such circumstances arising at the present time.

We (or our subsidiary companies) may also become subject to income, withholding or other taxes in certain jurisdictions by reason of our activities and operations, for example, as a result of being considered to have a permanent establishment in a jurisdiction other than the one in which we are resident for tax purposes.

It is also possible that taxing authorities in any jurisdictions where we have a legal presence or otherwise operate 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 currently have subsidiaries in the U.K., Switzerland, Ireland, and the U.S. If we succeed in growing our business, we expect to conduct increased operations through our subsidiaries in these and possibly other countries and tax jurisdictions. In part, the business of our group companies is conducted through intercompany services and distribution agreements.

Our corporate structure and intercompany transactions, including the manner in which we develop and use our intellectual property, are organized so that we can achieve our business objectives in a tax-efficient manner and in compliance with applicable transfer pricing rules and regulations. Where 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 policies and procedures are not binding on applicable tax authorities.

If tax authorities in any of the countries in which we operate were to successfully challenge our transfer prices as not reflecting arm's length terms, or the facts of aspects such as our operations, management or intellectual property ownership not being in accordance with our documented or intended transfer pricing positions, they could require us to adjust our transfer prices and/or reallocate our income to reflect revised transfer pricing or profit allocations, which could result in a higher tax liability to us. 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, subject however to there being in place a tax treaty between the relevant jurisdictions requiring the respective tax authorities to enter into a mutual agreement procedure ("MAP"). Even in this case, MAP processes may still result in the proposed reallocation of income being fully or partly upheld, and they typically take a number of years to conclude, resulting in uncertainty of outcome in the meantime.

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 may be uncertain. Also, tax laws are dynamic, and our tax liabilities could be adversely affected by changes in foreign currency exchange rates or by changes in relevant tax, accounting, and other laws, regulations, principles, and interpretations. In addition, our effective tax rate could be adversely affected if tax authority interpretations, for example, on audit or in seeking clearances or rulings, differ from our own.

The application of tax laws can be subject to diverging and sometimes conflicting interpretations by tax authorities of different 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 were, for example, to reallocate income to a higher tax jurisdiction, subject our income to double taxation, disagree with positions taken on deductibility, and/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.

We continue to assess the impact of 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 such changes and developments

in the tax laws of 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 U.K., Switzerland and Ireland), the U.S., Bermuda, and other jurisdictions. It could also be affected at a future date by certain changes resulting from the Organization for Economic Co-operation and Development ("OECD") and their action plans on Base Erosion and Profit Shifting ("BEPS"), as well as other initiatives led by the OECD or the EC. The OECD is working on proposals, commonly referred to as BEPS 2.0, which, if implemented, would make important changes to the international tax system, by allocating taxing rights in respect of certain profits of multinational enterprises above a fixed profit margin to the jurisdictions within which they carry on business (subject to certain revenue threshold rules which we do not currently meet but may meet in the future) and imposing a minimum effective tax rate on certain multinational enterprises. 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 earned and determined to be attributable for tax purposes; (2) the resolution of issues arising from any future tax audits with tax authorities resulting in liabilities in excess of those for which we have previously provided; (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 of relevant jurisdictions; and (7) challenges to the transfer pricing policies related to our structure.

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

A non-U.S. corporation is considered a CFC if more than 50% 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 (directly or indirectly), 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 value of all outstanding stock of such non-U.S. corporation) 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.

We believe that we and our non-U.S. subsidiaries were classified as CFCs in the taxable year ended on March 31, 2022. For any U.S. holders who hold 10% or more of the vote or value of our common shares directly or indirectly, 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 ("IRS"). 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. holder that is a U.S. corporation. Failure to comply with these reporting and tax paying obligations may subject such U.S. holder to significant monetary penalties and may prevent the statute of limitations from starting with respect to such U.S. holder's U.S. federal income tax return for the year for which reporting was due. 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.

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 ("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. In addition, special information reporting may be required.

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets 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. With respect to the taxable year that ended on March 31, 2022, we believe that we were not a PFIC. However, we cannot predict whether we will or will not be classified as a PFIC in the current or future taxable years because the PFIC tests are based upon the average value of our assets, including any goodwill and going concern value, and the nature and composition of our income and assets, in each taxable year, which cannot be known at this time. Because the determination of whether we are a PFIC for any taxable year is a fact-intensive determination made annually after the end of each taxable year, and because certain aspects of the PFIC rules are uncertain, we therefore cannot provide any assurances regarding our PFIC status for the current or future taxable years.

The implementation of our structures and arrangements has included consideration of potential 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, resulting in an adverse impact on the determination of whether we are classified as a PFIC.

General Risk Factors

Raising additional funds may cause dilution to existing shareholders and/or may restrict our operations.

To the extent that we raise additional funds by issuing equity or convertible debt securities, our existing shareholders' ownership interest 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. 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 raising additional capital, incurring additional debt, making capital expenditures, or declaring dividends.

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

We expect to hire additional employees. The market for talent in our industry is very competitive. Many of the other pharmaceutical companies we compete against for qualified personnel have greater financial and other resources, more favorable risk profiles and a longer operating history in the pharmaceutical 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 than what we have to offer. It is particularly difficult to recruit and hire new employees during the COVID-19 pandemic as conducting interviews remotely makes it more difficult to ensure we are recruiting and hiring high-quality employees, and the uncertainty created by the COVID-19 pandemic makes it less likely potential candidates will be willing to leave a stable job to explore a new opportunity.

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. If we lose one or more members of our senior management team or key employees or unable to attract and retain other personnel to accomplish our business objectives, our ability to successfully implement our business strategies could be seriously harmed.

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

We expect to continue 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 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 net product revenue could be adversely affected, and we may not be able to implement our business strategies. As a result, our future financial performance and our ability to complete clinical development, obtain regulatory approval, and commercialize our product candidates or any potential future product candidate may be adversely affected.

Our business is affected by macroeconomic conditions, including rising inflation, interest rates and supply chain constraints.

Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and overall economic conditions and uncertainties such as those resulting from the current and future conditions in the global financial markets. For instance, inflation could negatively impact us by increasing our cost of labor (through higher wages), commercial support, manufacturing and clinical supply expenditures. Recent supply chain constraints have led to higher inflation, which if sustained could have a negative impact on our operations. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the operation of our business and our ability to raise capital in order to fund our operations, if needed. Similarly, these macroeconomic factors could affect the ability of our third-party suppliers and manufacturers to manufacture clinical trial materials required for our product candidates, as well as commercial product to support our commercialization activities of our approved products. If our costs become subject to significant inflationary pressures, we may not be able to fully offset such higher costs with increased revenues. Our inability or failure to do so could harm our business, financial condition, and results of operations.

Potential product liability lawsuits against us could cause us to incur substantial liabilities and could impact ongoing and planned clinical studies as well as limit commercialization of any products that we may develop.

The use of any of our product candidates in clinical studies 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, healthcare providers, other pharmaceutical companies or others taking or otherwise coming into contact with our products or product candidates. On occasion, large monetary judgments have been awarded in class action lawsuits in which drugs have had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liabilities and costs.

In addition, regardless of merit or eventual outcome, product liability claims may result in:

- inability to commercialize our products or any future products;
- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical studies;
- significant costs to defend related litigation;
- distraction of management’s attention from our primary business;
- substantial monetary awards to patients or other claimants;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased demand for our products or any future products, if approved for commercial sale; and
- loss of net product revenue.

The product liability and clinical study insurance we currently carry, and any additional product liability and clinical study 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 commercially reasonable terms or in adequate amounts to protect us against losses due to liability. 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.

Use of social media platforms presents risks of inappropriate or harmful disclosures which could harm our business.

We believe that our potential 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 or 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, our products, or our product candidates on any social media platform. 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.

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.

Our operating results may fluctuate significantly and our future operating results could fall below expectations. 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 significant fluctuations in response to a variety of factors. Our quarterly and annual operating results may fluctuate significantly in the future. Any future net product revenue will depend on the successful commercialization and sales of our drug products and product candidates that receive marketing approval. Any future regulatory milestones, sales milestones and royalty payments we are eligible to earn under the terms of our collaboration agreements with Pfizer, Richter, Accord, or any potential future collaboration and license agreements, if any, will depend on the achievement of the underlying milestone event or level of sales activity. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including:

- the price, level of demand, and net revenues for our products, which may vary significantly as they are launched and compete for position in the marketplace;
- the achievement of regulatory milestones, commercial launch milestones, sales milestones, and/or royalties that we are eligible to earn pursuant to our collaboration or commercialization agreements;
- the extent to which coverage and adequate reimbursement is available from government and private payers such as Medicare Part D, Medicaid, the Department of Veterans Affairs, the Department of Defense, pharmacy benefit managers, health plans, self-insured organizations, insurance companies and other plan administrators with respect to our drug products and product candidates, if approved, and the competitive response from existing and potential future therapeutic approaches that compete with our approved products and our product candidates;
- inability to obtain additional funding, or investor perception that we may be unable to obtain additional funding, if needed, or funding on desirable terms;
- any delay in the commencement, enrollment, and ultimate completion of our clinical studies;
- actual or anticipated results of clinical studies of any of our product candidates or those of our competitors;
- any delay in submitting an NDA or similar application for any of our product candidates 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 any of our current or future product candidates;
- regulatory or legal developments in the U.S. or other countries or jurisdictions applicable to any of our products or current or future product candidates;
- adverse regulatory decisions or findings;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for any of our products or current or future product candidates, or the inability to do so at acceptable prices;
- inability to maintain a qualified sales force;
- inability to establish and maintain commercial capabilities and expertise including product marketing, sales, trade and distribution, pricing, market access, data analytics and insights, and other commercial operations functions;
- adverse developments or perceived adverse developments with respect to vendors on which we rely, including CMOs, CROs and third-party logistics providers;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we may provide to the public;
- failure to maintain effective internal control over financial reporting;
- failure to meet or exceed the estimates and projections of the investor 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 on us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- adverse developments or perceived adverse developments with respect to our manufacturing, collaboration and alliance partners and affiliates, including Takeda, Excella, Sumitovant, Sumitomo Pharma, Sunovion, Pfizer, Richter and/or Accord;
- 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 our management, or other key personnel;
- short sales of our common shares;
- sales or purchases of a substantial number of our common shares in the public market, by any of our significant shareholders, or the perception in the market that the holders of a large number of our common shares intend to sell or purchase common shares;
- sales or purchases of our common shares by our executive officers or members of our board of directors;
- issuance of additional shares of our common shares, or the perception that such issuances may occur;
- negative coverage in the media or securities analyst reports, whether accurate or not;
- any changes in our relationships with Sumitomo Pharma, Sumitovant, Sunovion and/or their respective affiliates, or actions taken or omission of actions with respect to the Sumitomo Pharma Loan Agreement, the Investor Rights Agreement, the Market Access Services Agreement or under the other agreements we entered with Sumitomo Pharma, Sumitovant, Sunovion and their respective affiliates;

- 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, our business, and our majority shareholder;
- various social, political, economic, industry, and market conditions in the U.S. and around the world (including wars and other forms of conflict, such as the conflict in Ukraine);
- effects of natural or man-made catastrophic events, including the COVID-19 pandemic; and
- the other factors described in this "Risk Factors" section.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or securities analysts or investors for any period. If our operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the public, or if the forecasts we provide to the public are below the expectations of securities analysts or investors, the price of our common shares could decline substantially. Such a share price decline could occur even when we have met any previously publicly stated operating results and/or earnings guidance that we may provide.

If we are unable to 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 to assess the effectiveness of our internal control over financial reporting annually and disclosure controls and procedures quarterly. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. In addition, we are also required to include in our Annual Report on Form 10-K 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. 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.

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

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.

Additionally, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant share price volatility in recent years. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations, and growth prospects.

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, if any, 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 Sumitomo Pharma 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.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit No.		Description of Document	Schedule / Form	File No.	Exhibit No.	Filing Date
2.1	+	Agreement and Plan of Merger, dated as of October 23, 2022, among Myovant Sciences Ltd., Sumitovant Biopharma Ltd., Merger Sub and, solely with respect to Article IX and Annex A, Sumitomo Pharma Co., Ltd.	8-K	001-37929	2.1	10/24/2022
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		Fifth Amended and Restated Bye-Laws.	10-Q	001-37929	3.3	02/10/2020
10.1	†*	Amended and Restated Manufacturing & Services Agreement by and between Excella GmbH & Co. KG and Myovant Sciences GmbH, dated April 2, 2021.				
10.2	†*	Amendment No. 3 to Market Access Services Agreement by and between Sunovion Pharmaceuticals Inc. and Myovant Sciences GmbH, dated March 15, 2021.				
10.3	†*	Amendment No. 4 to Market Access Services Agreement by and between Sunovion Pharmaceuticals Inc. and Myovant Sciences GmbH, dated August 9, 2022.				
10.4	†*	Letter Agreement by and between Myovant Sciences GmbH and Pfizer, Inc. dated September 19, 2022.				
10.5		Voting and Support Agreement, dated as of October 23, 2022, between Myovant Sciences Ltd. and Sumitovant Biopharma Ltd.	8-K	001-37929	10.1	10/24/2022
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		Inline XBRL Instance Document- the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH		Inline XBRL Taxonomy Extension Schema				
101.CAL		Inline XBRL Taxonomy Extension Calculation Linkbase				
101.DEF		Inline XBRL Taxonomy Extension Definition Linkbase				
101.LAB		Inline XBRL Taxonomy Extension Label Linkbase				
101.PRE		Inline XBRL Taxonomy Extension Presentation Linkbase				
104		Cover Page Interactive Data File - the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				

† Filed herewith.
†† Furnished herewith.
+ Certain of the exhibits and schedules to this exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5). The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.
* Portions of this exhibit have been omitted from this exhibit (indicated by asterisks) as such portions are both (a) not material and (b) is the type of information that the Registrant treats as private or confidential.

** 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/ Uneek Mehra

Uneek Mehra
(Duly Authorized Officer and Principal Financial Officer)

Date: October 26, 2022

Exhibit 10.1

EXECUTION COPY
CONFIDENTIAL

CERTAIN INFORMATION IDENTIFIED BY "[***]" HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

AMENDED AND RESTATED

MANUFACTURING & SERVICES AGREEMENT

BY AND BETWEEN

EXCELLA GMBH & CO. KG,

AND

MYOVANT SCIENCES GMBH.

EFFECTIVE DATE: April 04, 2019

RESTATEMENT DATE: April 2, 2021

AMENDED AND RESTATED MANUFACTURING & SERVICES AGREEMENT

This Amended and Restated Manufacturing & Services Agreement (the "**Agreement**") is made effective as of April 04, 2019 (the "**Effective Date**") by and between **Excella GmbH & Co. KG**, a company having its registered office at N✔rnberger Str. 12, 90537 Feucht, Germany and registered with the Amtsgericht N✔rnberg under the number HRA 17667 ("**Excella**" or "**Supplier**") and **Myovant Sciences GmbH**, a company having its principal place of business at Viaduktstrasse 8, 4051 Basel, Switzerland ("**Myovant**"), and amended and restated as of April 2, 2021 (the "**Restatement Date**"). Myovant and Supplier are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Myovant is a pharmaceutical company engaged in the development and commercialization of treatments for endocrine-related diseases or disorders;

WHEREAS, Supplier is a pharmaceutical contract development and manufacturing organization; and

WHEREAS, Myovant desires to procure a supply of Product(s) (defined below) from Supplier, and Supplier desires to provide such Product(s), all in accordance with the terms and conditions hereof.

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

ARTICLE 1
DEFINITIONS

The following capitalized terms used in this Agreement shall have the meanings specified below:

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

1.2 "**Applicable Laws**" means any applicable federal, state, local, municipal, foreign, or other law, statute, legislation, constitution, principle of common law, code, treaty ordinance, regulation, rule, or order of any kind whatsoever put into place under the authority of any Governmental Authority, including the FFDCA, Prescription Drug Marketing Act, the Generic Drug Enforcement Act of 1992 (21 U.S.C. §335a et seq.), U.S. Patent Act (35 U.S.C. §1 et seq.), Federal Civil False Claims Act (31 U.S.C. §3729 et seq.), and the Anti-Kickback Statute (42 U.S.C. §1320a-7b et seq.), all as amended from time to time, together with any rules, regulations, and compliance guidance promulgated thereunder. "Applicable Law" will include the applicable regulations and guidance of the FDA that constitute Good Manufacturing Practices (and, if and as appropriate under the circumstances, other comparable regulation and guidance of any applicable Governmental Authority).

1.3 "**Batch**" means a specific quantity of a Product that (a) is intended to have uniform character and quality pursuant to the Specifications and (b) is produced according to a single order during the same Manufacturing cycle.

1.4 "**Batch Documentation**" means, with respect to a Product, the documentation provided to Myovant or its designee at the time of delivery of such Product, as agreed upon by the Parties in the Quality Agreement or as required by Applicable Laws.

1.5 "**Business Day**" means a day other than Saturday, Sunday, or any other day on which commercial banks located in the State of New York, U.S., N✔rnberg, Germany or Zurich, Switzerland are authorized or obligated by Applicable Law to close.

1.6 "**Calendar Year**" means the twelve (12) month period ending on December 31; *provided*, *however*, that (a) the first Calendar Year of the Term will begin on the Effective Date and end on

December 31, 2019 and (b) the last Calendar Year of the Term will end upon the expiration or termination of this Agreement.

1.7 "**CMC**" means chemistry, manufacturing, and controls.

1.8 "**Commercial Product**" means a final, packaged pharmaceutical product consisting of: (a) the Drug Product; (b) the Drug Product and the Myovant Companion Product co-packaged together; or (c) Relugolix in a fixed-dose combination with any other active pharmaceutical ingredient(s).

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

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

1.11 "**Credit Note**" means a credit memo issued by one Party to the other Party and usable by this Party as: (i) an offset against amounts payable to the other Party or, (ii) if no such amounts are outstanding at the time of termination or expiration of this Agreement, for a refund from the other Party which the other Party shall pay no later than forty five (45) days after any such termination or expiration.

1.12 "**Detectable Defect**" is defined in Section 10.1.

1.13 "**Drug Product**" means a final pharmaceutical product consisting of bulk oral solid dosage tablets containing Relugolix.

1.14 "**Drug Substance**" means the active pharmaceutical ingredient Relugolix.

1.15 "**Excluded Affiliate**" means (1) for Myovant: (a) any Myovant Parent Affiliate or (b) any direct or indirect subsidiary of a Myovant Parent Affiliate, other than any Myovant Parent, that (i) is controlled (as defined in Section 1.1) by such Myovant Parent Affiliate but is not controlled by Myovant or any Myovant Parent and (ii) is established for the development and commercialization of compounds and products other than the Drug Product and (2) for Supplier: Fareva S.A.

1.16 "**Excluded Territory**" means, subject to Section 6.3, Japan, China Hong Kong, Indonesia, Korea, Malaysia, Philippines, Singapore, Taiwan, Thailand, and Vietnam.

1.17 "**Expiration Date**" is defined in Section 10.2.

1.18 "**Facility**" means Supplier's facility located at [***] or another facility as otherwise mutually agreed upon by the Parties in writing pursuant to Section 8.3.

1.19 "**FDA**" means the United States Food and Drug Administration, and any successor agency thereto.

1.20 "**FFDCA**" means the Federal Food, Drug and Cosmetic Act under United States Code, Title 21, as amended from time to time, together with any rules, regulations, and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto.

1.21 "**Firm Order**" is defined in Section 7.1.2.

1.22 "**Firm Order Period**" is defined in Section 7.1.2.

1.23 "**Force Majeure Event**" is defined in Section 20.1.

1.24 "**GnRH**" means gonadotropin-releasing hormone.

1.25 "**Good Manufacturing Practices**" or "**GMP**" means all applicable then-current standards for Manufacturing, including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. §§ 210, 211, 600 and 610 and all applicable FDA guidelines and requirements, (b) the principles detailed in the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time, and (c) cooperation with the conduct of any inspection by qualified persons to ensure compliance with the foregoing standards.

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

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

1.28 "**Intellectual Property Rights**" means any proprietary rights with respect to inventions, apparatuses, methods, processes, works of authorship or marks, including: (i) patents, patent applications, and certificates of invention; (ii) trade secrets, know-how, and similar rights in confidential or proprietary information; (iii) copyrights and moral rights; (iv) trademarks, trade names, logos, trade dress, and similar indicia of origin; and (v) similar proprietary rights under any laws and in any jurisdiction throughout the world.

1.29 "**Latent Defect**" is defined in Section 10.2.

1.30 "**Manufacture**" or "**Manufacturing**" means all activities by or on behalf of a Party related to the manufacturing of any Product, or any ingredient thereof, including test method development and stability testing, formulation, manufacturing scale-up, manufacturing for Development or Commercialization, labeling, filling, processing, packaging, in-process and finished Product(s) testing, shipping, storing, or release of any Product or any ingredient thereof, quality assurance and quality control activities related to manufacturing and release of any Product, ongoing stability tests, and regulatory activities related to any of the foregoing. When used as a noun, "**Manufacture**" or "**Manufacturing**" means any and all activities involved in Manufacturing.

1.31 "**Myovant Background IP**" the Intellectual Property Rights owned or controlled by Myovant or its Affiliate(s) as of the Effective Date or thereafter.

1.32 "**Myovant Companion Product**" means any pharmaceutical product or preparation containing estradiol and/or norethindrone acetate that is (a) Manufactured, used, sold, offered for sale, imported or otherwise developed or Commercialized by or on behalf of Myovant, its Affiliates or any Myovant Licensee and (b) is co-packaged or co-formulated with Drug Product.

1.33 "**Myovant Licensee**" has the meaning set forth in Section 3.1.

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

1.35 "**Myovant Parent Affiliate**" means any Person that controls (as defined in Section 1.1) the Myovant Parent, including, as of the Restatement Date, Sumitovant Biopharma Ltd.

1.36 "**Myovant Technology**" means all Intellectual Property Rights that are owned or controlled by Myovant or its Affiliates as of the Effective Date and during the Term solely to the extent the use or practice of such Intellectual Property Rights is necessary for the Manufacture of Product(s) to be supplied to Myovant in accordance with the terms and conditions of this Agreement.

1.37 "**NDA**" means a (a) New Drug Application or supplemental New Drug Application as contemplated by Section 505(b) of the FFDCA, submitted to the FDA pursuant to 21 C.F.R. § 314, including any amendments thereto or (b) any comparable applications filed in or for countries or jurisdictions outside of the United States to obtain Regulatory Approval to Commercialize a Commercial Product in that country or jurisdiction.

1.38 "**Notified Party**" has the meaning set forth in Section 6.2.

1.39 "**Permits**" means any licenses, permits, registrations, certifications or other approvals from a Governmental Authority.

1.40 "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.

1.41 "**Product(s)**" means Drug Substance and/or RSM, as applicable.

1.42 "**Project Invention**" is defined in Section 15.2.

1.43 "**Purchase Order**" is defined in Section 7.1.3.

1.44 "**Qualified Territory**" means the countries in the Territory that are listed on Exhibit A.

1.45 "**Quality Agreement**" means the Quality Assurance Agreement between the Parties for the supply of Product(s) under this Agreement to be entered into in accordance with Section 8.4.

1.46 "**Quality Release**" means certification by Supplier's quality control department that each Product that is Manufactured by or on behalf of Supplier complies with the Quality Agreement and Supplier's quality release specifications as confirmed by release testing.

1.47 "**Recall**" means a Party's removal or correction of Commercial Product following (a) notice or request of any Regulatory Authority or (b) the good faith determination by such Party that an event, incident, or circumstance has occurred that required such a recall of such Commercial Product. A Recall does not include a market withdrawal or a stock recovery.

1.48 "**Regulatory Approval**" means the approval(s), authorizations or reviews (including "safe-to-proceed" letters) of the applicable Regulatory Authority(ies) in a country or jurisdiction that are necessary to conduct research and clinical development of a pharmaceutical product or to market, promote, sell or distribute a pharmaceutical product.

1.49 "**Regulatory Authority**" means any applicable Governmental Authority involved in granting Regulatory Approval or issuing a Recall for a Commercial Product or Product(s), including the FDA.

1.50 "**Regulatory Materials**" means regulatory applications, filings, submissions, notifications, registrations, Regulatory Approvals, or other submissions, including any written correspondence or meeting minutes, made to, made with, or received from any Regulatory Authority submitted to a Regulatory Authority in any country for the purpose of obtaining Regulatory Approval from that Regulatory Authority (including all NDAs, and associated common technical documents) and any amendments and supplements thereto, and all data and other information contained in, and Regulatory Authority correspondence relating to, any of the foregoing. Regulatory Materials include the Product NDAs, and amendments and supplements thereto.

1.51 "**Regulatory Qualifications**" is defined in Section 17.2.1(a).

1.52 "**Relugolix**" means the GnRH receptor antagonist that, as of the Effective Date, is being developed by Myovant or its Affiliates.

1.53 "**Rolling Forecast**" is defined in Section 7.1.1.

1.54 "**RSM**" means regulatory starting material needed for the Manufacture of Drug Substance as specified on Schedule 1.54 as may be updated from time to time at Myovant's sole option by written notice to Supplier.

1.55 "**RSM Option Payment**" is defined in Section 7.1.3(a).

1.56 "**Scope of Work**" is defined in Section 13.2.

1.57 "**Shelf-Life**" is defined in Section 7.2.1.

1.58 "**Specifications**" means, with respect to a country or region, the specifications for the design, composition, Manufacture, packaging, and/or quality control of the Product(s) applicable to such country or region, as set forth in Exhibit B attached hereto, which may be amended from time-to-time.

1.59 "**Subcontractor**" is defined in Section 3.3

1.60 "**Supplier Background IP**" means the Intellectual Property Rights owned or controlled by Supplier as of the Effective Date or thereafter.

1.61 "**Supplier Technology**" means pre-existing products, materials, tools, methodologies, technologies or Intellectual Property Rights of Supplier embodied in the Project Inventions; provided that Supplier documents its pre-existing ownership of any such Supplier Technology embodied in any Project Invention.

1.62 "**Technology Transfer Plan**" shall have the meaning assigned to it in Section 13.1.

1.63 "**Term**" is defined in Section 19.1.

1.64 "**Territory**" means all countries in the world except for the Excluded Territory.

1.65 "**Third Party**" means a Person other than Supplier, Myovant or their respective Affiliates.

1.66 "**United States**" or "**U.S.**" means the United States of America and its territories, districts, commonwealths and possessions (including the Commonwealth of Puerto Rico).

ARTICLE 2
PRODUCT SUPPLY

2.1 Purchase and Supply. Subject to the terms and conditions set forth in this Agreement and the Quality Agreement, Supplier shall supply to Myovant or, at Myovant's request, any Myovant Licensee or their designees, and Myovant shall obtain from Supplier, certain quantities of Product(s) ordered in accordance with this Agreement. For clarity, Myovant may use, sell or otherwise transfer to any Third Party the Product(s) supplied hereunder, or any Commercial Product that incorporates such Product(s), as necessary to meet some or all of the requirements of Myovant, its Affiliates, Subcontractors and Myovant Licensees in connection with the Commercialization of Commercial Product as authorized and contemplated herein. At Myovant's request, Supplier shall negotiate in good faith with any Myovant Licensee to supply Product(s) directly to such Myovant Licensee under substantially the same terms and conditions as this Agreement, including pricing.

2.2 Exclusivity. During the Term and for a period of [***] thereafter, Supplier shall not, without Myovant's written consent, develop, Manufacture or supply any Drug Substance or RSM, or any product containing Relugolix, for or to any Third Party.

ARTICLE 3
GRANT OF RIGHTS

3.1 License Grants to Myovant. Subject to the terms and conditions of this Agreement, Supplier hereby grants to Myovant a worldwide, perpetual, irrevocable, non-exclusive, royalty-free, fully paid-up, license (with the right to sublicense) to: (a) the Supplier Technology and the Supplier Background IP as necessary for Myovant's use of the Project Inventions for any and all purposes; and (b) the Supplier Technology and Supplier Background IP as far as necessary and for the sole purpose to package, market, distribute, offer to sell, sell and have sold Product(s), either on its own or as part of a Commercial Product. For clarity, Myovant will have the right to grant sublicenses, through multiple tiers, of the rights granted to Myovant under this Section 3.1 to its Affiliate(s) and/or any Third Parties (each, a "**Myovant Licensee**").

3.2 License Grants to Supplier. Subject to the terms and conditions of this Agreement, Myovant hereby grants to Supplier:

(a) a worldwide, perpetual, irrevocable, non-exclusive, fully royalty-free, fully paid-up license, without the right to grant sublicenses, under the Project Inventions to manufacture products other than (i) the Product(s), or (ii) products that compete with the Product(s), in each case if and to the extent that the Project Inventions are also capable to be used for the manufacturing by Supplier of products other than the Products; and

(b) a non-exclusive, non-transferrable, non-sublicensable license under the Myovant Technology solely to the extent necessary to permit Supplier to perform its obligations under this Agreement during the Term.

3.3 Subcontractors. In performing its activities under this Agreement, Supplier may engage consultants, subcontractors or other vendors to conduct its obligations thereunder or hereunder (each, a "**Subcontractor**"); *provided that* (a) Supplier remains responsible for (i) the management of its Subcontractors, (ii) fulfillment by its Subcontractors of all obligations set forth under this Agreement as if the Subcontractor were a party hereto, and (iii) any breach of this Agreement by a Subcontractor, and (b) Supplier will terminate promptly any Subcontractor, and will give the other Party notice of such termination, in the case of any material breach of this Agreement by a Subcontractor. In the event that Supplier wishes to engage a Subcontractor to perform any obligations subject to oversight by any Regulatory Authority, then, without limiting the generality of the foregoing, Supplier shall: (A) provide prior written notice to Myovant, which notice must identify, at a minimum, the Person whom would be acting as such a Subcontractor and a description of the work to be conducted by such Person; and (B) not permit any such Subcontractor to perform any work in connection with this Agreement until Myovant has provided written consent. Without limitation, such contracts entered into with Subcontractors will contain provisions, including those relating to Intellectual Property Rights, confidentiality, and non-use that are no less restrictive than those set forth in this Agreement.

3.4 No Implied License. No license or other right is or will be created or granted hereunder by implication, estoppel, or otherwise. All licenses and rights are or will be granted only as expressly provided in this Agreement.

ARTICLE 4
PRICE

4.1 Price. In consideration for all Manufacturing activities performed and materials used by Supplier or its Subcontractors in the Manufacture of Product(s) under this Agreement, including other raw materials, consumables, maintenance, direct and indirect labor costs, depreciation and a profit margin thereon, Myovant shall pay Supplier for quantities of Product(s) delivered to Myovant, its Affiliates or their designees under this Agreement pursuant to a Firm Order in accordance with Section 7.1.2, and pursuant to the corresponding Purchase Order in accordance with Section 7.1.3, in accordance with the applicable prices set forth in Schedule 4.1. For clarity, Supplier may Manufacture the Drug Substance using RSM that is Manufactured by Supplier, sourced from a Third Party that is agreed by Myovant, or provided by Myovant, at Myovant's option as indicated in the applicable Firm Order and corresponding Purchase Order.

[***].

4.2 Invoicing. Supplier shall submit an invoice to Myovant for Product(s) no earlier than release by Supplier of such Product(s) in accordance with the Quality Agreement and make available for shipment of such Product(s) to Myovant in accordance with Section 7.2 and Section 9.1; provided, however, that Supplier

may submit a request for deposit payment for RSM Option Payments in accordance with Section 7.1.3(a). In addition, Supplier shall deliver each such invoice to: [***]. Each invoice shall be accompanied by the following information: applicable Purchase Order number(s), quantities of Product(s), the corresponding prices and lot numbers for each of the foregoing in accordance with Section 4.1, any applicable payment for RSM Option Payments received by Supplier in accordance with Section 7.1.3(a), freight charges and the total amount to be remitted by Myovant; in each case, in accordance with this Agreement. Without limiting the generality of the foregoing, each invoice submitted to Myovant shall be accompanied by the relevant Batch Documentation for such shipment of Product(s). Myovant shall pay such invoices in accordance with Article 14.

4.3 Currency. All payments hereunder shall be made in Euros.

ARTICLE 5
MANUFACTURING FACILITIES

5.1 Facility. The Parties acknowledge and agree that Supplier will Manufacture the Product(s) under this Agreement only at the Facility.

ARTICLE 6
REGULATORY ACTIVITIES AND RESPONSIBILITIES

6.1 General Obligations of Supplier; Audits. Supplier shall, or shall cause its Affiliates or Third Parties on its behalf to, (a) perform its obligations under this Agreement in compliance with all Applicable Laws, including all GMPs, and in accordance with the Quality Agreement, (b) undertake all regulatory activity with respect to the Manufacture of the Product(s), including components thereof in accordance with this Agreement and as otherwise required by Applicable Laws or Regulatory Authorities. Supplier shall be responsible for maintaining all Permits and establishment fees required by any Regulatory Authority with respect to any Supplier Manufacturing facility where any aspect of the Product(s) is Manufactured, including but not limited to the Facility. Supplier shall support Myovant in audits of quality and compliance systems of Supplier (not more than one (1) Myovant audits in any twelve (12) month period) in addition to other customary matters related to regulatory compliance. Additional "for cause" audit(s) that are required to address legitimate quality concerns will not be considered an annual audit and will be at no cost to Myovant.

6.2 Communication with Regulatory Authorities. Notwithstanding anything to the contrary in the Quality Agreement, following receipt by a Party (the "**Notified Party**") or its Affiliate(s) or Subcontractor(s) of any regulatory inquiry or communication, or the occurrence of any inspection, regarding the Manufacture of Product(s) and/or Commercial Product in compliance with GMP, the Notified Party shall promptly (but in no event later than three (3) Business Days after the Notified Party receives such inquiry or communication or twenty-four (24) hours such without-notice-inspection commences, as applicable) notify the other Party in writing thereof. If the Notified Party or its Affiliate(s) or Subcontractor(s) receive notice of an inspection or an inspection visit by any Governmental Authority that directly involves Product(s) or Commercial Product or is likely to materially impact Supplier's ability to supply Product(s) to Myovant hereunder, the Notified Party shall give the other Party prompt written notification thereof (but in no event later than three (3) Business Days after Notified Party receives such notice) and the Notified Party shall provide the other Party with copies of applicable documentation with respect thereto, and such other Party shall have a reasonable opportunity to review and comment on the Notified Party's proposed response; *provided, however*, that such other Party's opportunity to review and comment shall not be extended so as to cause any response of the Notified Party to be later than is required by such Governmental Authority. Unless prohibited by Applicable Law, the Notified Party shall allow a representative of the other Party to be present at and observe any inspection by any Governmental Authority concerning Product(s) or Commercial Product; provided that, if such other Party is Myovant, then Supplier shall, in addition (and unless prohibited by Applicable Law), allow a representative of any licensee of Myovant to be present at and observe any such inspection if such representative agrees to terms of confidentiality and other terms and conditions required by Supplier in connection with entering its facility. All other communications with Regulatory Authorities, including without limitations any regulatory audits, shall be governed by the Quality Agreement.

6.3 Expansion of Qualified Territory. If, after the Effective Date, Myovant, or any of Myovant's Affiliates or licensees or sublicensees, obtains Regulatory Approval to market, promote or use Commercial Product in any country or jurisdiction of the Territory other than those within the Qualified Territory as of the date of such Regulatory Approval, then: (a) Supplier shall, at Myovant's request, exert reasonable efforts to obtain Regulatory Qualifications as promptly as possible in such new country(ies) or jurisdiction(s), and (b) such new country(ies) or jurisdiction(s) will automatically be added to the Qualified Territory and the representations, warranties and covenants described herein will apply with respect thereto; provided, however, that in the event the business case for seeking such Regulatory Qualifications of Supplier, as requested by Myovant, does not reasonably

justify the efforts related to this country, then the Parties agree to meet and to negotiate the cost responsibility before starting the Regulatory Qualifications process.

ARTICLE 7
FORECASTING AND ORDERING

7.1 Forecasts and Purchase Orders.

7.1.1 Forecasts. No later than the period as specified below under "Lead Time" prior to the intended supply of the first commercial batches, and thereafter no later than the [***] during the remainder of the Term, Myovant shall submit to Supplier, at the contact information provided below, Myovant's [***] forecast for its desired quantities of the Product(s) to be delivered to Myovant [***] covering the period specified below under "Forecast Period" (each, a "**Rolling Forecast**"). Myovant will submit each Rolling Forecast to the addressee listed in Schedule 7.1.1, which Supplier may update or change by providing written notice to Myovant in accordance with Section 20.2 of this Agreement. The Rolling Forecast shall set forth the [***].

7.1.2 Binding Quantities. With respect to each Rolling Forecast submitted by Myovant in accordance with Section 7.1.1, the first number of months specified below under "Firm Order Period" (each as applicable, a "**Firm Order Period**") [***] ("**Firm Order**"). [***].

Product	Lead Time	Forecast Period	Firm Order Period
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

7.1.3 Purchase Orders.

(a) **Issuance and Acceptance**. With its submission of the first Rolling Forecast, Myovant shall submit a separate purchase order for Product(s) (each, a "**Purchase Order**") for the Firm Order Period as set forth in the first Rolling Forecast to Supplier. Each Purchase Order shall specify [***]. Thereafter, with each Rolling Forecast submitted to Supplier pursuant to Section 7.1.1, Myovant shall submit a Purchase Order for the month of the Rolling Forecast that has become a Firm Order for the first time (*i.e.*, the month for which no Purchase Order was previously submitted). With respect to [***], the Parties will consult and mutually agree in writing on [***]; and each such payment, a "**RSM Option Payment**"). [***]. To the extent of any conflict between a Purchase Order and this Agreement, this Agreement shall control.

(b) **Deviations from the Firm Order Period**. If the quantity set forth in a Purchase Order exceeds the quantity set forth in the corresponding month of the Firm Order Period, Supplier shall use reasonable efforts to satisfy the amount contained in a Purchase Order; provided, however, that (i) Supplier shall not reject any Purchase Order that, considered in the aggregate with other Purchase Orders placed pursuant to a Firm Order Period in a Rolling Forecast, is for an aggregate quantity of Product(s) totaling up to [***] of the quantities identified in such Firm Order Period, and (ii) Supplier shall not be in breach of this Agreement if it does not deliver quantities in excess of [***] of the quantity set forth in corresponding month of the Firm Order Period. For the avoidance of doubt, such reasonable efforts shall not require Supplier to reschedule or otherwise delay either any Manufacturing runs for any other product or any planned shut-down of a Manufacturing facility, including without limitation the Facility.

(c) **Cancellations**. If Myovant cancels any Firm Order for Drug Substance or RSM, then Myovant shall make the applicable payment as set forth in Schedule 7.1.3. If Myovant pays [***] of such Firm Order, then Supplier shall deliver the Drug Substance or RSM pursuant to Section 7.2. If Myovant reimburses Supplier for raw materials and/or intermediates, then Supplier shall store such raw materials in suitable conditions, and use such raw materials and/or intermediates to fulfill the next subsequent Firm Orders of Drug Substance or RSM.

7.2 Delivery. Subject to Section 20.1, Supplier shall supply the Product(s) ordered under a Purchase Order by way of delivery pursuant to Article 9. If Supplier is unable to meet the specified delivery date,

Supplier shall promptly notify Myovant and provide to Myovant an alternative delivery date which is as close to the original delivery date as reasonably possible.

7.2.1 Shelf-Life. With respect to the manufacture of Product(s) under this Agreement, at the time Product is made available for shipment to Myovant, such Product shall have no less than [***] of its Shelf-Life remaining. For purposes of this Section 7.2.1, the term "**Shelf-Life**" means the length of time that elapses between the date that such Product is released by Supplier and the date that such Product must be re-tested as determined by Supplier based on current stability results as of the date such Product is made available for shipment by Supplier to Myovant. For illustrative purposes, [***]. In the case of such remaining Shelf-Life at delivery being (or anticipated to be) less than the foregoing, then Supplier shall notify Myovant in writing promptly after Supplier's receipt of the applicable Purchase Order and may deliver the Product on a schedule agreed to in writing by Myovant.

7.2.2 Testing by Supplier. Prior to delivery by Supplier pursuant to Section 9.1, Supplier shall undertake release testing to obtain a Quality Release for each Batch of the Product(s) that is Manufactured pursuant to a Purchase Order and in accordance with the terms of the Quality Agreement.

7.2.3 Provision of Records. With each Batch of Product(s) delivered by Supplier pursuant to Section 9.1, Supplier shall provide for each Batch all Batch Documentation, including a certificate of analysis, Quality Release and certificate of conformance, in each case in accordance with the terms of the Quality Agreement.

7.2.4 Delayed Deliveries. Supplier shall notify Myovant immediately if Supplier believes that it may not be able to deliver the Product(s) by the delivery date specified in the relevant Purchase Order. Upon such notice, the Parties shall discuss in good faith ways in which the delay can be avoided (or if it cannot be avoided, shortened) and Supplier shall consider and implement in good faith any reasonable suggestion by and discussion/agreement with Myovant to avoid or mitigate the delay. Notwithstanding the foregoing, unless otherwise agreed to in writing by both Parties, if Supplier delivers the Product(s) more than [***] after the delivery date specified in the relevant Purchase Order, and the failure to deliver is not as a result of a Force Majeure Event and attributable to Supplier, then Supplier shall discount the price for the affected shipment(s) of Product(s) by [***] per each [***] period exceeding the aforementioned [***] after such delivery date, up to [***] of the price for such Product(s) over a period ending [***] after such originally specified delivery date. At Myovant's option, any such discounted amounts under this Section 7.2.4 shall be payable to Myovant as a set-off against other payments that Myovant may owe Supplier. If Supplier has not delivered such Product(s) after such [***] period has elapsed, then, in addition to any other remedies Myovant may have under this Agreement, Myovant shall be entitled to deduct the applicable RSM Option Payment (or applicable portion thereof) from any other payments that Myovant may owe Supplier. If Supplier fails to deliver Product(s) in the quantities and by the delivery dates specified in the relevant Purchase Order or based on the mutual agreement for any [***] in a Calendar Year, and the failure to deliver is not as a result of a Force Majeure Event, Myovant shall, notwithstanding anything in this Agreement to the contrary, have the right to terminate this Agreement due to a material breach by Supplier without notice or cure period. Myovant's exercise of its rights and remedies set forth in this Section 7.2.4 shall not limit or waive any of its other rights or remedies set forth herein or which may otherwise be available in law or equity.

7.3 Notice of Potential Inability to Supply. Supplier shall inform Myovant of any events that may prevent Supplier from fulfilling its supply obligations with respect to amounts of Product(s) ordered pursuant to any portion of any Firm Order as soon as reasonably practicable after becoming aware of such events, but in no event less than forty-eight (48) hours after Supplier obtains knowledge of any potential delay in Manufacturing or supply of Product(s) hereunder. In the event Supplier notifies Myovant of a potential inability to supply Product(s), the Parties shall discuss in good faith how to resolve or avoid (or, if not capable of resolution or avoidance, shorten) such supply problems. Without limiting the generality of the foregoing, Supplier will consider and implement in good-faith any reasonable suggestion of Myovant to resolve or avoid, or otherwise or shorten, any delay in Manufacturing or supply of Product(s).

7.4 Supply Shortage. If Supplier is unable to deliver [***] of the quantities of Product(s) that have been ordered by Myovant in accordance with Section 7.1.3, then Supplier shall fulfill any and all outstanding Purchase Orders from Myovant giving reasonable priority compared to any orders from Third Parties.

ARTICLE 8
MANUFACTURING

8.1 Conformance with GMP. Supplier shall supply the Product(s) that conforms to GMPs, Applicable Laws, the Specifications, the Quality Agreement, the Product(s) NDAs and Regulatory Approvals, and other terms of this Agreement, including Section 7.2.1 (Shelf-Life).

8.2 Manufacturing Changes.

8.2.1 Myovant may request to amend, modify or supplement the Specifications or the Manufacturing process with respect to the Products upon written notice to Supplier (each such amendment, modification or supplement, a "**Manufacturing Change**"). The implementation of any such Manufacturing Change shall be subject to this Section 8.2 and the Quality Agreement.

8.2.2 [***].

8.3 Modifications. Supplier shall not modify the Specifications, Manufacturing, and testing processes, in each case, employed with regard to the Manufacture of the Product(s) or any component thereof, other than as agreed in writing.

8.4 Manufacturing Location. Supplier shall supply Product(s) for which the final Manufacturing processes have been performed solely at the Facility, in each case unless otherwise mutually agreed in writing.

8.5 Quality Agreement. Within [***] of execution of this Agreement (or such later date as the Parties may agree in writing), the Parties will enter into the Quality Agreement, which will define roles and responsibilities, change control, release authority, GMP requirements, sampling, testing and retain plans, specifications, preventative maintenance, dispute resolution and other aspects related to quality of Product(s). In addition, the Quality Agreement will detail the Parties' obligations with respect to regulatory audits and will control over this Agreement with respect to quality issues to the extent this Agreement, including without limitation Section 6.1, contradicts the Quality Agreement.

8.6 Resources. Supplier agrees to allocate adequate resources to execute its obligations under this Agreement, including all Scopes of Work. Each Party agrees to respond promptly in the performance of their respective obligations beginning upon the execution of this Agreement or upon the execution of the applicable Scope of Work, as the case may be.

ARTICLE 9
DELIVERY, TITLE AND RISK OF LOSS

9.1 Shipment Terms; Title; Risk of Loss. Except as otherwise provided under Article 13 of this Agreement, all Product(s) will be shipped to Myovant or its designee [***] to Myovant's designated site, freight collect, by a common carrier designated by Myovant in the Purchase Order, at Myovant's expense. Title and risk of loss will transfer to Myovant, and delivery shall be deemed to have occurred, when goods are placed at Myovant's or its designee's disposal.

9.2 Labeling and Packaging. Supplier shall label and package Product(s) in accordance with Applicable Laws, and Myovant's reasonable instructions, regarding pharmaceutical products shipped in bulk for further processing, labeling, or repackaging.

ARTICLE 10
NON-CONFORMING PRODUCT(S)/RETURNS

10.1 Claims for Detectable Defects. Myovant shall notify Supplier within ten (10) Business Days after receipt by Myovant or its designated dosage form (with respect to Drug Substance) manufacturer or drug substance (with respect to RSM) manufacturer of any shipment of the Product(s) supplied by or on behalf of Supplier of the existence and nature of any defect in or failure of the Product(s) to comply with Section 6.1 or Section 8.1 at the time of delivery that could have been detected by a reasonable physical inspection of the Product(s) at the time of delivery ("**Detectable Defects**"). If such notice is not provided within such thirty (30) days period, then such Product(s) will be deemed not to have any Detectable Defects, Myovant will be deemed to have accepted the Product(s), and Supplier will have no further responsibility for such Detectable Defects. A non-conformity relating to stability of the Product(s) shall not be considered a Detectable Defect.

10.2 Claims for Latent Defects. Myovant shall notify Supplier within ten (10) Business Days upon discovery of any defect in or failure of the Product(s) to comply with Section 6.1 or Section 8.1 that is not a Detectable Defect (such defect or failure, a "**Latent Defect**"). Claims that are submitted by Myovant shall state the nature of the alleged defect, including how such alleged defect was discovered, in detail reasonably sufficient to enable Supplier to identify the nature of the alleged defect or to dispute the same, and to determine that the defect existed at the time of delivery. However, Myovant may only claim for Latent Defects for Product sold before the applicable expiration date listed on the container/labels of a Product and approved by the relevant Regulatory Authority, including any extensions or updates from time to time after the transfer of title and loss from Supplier to Myovant according to Section 9.1 (the "**Expiration Date**"). For clarity, if Myovant discovers that a Product that was sold before its expiration date had a Latent Defect at the time of such sale, then Myovant may make a claim for such Latent Defect at any time, including after such expiration date.

10.3 Provision of Samples. Myovant shall, when notifying Supplier of an alleged defect, provide samples of any allegedly defective Product(s) and copies of written reports or investigations performed by or on behalf of Myovant on such allegedly defective Product(s).

10.4 Referral to Independent Laboratory. In the event of a dispute between the Parties as to any defect in a Product(s), including whether a defect was a Detectable Defect, a Latent Defect or whether such defect existed at the time of delivery, that cannot be resolved within thirty (30) days of a claim being made to Supplier pursuant to Section 10.1 or Section 10.2, the matter shall promptly (but in no case later than ten (10) Business Days after the expiration of such thirty (30) day period) be submitted to an independent laboratory to be mutually agreed between the Parties. The independent laboratory will examine the Product(s) at issue and determine the existence and, if relevant, the timing of any defect in the Product(s). The decision of the independent laboratory shall be binding on the Parties, except in the case of fraud. Myovant shall bear the costs of the independent laboratory if the independent laboratory finds that the Product(s) was not defective or that such defect did not exist at the time of delivery. Supplier shall bear the costs of the independent laboratory if the independent laboratory finds that the Product(s) was defective at the time of delivery.

10.5 Credit Note; Replacement Product(s); Defective Product(s). Following a claim from Myovant pursuant to Section 10.1 or Section 10.2, and without limiting any of Myovant's remedies with respect to any breach by Supplier of this Agreement, or the remedies set forth in Sections 7.2.4 or 7.4, Supplier's sole obligation with respect to replacing defective Product(s) in the event that Supplier accepts Myovant's claim as valid or the independent laboratory decides in favor of Myovant's claim, shall be to either, at Myovant's election: (a) provide Myovant with a Credit Note equal to (i) the price paid by Myovant for the defective Product(s) and (ii) the costs paid by Myovant, if any, to any independent laboratory used in connection in accordance with Section 10.4 with respect to such determination; or (b) replace the defective Product(s) as soon as commercially practicable. Any Product that is agreed or determined to be defective shall be, as directed by Supplier, either destroyed by Myovant or returned to Supplier, in both cases at Supplier's expense. Except for Supplier's obligations under Article 12 and Article 18, Supplier shall have no liability for defective Product(s) other than as provided in this Article 10.

ARTICLE 11
STORAGE, HANDLING AND TRANSPORT

11.1 Supplier's Responsibilities. The Product(s) shall be Manufactured by or on behalf of Supplier and stored, handled, packaged, and transported in accordance with the requirements of this Agreement, the Quality Agreement and all Applicable Laws. Supplier shall maintain appropriate quality assurance and quality control standards and record-keeping practices, including systems, resources and procedures in order to satisfy these obligations.

11.2 Notice of Inspections by Regulatory Authorities. The Parties' obligations with respect to any inspections or audits by any Regulatory Authority related to the Product(s) shall be governed by Section 6.2 and the Quality Agreement.

ARTICLE 12
RECALL

Each Party will promptly notify the other Party upon its determination that any event, incident, or circumstance has occurred, including but not limited to any field alert made pursuant to 21 C.F.R. part 314.81(b)(1), that may result in the need for a Recall or market withdrawal of a Product(s) and/or Commercial Product (but in no event later than twenty-four (24) hours and in all cases prior to the execution of such Recall or market withdrawal). For all such Recalls, the Parties will reasonably consult with each other with respect to the actions to be taken to address such Recall. Subject to this Article 12, for all Recalls, market withdrawals, and stock recoveries that are taken with respect to any Commercial Product and/or any Product(s) that is in Myovant's possession or control,

Myovant will be responsible for execution, and Supplier will take such actions as reasonably requested by Myovant in connection therewith and otherwise reasonably cooperate in all such efforts. All expenses incurred in connection with any Recall (including expenses for notification, destruction, and return of the affected Product(s) and/or Commercial Product and any refund to customers of amounts paid for such Product(s) and/or Commercial Product) will be the sole responsibility of Supplier (except to the extent such Recall is caused by the Myovant Companion Product or in any other way not attributable to Supplier).

ARTICLE 13
TECHNOLOGY TRANSFER; SUPPORT SERVICES

13.1 Technology Transfer. At Myovant's request, and at its cost in accordance with a mutually agreed Scope of Work in accordance with Section 13.2, Supplier shall transfer to Myovant or its designee all know-how and technology necessary or useful for the Manufacture of Drug Substance and RSM. Myovant shall initiate and oversee such technology transfer, and shall in good faith assess the progress of such transfer until it is completed to contents agreed by the Parties. Upon such request by Myovant for a technology transfer, the Parties will work in good faith to establish a mutually agreed, detailed technology transfer plan, including tasks, deliverables, timelines and budgets (the "**Technology Transfer Plan**"). Upon adoption of the Technology Transfer Plan, each Party will perform such tasks as are assigned to it as described therein. For clarity, if Supplier elects to transfer the manufacture of any Product(s) to another facility within the [***] of affiliated companies, including [***], then Supplier will bear the cost of such transfer.

13.2 Support Services. Beginning on the Effective Date and continuing during the Term, upon reasonable request of Myovant, Supplier shall provide Myovant or its designee with reasonable technical, regulatory, CMC and other related services in support of the Manufacturing of Product(s) (collectively, the "**Support Services**"). Any Support Services provided by Supplier will be documented in work orders, executed by both Parties and substantially in the form attached as Exhibit C (each a "**Scope of Work**"). Each Scope of Work shall include milestone payments as mutually agreed. In addition, the Parties may mutually agree to adjust activities and/or costs under any Scope of Work, with discussions regarding such adjustments to be conducted in good faith by each Party. Supplier will perform Support Services from Supplier's or its Affiliates' facilities unless otherwise expressly set forth in a Scope of Work.

13.3 Reimbursement for Support Services. Myovant shall compensate Supplier in accordance with the milestone achievements and corresponding payment terms for Supplier's achievement thereof as set forth in any applicable Scope of Work. Supplier shall invoice Myovant within thirty (30) days after the end of each month during the Term for all milestone payments accrued by Supplier through its provision of the Support Services in each then-current Scope of Work, which shall include a brief description of work performed, and Myovant shall pay such invoice in accordance with Article 14.

ARTICLE 14
PAYMENT TERMS

14.1 Payment Terms. Myovant shall pay any amount invoiced by Supplier pursuant to Section 4.2 that is not disputed in writing by Myovant within forty-five (45) days after receipt of such invoice and, with respect to payments for Product(s), a determination, in accordance with Section 10.1, that such Product(s) does not have any Detectable Defects. Myovant shall make all payments for invoices issued by Supplier in Euros via an Automatic Clearing House payment to Supplier's account designated by Supplier.

14.2 Taxes. Myovant shall pay any applicable taxes, including sales, use, excise, value-added, service, goods and services, and consumption taxes imposed by relevant taxing authorities as a result of payments it makes to Supplier pursuant to this Agreement. All other taxes, including but not limited to income tax, gross receipts tax and foreign withholding tax, applicable to payments Myovant makes to Supplier pursuant to this Agreement shall be the sole responsibility of Supplier. Each Party will provide to the other Party any resale exemption, multiple points of use certificates, treaty certification and other exemption information reasonably requested by the other Party.

14.3 Late Payment. If Myovant does not pay or dispute in writing any invoiced amount within thirty (30) days of issuance of such invoice, simple interest shall thereafter accrue on the sum due to Supplier until the date of payment at the per annum rate of [***] or the maximum rate allowable by Applicable Laws, whichever is lower.

ARTICLE 15
INTELLECTUAL PROPERTY

15.1 Background IP. Except as otherwise set forth explicitly herein, Myovant will have and retain full and exclusive right, title and ownership interest in and to the Myovant Background IP. Supplier will have and retain full and exclusive right, title and ownership interest in and to the Supplier Background IP.

15.2 Project Inventions. All discoveries, inventions, improvements, processes, formulations, methods, data and information generated, developed or derived by or on behalf of Supplier under this Agreement (i) from Myovant Technology or Myovant's Confidential Information, (ii) from any Product or (iii) in the provision of the Manufacturing services, shall in each case belong to Myovant to the extent that it is not generally applicable to the business of Supplier and is unrelated to the manufacture or supply of Products (each, a "**Project Invention**"). Supplier hereby assigns to Myovant all of Supplier's right, title and interest in, to and under each Project Invention. At Myovant's request and expense, Supplier shall cooperate with Myovant in connection with applying for, prosecuting and enforcing any Intellectual Property Rights that claim or cover any Project Invention. Notwithstanding the foregoing, Supplier will retain ownership of any Supplier Technology, subject to the license granted to Myovant in accordance with Section 3.1.

ARTICLE 16
CONFIDENTIALITY

16.1 Nondisclosure and Non-Use. Each Party agrees that, during the Term and for a period of [***] thereafter, a Party (the "**Receiving Party**") receiving Confidential Information of the other Party (the "**Disclosing Party**") will (a) maintain in confidence such Confidential Information using not less than the efforts such Receiving Party uses to maintain in confidence its own confidential or proprietary information of similar kind and value, (b) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted below, and (c) not use such Confidential Information for any purpose, except to exercise its right and perform its obligations under this Agreement (it being understood that this Section 16.1 will not create or imply any rights or licenses not expressly granted under this Agreement). Notwithstanding anything to the contrary in the foregoing, the obligations of confidentiality and non-use with respect to any trade secret within such Confidential Information will survive for so long as such Confidential Information remains protected as a trade secret under Applicable Law.

16.2 Exceptions. The obligations in Section 16.1 will not apply with respect to any portion of the Confidential Information that the Receiving Party can show by competent evidence:

16.2.1 is publicly disclosed by the Disclosing Party, either before or after it is disclosed to the Receiving Party hereunder;

16.2.2 is known to the Receiving Party or any of its Affiliates at the time of its receipt, and not through a prior disclosure by the Disclosing Party, without any obligation to keep it confidential or any restriction on its use, prior to such disclosure by the Disclosing Party;

16.2.3 is subsequently disclosed to the Receiving Party or any of its Affiliates on a non-confidential basis by a Third Party that, to the Receiving Party's knowledge, is not bound by a similar duty of confidentiality or restriction on its use;

16.2.4 is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party or any of its Affiliates, generally known or available, either before or after it is disclosed to the Receiving Party;

16.2.5 is independently discovered or developed by or on behalf of the Receiving Party or any of its Affiliates without the aid, use of, access to, or application of any of the Confidential Information belonging to the Disclosing Party; or

16.2.6 is the subject of written permission to disclose provided by the Disclosing Party.

16.3 Authorized Disclosure.

16.3.1 Permitted Disclosure. Notwithstanding the provisions of Section 16.1, the Receiving Party may disclose Confidential Information belonging to the Disclosing Party only to the extent such

disclosure is reasonably necessary in the following instances: (a) filing of Regulatory Materials in order to obtain or maintain Regulatory Approvals; (b) prosecuting or defending litigation; (c) complying with Applicable Law or regulation or order of any or court or Government Authority, including responding to a subpoena in a Third Party litigation; (d) to its Affiliates, sublicensees or prospective sublicensees, Subcontractors or prospective Subcontractors, payors, consultants, agents, and advisors on a "need-to-know" basis in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, each of whom prior to disclosure must be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are substantially similar to those set forth in this Article 16 (but which obligations may be of shorter duration for Third Parties, but at least five (5) years); or (e) to any actual or potential sources of financing (debt, equity, or otherwise) with respect to the Receiving Party or its Affiliate(s), including but not limited to bona fide third party institutional lenders who are or may be engaged to provide debt financing to the Receiving Party or its Affiliate(s); *provided*, *however*, that, in each of the above situations, the Receiving Party will remain responsible for any failure by any Person who receives Confidential Information pursuant to Article 16 to treat such Confidential Information as required under this Article 16.

16.3.2 Notice; Confidential Treatment. If and whenever any Confidential Information is disclosed in accordance with this Section 16.3, such disclosure will not cause any such information to cease to be Confidential Information except to the extent that such disclosure results in a public disclosure of such information (other than by breach of this Agreement). Notwithstanding the foregoing, if a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 16.3.1(a), (b), or (c), then it will, except where illegal, (a) give reasonable advance notice to the other Party of such disclosure and use not less than the same efforts to secure confidential treatment of or a protective (or similar) order for such Information as it would to protect its own Confidential Information from disclosure, and (b) only disclose the minimum amount of Confidential Information reasonably required for the purpose of such disclosure.

16.4 Terms of this Agreement. The Parties acknowledge that this Agreement and all of the respective terms of this Agreement will be treated as Confidential Information of both Parties. Neither Party nor its Affiliates shall disclose any terms or conditions of this Agreement to any Third Party without the prior consent of the other Party, except to a Third Party in connection with (a) a financing (or proposed financing) or an equity investment (or proposed investment) in such Party or its Affiliates, including to its shareholders and prospective shareholders, (b) the entry into any agreement with respect to the Development, Manufacture, or Commercialization of a Commercial Product, (c) a merger, consolidation, or similar transaction by such Party or its Affiliates or (d) the sale of all or substantially all of the assets of such Party or its Affiliates to which this Agreement relates; *provided that* (i) all such disclosures are made in accordance with this Article 16; (ii) such Third Party executes a non-use and non-disclosure agreement with confidentiality and non-use obligations similar to those contained in this Agreement and (iii) Myovant may disclose this Agreement or any of its respective terms to a competitor of Supplier's only with Supplier's written consent, not to be unreasonably withheld or delayed.

16.5 Publicity. Each Party agrees not to issue any press release or other public statement disclosing other information relating to this Agreement or the transactions contemplated hereby that contains information not previously publicly disclosed without the prior written consent of the other Party, not to be unreasonably withheld, conditioned, or delayed.

16.6 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that could result to a Party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 16. In addition to all other remedies, a Party will be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 16.

ARTICLE 17
REPRESENTATIONS AND WARRANTIES

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

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

17.1.2 Corporate Power, Authority and Binding Agreement. As of the Effective Date, (a) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (b) it has taken all necessary corporate action on its part required to authorize the

execution and delivery of this Agreement and the performance of its obligations hereunder; and (c) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

17.2 Further Supplier Representations, Warranties and Covenants. Supplier hereby represents, warrants and covenants to Myovant that:

17.2.1

(a) Supplier possesses, as of the Effective Date and, with respect to any country added to the Qualified Territory in accordance with Section 6.3, as of the date such country is added, all regulatory qualifications, certifications, licenses and permits necessary to Manufacture Product(s) that may, subject to Myovant possessing the applicable Regulatory Approval, be lawfully promoted, sold and used (collectively, "**Regulatory Qualifications**") in each country within the Qualified Territory.

(b) Supplier will maintain such Regulatory Qualifications at all times during the Term with respect to the Qualified Territory as of the Effective Date.

(c) If and to the extent Supplier obtains, in accordance with Section 6.3, applicable Regulatory Qualifications for countries or jurisdictions added after the Effective Date to the Qualified Territory, the Supplier will maintain such Regulatory Qualifications at all times thereafter during the Term.

(d) Supplier shall allocate such resources as necessary to execute its obligations under this Agreement, including each Scope of Work.

(e) Supplier shall not, nor permit any of its Affiliates to, sell or otherwise transfer or dispose of any equipment or tools, if any, or consumables funded by Myovant, if any, including any transfer of such equipment or tools to another facility (other than the Facility) of Supplier or its Affiliates, without Myovant's prior written consent.

17.2.2 All Product(s) supplied pursuant to this Agreement, upon delivery to Myovant or Myovant's designee in accordance with Section 9.1:

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

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

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

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

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

17.2.3 Supplier, its Affiliates and any employee of, contractor of or other Person retained by Supplier or its Affiliates, in each case directly or indirectly performing any activities under this Agreement, are not currently, have never been, and, to the best of Supplier's knowledge, are not the subject of a proceeding that could lead to Supplier, any of its Affiliates or any such employee of Supplier or its Affiliates becoming, as applicable, (i) debarred by the FDA under 21 U.S.C. § 335a, (ii) excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs or in any similar state program, (iii) listed on the FDA's Disqualified and Restricted Lists for clinical investigators, or (iv) convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a) or could otherwise lead to be excluded, debarred, suspended or declared ineligible, but has not yet been excluded, debarred, suspended, or otherwise declared ineligible, nor has any such Person to Supplier's knowledge engaged in conduct that could lead to such exclusion, debarment, suspension, or ineligibility. Supplier shall not engage, directly or indirectly, any Person to perform services hereunder if that Person has ever been, is currently, or, to the best of Supplier's knowledge, is the subject of a proceeding that could lead to that Person becoming, as applicable, any of (i)-(iv) above. If Supplier receives notice of, or otherwise becomes aware

of, the debarment, proposed debarment or such other exclusion, suspension, restriction or sanction of itself, or any employee of Supplier or an Affiliate of Supplier that is performing any activities under this Agreement, then Supplier shall notify Myovant immediately and Myovant shall have the right to immediately terminate this Agreement.

17.2.4 Each employee of, contractor of or other Person retained by Supplier or its Affiliates, in each case directly or indirectly performing any activities under this Agreement, has entered into, or will enter into prior to commencing the Manufacturing and other services under this Agreement, a written agreement which assigns to Supplier all Project Inventions created by such Supplier personnel during the course of his or her employment by, or other provision of services to, Supplier.

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

ARTICLE 18
INDEMNIFICATION; NO CONSEQUENTIAL DAMAGES; INSURANCE; LIMITATION OF LIABILITY

18.1 Indemnification by Myovant. Myovant hereby agrees to defend, indemnify, and hold harmless Supplier and its Affiliates, and each of their respective directors, officers, employees, agents and representatives (each, a "**Supplier Indemnitee**") from and against any and all claims, suits, actions, demands or other proceedings brought by any Third Party (each, a "**Claim**") and all liabilities, expenses, damages, or losses, including reasonable legal expense and attorneys' fees but excluding lost profits (collectively, "**Losses**"), to which any Supplier Indemnitee may become subject as a result of any such Claim to the extent such Claim arise or result from: (a) the Manufacture or Commercialization of the Product(s) or Commercial Product in the Territory, in each case, by or on behalf of Myovant, its Affiliate, or its Sublicensee; (b) the breach by Myovant of any warranty, representation, covenant, or agreement made by Myovant in this Agreement; (c) the negligence, gross negligence or willful misconduct of Myovant, its Affiliate, or its Sublicensee, or any officer, director, employee, agent, or representative thereof; and (d) the failure to comply with Applicable Law by or on behalf of Myovant in connection with the Product(s) or Commercial Product, or this Agreement; except, with respect to each of subsections (a) through (d) above, to the extent such Losses arise directly from the negligence, gross negligence, or willful misconduct of any Supplier Indemnitee or the breach by Supplier of any warranty, representation, covenant, or agreement made by Supplier in this Agreement.

18.2 Indemnification by Supplier. Supplier hereby agrees to defend, indemnify, and hold harmless Myovant and its Affiliates and each of their respective directors, officers, employees, agents and representatives (each, an "**Myovant Indemnitee**") from and against any and all Losses to which any Myovant Indemnitee may incur, suffer, or be required to pay as a result of, or arising in connection with, any Claim to the extent such Claims arise or result directly from: (a) the breach by Supplier of any warranty, representation, covenant, or agreement made by Supplier in this Agreement; (b) the negligence, gross negligence, or willful misconduct of Supplier or its Affiliates or Subcontractors, or any officer, director, employee, agent or representative thereof; and (c) the failure to comply with Applicable Law by or on behalf of Supplier in connection with the Product(s) or this Agreement; except, with respect to each of subsections (a) through (c) above, to the extent such Losses result directly from the negligence, gross negligence, or willful misconduct of any Myovant Indemnitee, or the breach by Myovant of any warranty, representation, covenant, or agreement made by Myovant in this Agreement.

18.3 Indemnification Procedures.

18.3.1 Notice. Promptly after a Supplier Indemnitee or a Myovant Indemnitee (each, an "**Indemnitee**") receives notice of a pending or threatened Claim, such Indemnitee will give written notice of the Claim to the Party from whom the Indemnitee is entitled to receive indemnification pursuant to Section 18.1 or Section 18.2, as applicable (the "**Indemnifying Party**"). However, an Indemnitee's delay in providing or failure to provide such notice will not relieve the Indemnifying Party of its indemnification obligations, except to the extent it can demonstrate prejudice due to the delay or lack of notice.

18.3.2 Defense. Upon receipt of notice under Section 18.3.1 from the Indemnitee, the Indemnifying Party will have the duty to either compromise or defend, at its own expense and by counsel

(reasonably satisfactory to Indemnitee), such Claim. The Indemnifying Party will promptly (and in any event not more than twenty (20) days after receipt of the Indemnitee's original notice) notify the Indemnitee in writing that it acknowledges its obligation to indemnify the Indemnitee with respect to the Claim pursuant to this Article 18 (Indemnification; Insurance) and of its intention either to compromise or defend such Claim. Once the Indemnifying Party gives such notice to the Indemnitee, (a) the Indemnifying Party will have the right to control the defense and settlement of such Claim, subject to this Section 18.3 and (b) the Indemnifying Party is not liable to the Indemnitee for the fees of other counsel or any other expenses subsequently incurred by the Indemnitee in connection with such defense, other than the Indemnitee's reasonable expenses of investigation and cooperation. However, the Indemnitee will have the right to employ separate counsel and to control the defense of a Claim at its own expense.

18.3.3 Cooperation. The Indemnitee will cooperate fully with the Indemnifying Party and its legal representatives in the investigation and defense of any Claim. The Indemnifying Party will keep the Indemnitee informed on a reasonable and timely basis as to the status of such Claim (to the extent the Indemnitee is not participating in the defense of such Claim) and conduct the defense of such Claim in a prudent manner.

18.3.4 Settlement. If an Indemnifying Party assumes the defense of a Claim, no compromise or settlement of such Claim may be effected by the Indemnifying Party without the Indemnitee's written consent (which consent will not be unreasonably withheld, conditioned, or delayed), unless: (a) there is no finding or admission of any violation of law or any violation of the rights of any person and no effect on any other claims that may be made against the Indemnitee; (b) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party; and (c) the Indemnitee's rights under this Agreement are not adversely affected. If the Indemnifying Party fails to assume defense of a Claim within a reasonable time, the Indemnitee may settle such Claim on such terms as it deems appropriate with the consent of the Indemnifying Party (which consent will not be unreasonably withheld, conditioned, or delayed), and the Indemnifying Party will be obligated to indemnify the Indemnitee for such settlement as provided in this Article 18.

18.4 Insurance. Supplier shall maintain Commercial General Liability insurance for e.g. corporate property, drug, drug substance, recall and logistics during the Term, but in no event shall such insurance be in an amount less than [***] per occurrence/annual aggregate during the Term. In addition, during the term of Commercialization of any Commercial Product and for a period of at least [***] thereafter, Supplier shall maintain Product Liability and Professional Liability insurance in an amount not less than [***] per occurrence and annual aggregate that covers occurrences during the period in which there is any Commercialization of Commercial Product and, if such policy is a claims-made policy, for a period of at least [***] thereafter. Supplier shall provide a certificate of insurance evidencing such coverage to Myovant upon its written request. Supplier shall notify Myovant [***] in advance of cancelation of any such insurance.

18.5 No Consequential or Punitive Damages. NEITHER PARTY HERETO WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, PUNITIVE OR MULTIPLE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER OR FOR ANY LOSS OR INJURY TO THE OTHER PARTY'S PROFITS OR GOODWILL ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. THIS SECTION 18.5 DOES NOT APPLY TO A BREACH OF A PARTY'S OBLIGATIONS UNDER ARTICLE 16 (CONFIDENTIALITY) OR TO A PARTY'S OBLIGATIONS PURSUANT TO SECTION 18.1 (INDEMNIFICATION BY MYOVANT) AND 18.2 (INDEMNIFICATION BY SUPPLIER).

18.6 Limitation of Liability. Except for violations of law, fraud, willful misconduct, gross negligence, a breach of its obligations of confidentiality and non-use, or its indemnity obligations, Supplier's liability to Myovant under this Agreement for any and all claims for losses (whether grounded in contract, tort, indemnity or otherwise) shall not exceed [***] prior to the date such claim or loss first arose.

ARTICLE 19
TERM AND TERMINATION

19.1 Term. This Agreement shall commence on the Effective Date and shall continue until the [***] of the Effective Date (the "**Initial Term**"). At the end of the Initial Term, this Agreement shall continue automatically for additional [***] periods (each, a "**Renewal Term**," and together with the Initial Term, the "**Term**") under the same terms and conditions until terminated in accordance with the terms hereof or until a Party provides at least [***] written notice of non-renewal to the other Party prior to expiration of the then-current Initial Term or Renewal Term, as applicable.

19.2 Termination.

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

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

19.3 Consequences of Termination.

19.3.1 Termination of this Agreement by Myovant for Supplier's Material Breach or Bankruptcy. If this Agreement is terminated by Myovant pursuant to Section 19.2.1 (Termination for Material Breach) or Section 19.2.2 (Termination for Bankruptcy), then Myovant may elect to cancel any Purchase Order(s) without any liability for amounts due thereunder and will be released from any liability for any Firm Orders then in effect for Product(s).

19.3.2 Termination of this Agreement by Supplier for Myovant's Material Breach or Bankruptcy. If this Agreement is terminated by Supplier pursuant to Section 19.2.1 (Termination for Material Breach) prior to a final, binding determination that Myovant materially breached this Agreement or pursuant to Section 19.2.2 (Termination for Bankruptcy), then Supplier shall continue to supply Product(s) pursuant to this Agreement until the Technology Transfer Plan is complete or a Third Party supplier is able to Manufacture and supply Product(s) to Myovant in sufficient quantity and quality to replace Supplier's obligations under this Agreement, whichever occurs first. However, the start of production of such Products shall be subject to an upfront payment to be made by Myovant including the cost of any raw materials and intermediates used for the production and the price of the Products itself.

19.3.3 Transition of Manufacturing. Upon the expiration or any termination of the Agreement, the Parties will discuss in good faith the transition of Manufacture and supply activities of the Product(s). Upon reasonable request by Myovant, Supplier may assist so far as reasonably needed in the transition by participating in the technology transfer activities to Myovant or Myovant's third party supplier. Such activities by Supplier shall be limited to documentation and consulting services and at all times, Myovant shall remain the owner and assessor of the transfer. Such activities by Supplier will be at Myovant's expense unless the MSA is terminated for cause solely attributable to Supplier.

19.4 Survival of Obligations. Termination or expiration of this Agreement shall not relieve a Party of any obligation to make a payment that was owed prior to or on the effective date of such termination, including amounts invoiced prior to such termination or expiration, nor prejudice either Party's right to obtain performance of any obligation provided for in this Agreement that expressly survives termination or expiration. All provisions of this Agreement that, in accordance with their terms, are intended to have effect after the expiration or termination of this Agreement shall survive such termination or expiration, including Sections 3.13.1, 3.2(a), 3.4, 17.2.4, 19.3, this 19.4, and 19.5 and Articles 1, 6 (solely to the extent necessary to fulfill any obligation to a Regulatory Authority after termination or expiration), 10, 12, 14, 15, 16 (for the period specified in Section 16.1), 18 and 20.

19.5 Remedies. Except as otherwise expressly provided herein, exercise by a Party of its rights under this Article 19 shall not limit remedies which may otherwise be available to a Party in law or equity.

ARTICLE 20
GENERAL PROVISIONS

20.1 Force Majeure Event. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by causes beyond the reasonable control of the affected Party, including embargoes, epidemics, war, acts of war (whether war be declared or not), acts of terrorism, sabotage, insurrections, riots, civil commotions, strike, fire, floods, earthquake, or other acts of God, or acts, omissions or delays in acting by any governmental authority, and which in each case is not caused by the gross negligence or intentional misconduct of such Party (each such event or cause, a "**Force Majeure Event**") and the nonperforming Party promptly provides notice of such prevention to the other Party. Such excusal shall be continued so long as the condition constituting a Force Majeure Event continues and the nonperforming Party takes reasonable efforts to mitigate the condition. If a Force Majeure Event persists for more than ninety (90) days, the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such Force Majeure Event.

20.2 Notices. Any notice, request, or other communication permitted or required under this Agreement will be in writing, will refer specifically to this Agreement and will be hand delivered or sent by a recognized overnight delivery service, expenses prepaid, or by facsimile (with transmission confirmed), to the following addresses or to such other addresses as a Party may designate by written notice in accordance with this Section 20.2:

If to Supplier:

Excella GmbH & Co KG
N✔rnberger Str. 12
90537 Feucht
Germany

If to Myovant:

Myovant Sciences GmbH
Viaduktstrasse 8
4051 Basel
Switzerland

Copy to:

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

20.3 Dispute Resolution.

20.3.1 Exclusive Dispute Resolution Mechanism. The Parties agree that the procedures set forth in this Section 20.3 will be the exclusive mechanism for resolving disputes, actions, claims, controversies, suits, or proceedings between the Parties arising in whole or in part out of, related to, based upon or in connection with this Agreement, the Quality Agreement or the subject matter of either (each, a "**Dispute**", and collectively, the "**Disputes**").

20.3.2 Resolution by Executive Officers. Except as otherwise provided in this Section 20.3.2, in the event of any Dispute that is not resolved, the Parties will first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves on an informal basis for a period of ten (10) Business Days after receipt of written notice of such Dispute by a Party. If such Dispute is not resolved by the Parties' informal discussions within such ten (10) Business Day period, either Party may, by written notice to the other Party, refer the Dispute to the senior executive officer (or his or her delegate) (each, an "**Executive Officer**") of the other Party for attempted resolution by good faith negotiation within ten (10) Business Days

after such notice is received. Each Party may, in its sole discretion, seek resolution of any and all Disputes that are not resolved under this Section 20.3.2 in accordance with Section 20.3.3.

20.3.3 Arbitration. If the Parties are unable resolve a given Dispute pursuant to Section 20.3.2 within ten (10) Business Days of referring such dispute to the Executive Officers, either Party may have the given Dispute settled by binding arbitration in the manner described below:

(a) Arbitration Request. If a Party intends to begin an arbitration to resolve a dispute arising under this Agreement, such Party shall provide written notice (the "**Arbitration Request**") to the other Party of such intention and the issues for resolution. From the date of the Arbitration Request and until such time as the dispute has become finally settled, the running of the time periods as to which a Party must cure a breach of this Agreement becomes suspended as to the subject matter of the dispute.

(b) Additional Issues. Within ten (10) days after the receipt of the Arbitration Request, the other Party may, by written notice, add additional issues for resolution.

(c) Arbitration Procedure. Except as expressly provided herein, the sole mechanism for resolution of any claim, dispute or controversy arising out of or in connection with or relating to this Agreement or the breach or alleged breach thereof shall be arbitration by the International Chamber of Commerce ("**ICC**") in New York, USA, or in such other venue as the Parties agree, under New York law except as provided herein. All proceedings shall be held in English and a transcribed record prepared in English. The Parties shall choose, by mutual agreement, one arbitrator within thirty (30) days of receipt of notice of the intent to arbitrate. If no arbitrator is appointed within the times herein provided or any extension of time that is mutually agreed on, the ICC shall make such appointment within thirty (30) days of such failure. The award rendered by the arbitrator shall not include costs of arbitration, attorneys' fees or costs for expert and other witnesses. Within forty-five (45) days of initiation of arbitration, the Parties shall reach agreement upon and thereafter follow procedures directed at assuring that the arbitration will be concluded and the award rendered within no more than six (6) months from selection of the arbitrator. Failing such agreement, the ICC will design and the Parties will follow procedures directed at meeting such a time schedule. The arbitrator (i) shall not have any power or authority to add to, alter, amend or modify the terms of this Agreement but shall specify rules sufficient to allow reasonable discovery by the Parties; (ii) shall establish and enforce appropriate rules to ensure that the proceedings, including the decision, be kept confidential and that all Confidential Information of the Parties be kept confidential and be used for no purpose other than the arbitration; (iii) shall have the power to enforce specifically this Agreement and the terms and conditions hereof in addition to any other remedies at law or in equity; and (iv) shall issue all decisions in writing. Nothing in this Agreement shall be deemed as preventing either Party from seeking injunctive relief (or any other provisional remedy) from any court having jurisdiction over the Parties and the subject matter of the dispute as necessary to protect either Party's name, proprietary information, trade secrets, know-how or any other proprietary right or otherwise to avoid irreparable harm. If the issues in dispute involve scientific or technical matters, any arbitrator chosen hereunder shall have educational training and/or experience sufficient to demonstrate a reasonable level of knowledge in the field of biotechnology. Judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof.

20.4 Audits.

20.4.1 Facility Audits. In addition, in accordance with the Quality Agreement, Myovant shall have the right, upon at least [***] notice to Supplier, and such date to be reasonably agreed upon by the Parties, either by itself or through independent outside auditors or consultants, not more than once per Calendar Year during the Term of this Agreement, unless reasonable cause is shown, to inspect and audit, at its sole expense and during normal business hours and in a manner that does not interfere unreasonably with operations, any areas in the Facility or any other Manufacturing facilities in which any portion of the Manufacturing, packaging or other activities with respect to any Product(s) is performed, including any Regulatory Materials and other information reasonably related to the subject matter set forth herein located at the Facility or such Manufacturing facility. The information obtained during the course of such audit shall be considered Confidential Information and subject to Article 16.

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

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

20.7 Assignment. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective heirs, successors and permitted assigns. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, which consent shall not be unreasonably withheld, delayed or conditioned; *provided, however*, that each Party may, without the other Party's prior written consent: (a) assign its rights and obligations under this Agreement to its Affiliate or, in the case of Myovant, to its licensee, provided that any assignment by Supplier to an Affiliate must occur in connection with the sale or other transfer to such Affiliate of all or substantially all of the assets of the business to which this Agreement relates; and (b) assign this Agreement to its successor in connection with the sale or other transfer of all or substantially all of the assets of the business to which this Agreement relates (whether such transaction occurs by way of a sale of assets, merger, consolidation or similar transaction). Any successor or assignee of rights or obligations permitted hereunder will, in writing to the other Party, expressly assume performance of such rights or obligations. Any permitted assignment will be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 20.7 will be null, void and of no legal effect. Notwithstanding anything to the contrary in this Agreement or the Quality Agreement, this Agreement may only be assigned to an assignee to whom the Quality Agreement is assigned at the same time, and the Quality Agreement may only be assigned to an assignee to whom this Agreement is assigned at the same time. For clarity, any assignment by Supplier under this Section 20.7 shall not result in any change to the requirement that Supplier (including its assignee) shall Manufacture the Product(s) only at the Facility in accordance with Section 5.1.

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

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

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

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

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

20.13 Entire Agreement. This Agreement, including the Exhibits and Schedules hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions, or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change, or addition to this Agreement will be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party except as otherwise expressly provided in Section 6.3. In the event of any inconsistency between the body of this Agreement and the Exhibits or Schedules to this Agreement or any subsequent agreements ancillary to this Agreement, unless otherwise expressly stated to the contrary in such Exhibit, Schedule or subsequent ancillary agreement, the terms contained in this Agreement will control.

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

[Signature Page Follows]

THIS AMENDED AND RESTATED MANUFACTURING & SERVICES AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the Restatement Date.

MYOVANT SCIENCES GMBH

Signature: /s/ Slava Rakov

Name: Slava Rakov

Title: VP, Medical Affairs

Date: 4/17/2021

EXCELLA GMBH & CO. KG

Signature: /s/ J✔ergen Bank

Name: J✔ergen Bank

Title: General Manager

Date: April 14, 2021

EXCELLA GMBH & CO. KG

Signature: /s/ Pablo Magnani

Name: Pablo Magnani

Title: V.P. Global API

Date: April 14, 2021

Exhibit 10.2

EXECUTION COPY

CERTAIN INFORMATION IDENTIFIED BY "[***]" HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

AMENDMENT NO. 3 TO MARKET ACCESS SERVICES AGREEMENT

This Amendment No. 3 (this "Amendment") is entered into as of March 15, 2021 (the "Amendment Effective Date") by and between Sunovion Pharmaceuticals Inc., a Delaware corporation, having a principle place of business at 84 Waterford Drive, Marlborough, MA 01752 ("Sunovion") and Myovant Sciences GmbH, a Swiss corporation, having a principle place of business at Viaduktstrasse 8, 4051 Basel, Switzerland ("Myovant"). Capitalized terms used in this Amendment that are not defined in this Amendment shall have the meaning set forth in the Agreement (as defined below).

A. Sunovion and Myovant entered into that certain Market Access Services Agreement dated August 1, 2020 (the "Agreement"); and

B. Sunovion and Myovant desire to amend certain rights and obligations under the Agreement regarding (i) certain RCP Services, and (ii) add the definition of Specialty Pharmacy to the Agreement.

THEREFORE, in consideration of the mutual covenants and promises contained herein, and for good and valuable consideration the receipt and sufficiency of which is hereby acknowledged, intending to be legally bound hereby, it is understood and agreed upon by and between the Parties as follows:

1. AMENDMENTS

1. The following is added to the definitions section as 1.93.1:

   "Specialty Pharmacy" means [***], and any other specialty pharmacies as contracted with from time to time.

2. Section 4.6 RCP Services of the Agreement is deleted in its entirety and replaced with the following:

   "RCP Services. Sunovion, subject to Section 4.1 and 4.3.2 (as Section 4.3.2 relates to the Prostate Cancer Product), shall perform the RCP Services. Notwithstanding the foregoing, Myovant shall be responsible for performing the RCP Services listed in section 4.6.1 herein."

3. The following is added as section 4.6.1 to the Agreement:

   "4.6.1 RCP Services for [***] shall be performed by Myovant inclusive of invoice validation, processing and payment."

4. Exhibit E of the Agreement is deleted in its entirety and replaced with Attachment 1 to this Amendment titled Exhibit E.

2. MISCELLANEOUS

2.1 Entire Agreement. This Amendment, together with the Agreement, constitutes the entire agreement between the Parties with respect to the specific subject matter of the Agreement and supersedes all other prior negotiations, discussions, agreements or understandings, whether written or oral, with respect to the subject matter the Agreement. In the event of a conflict between this Amendment and the Agreement, this Amendment shall prevail.

2.2 Counterparts. This Amendment may be executed in any number of counterparts, each of which will be deemed to be an original, and all of which together will constitute one and the same instrument.

[Signature Page to Follow]

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be executed in duplicate by their duly authorized representatives, effective as of the Amendment Effective Date.

Sunovion Pharmaceuticals Inc.	**Myovant Sciences GmbH**
By: /s/ Thomas Gibbs	By: /s/ Viatcheslav Rakov
Name: Thomas Gibbs	Name: Viatcheslav Rakov
Title: SVP and Chief Commercial Officer	Title: VP Medial Clinical

ATTACHMENT 1

EXHIBIT E — RCP SERVICES

RCP Services shall include the following obligations with respect to the Products:

1. RCP Payment Validation. With the exception of the RCP Services listed in section 4.6.1, Sunovion shall validate all invoices for RCP Payments received from Market Access Customers, GPOs, IDNs, Wholesalers, Specialty Distributors, 3PL Providers, and Government Entities to ensure such invoices are consistent with the terms and conditions of the applicable contract and apply to eligible utilization of the applicable Products only, using a validation process agreed upon in writing by the Parties.

2. RCP Payment Administration. With the exception of the RCP Services listed in section 4.6.1, Sunovion shall process and pay, using funds from the Escrow Fund and pursuant to the terms and conditions of the applicable contract, all validated RCP Payments.

Exhibit 10.3

CERTAIN INFORMATION IDENTIFIED BY "[***]" HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

AMENDMENT NO. 4
TO
MARKET ACCESS SERVICES AGREEMENT

This Amendment No. 4 (this "Amendment") is entered into as of August 9, 2022 (the "Amendment Effective Date") by and between Sunovion Pharmaceuticals Inc., a Delaware corporation, having a principle place of business at 84 Waterford Drive, Marlborough, MA 01752 ("Sunovion") and Myovant Sciences GmbH, a Swiss corporation, having a principle place of business at Viaduktstrasse 8, 4051 Basel, Switzerland ("Myovant"). Capitalized terms used in this Amendment that are not defined in this Amendment shall have the meaning set forth in the Agreement (as defined below).

RECITALS

A. Sunovion and Myovant entered into that certain Market Access Services Agreement dated August 1, 2020 and amended as of December 14, 2020, January 25, 2021, March 15, 2021 and August 9, 2022 (collectively, the "Agreement");

B. Sunovion and Myovant acknowledge and agree the amendment titled "Amendment No. 1 to Market Access Services Agreement" to the Agreement entered into by and between the parties effective December 14, 2020 is the first amendment to the Agreement;

C. Sunovion and Myovant acknowledge and agree the amendment titled "Amendment No. 2 to Market Access Services Agreement" entered into by and between the parties effective January 25, 2021 is the second amendment to the Agreement;

D. Sunovion and Myovant acknowledge and agree the amendment titled "Amendment No. 3 to Market Access Services Agreement" entered into by and between the parties effective March 15, 2021 is the third amendment to the Agreement;

E. Sunovion and Myovant acknowledge and agree the amendment titled "Amendment No. 3 to Market Access Services Agreement" entered into by and between the parties effective August 9, 2022 and attached hereto as Attachment 1, is the fourth amendment to the Agreement and due to a scrivener's error was mislabeled as the third amendment to the Agreement; and

F. Sunovion and Myovant acknowledge and agree that references to "Amendment No. 4 to the Market Access Services Agreement" shall include both (i) the amendment titled "Amendment No. 3 to Market Access Services Agreement" entered into by and between the parties effective August 9, 2022 and (ii) this Amendment.

THEREFORE, in consideration of the mutual covenants and promises contained herein, and for good and valuable consideration the receipt and sufficiency of which is hereby acknowledged, intending to be legally bound hereby, it is understood and agreed upon by and between the parties the Recitals to this Amendment are incorporated into and shall constitute a part of the Agreement.

[Signatures to follow on next page.]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed by their duly authorized representatives to be effective as of the Amendment Effective Date.

Sunovion Pharmaceuticals Inc.	**Myovant Sciences GmbH**
By: /s/ Lisa Mullett	By: /s/ Matthew Lang
Print Name: Lisa Mullett	Print Name: Matthew Lang
Title: Chief Commercial Officer	Title: General Manager

ATTACHMENT 1

AMENDMENT NO. 3
TO
MARKET ACCESS SERVICES AGREEMENT

This Amendment No. 3 (this "Amendment") is entered into as of August 9, 2022 (the "Amendment Effective Date") by and between Sunovion Pharmaceuticals Inc., a Delaware corporation, having a principle place of business at 84 Waterford Drive, Marlborough, MA 01752 ("Sunovion") and Myovant Sciences GmbH, a Swiss corporation, having a principle place of business at Viaduktstrasse 8, 4051 Basel, Switzerland ("Myovant"). Capitalized terms used in this Amendment that are not defined in this Amendment shall have the meaning set forth in the Agreement (as defined below).

RECITALS

A. Sunovion and Myovant entered into that certain Market Access Services Agreement dated August 1, 2020 and amended as of December 14, 2020 and January 25, 2021 (collectively, the "Agreement"); and

B. Sunovion and Myovant desire to amend certain rights and obligations under the Agreement regarding the Monthly Flat Service Charge

THEREFORE, in consideration of the mutual covenants and promises contained herein, and for good and valuable consideration the receipt and sufficiency of which is hereby acknowledged, intending to be legally bound hereby, it is understood and agreed upon by and between the Parties as follows:

1. AMENDMENTS

1.1 Section 1.59 of the Agreement is hereby deleted in its entirety and replaced as follows:

""Monthly Flat Service Charge" means, subject to Section 8.2.2, (i) [***] per calendar month [***], and (ii) an adjusted amount for each year after [***] consistent with Section 8.2.2; provided that, (i) if a contract year begins after the first day of a calendar month, such amount shall be multiplied by a fraction where the numerator is the number of days in such calendar month that are on or after first day of the contract year and the denominator is the number of days in such calendar month, and (ii) if a contract year ends before the last day of a calendar month, such amount shall be multiplied by a fraction where the numerator is the number of days in such calendar month that are on or before the last day of the contract year and the denominator is the number of days in such calendar month."

2. MISCELLANEOUS

2.1 Entire Agreement. This Amendment, together with the Agreement, constitutes the entire agreement between the Parties with respect to the specific subject matter of the Agreement and supersedes all other prior negotiations, discussions, agreements or

understandings, whether written or oral, with respect to the subject matter the Agreement. In the event of a conflict between this Amendment and the Agreement, this Amendment shall prevail.

2.2 Counterparts. This Amendment may be executed in any number of counterparts, each of which will be deemed to be an original, and all of which together will constitute one and the same instrument.

[Signatures to follow on next page.]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed by their duly authorized representatives to be effective as of the Amendment Effective Date.

Sunovion Pharmaceuticals Inc.	**Myovant Sciences GmbH**
By: /s/ Lisa Mullett	By: /s/ Viatcheslav Rakov
Print Name: Lisa Mullett	Print Name: Viatcheslav Rakov
Title: Chief Commercial Officer, Interim	Title: VP Medical - Clinical

Exhibit 10.4

CERTAIN INFORMATION IDENTIFIED BY "[***]" HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

September 19, 2022

Re: Canada Termination – Section 15.5 of Collaboration and License Agreement between Myovant Sciences GmbH ("Myovant") and Pfizer Inc. ("Pfizer") dated as of December 26, 2020

This letter agreement (the "**Letter Agreement**") relates to the Collaboration and License Agreement between Myovant and Pfizer dated as of December 26, 2020 (the "**Myovant/Pfizer Agreement**"), under which Myovant and Pfizer have agreed to co-exclusively co-develop, co- commercialize and co-promote the WH Product(s) and the Oncology Products(s) in the Field in the Co-Promotion Territory (each as defined in the Myovant/Pfizer Agreement), among other activities, in accordance with the terms of the Myovant/Pfizer Agreement. Unless otherwise noted, capitalized terms used, but not defined herein, shall have the respective meanings ascribed to them in the Myovant/Pfizer Agreement, as the context requires.

The Parties now wish to enter into this Letter Agreement to acknowledge Pfizer's termination of its rights under the Myovant/Pfizer Agreement for the territory of Canada with respect to the Oncology Product in the Oncology Field.

In accordance with Section 15.5 of the Myovant/Pfizer Agreement, this Letter Agreement will serve as written notice to Myovant that Pfizer is terminating its rights under the Myovant/Pfizer Agreement with respect to the Oncology Product for prostate cancer in Canada; [***].

"**Myovant Canada Oncology Expenses"** as used herein means any costs incurred by Myovant to Manufacture, Develop or Commercialize the Oncology Product for prostate cancer in or for Canada.

"**Sublicense**" as used herein means any right granted, license given or agreement entered into by Myovant or its Affiliates in which Myovant or its Affiliates grants or otherwise transfers any rights to the Oncology Product to a Third Party [***].

"**Sublicensee**" means any Third Party to which Myovant or its Affiliates has granted a Sublicense under this Letter Agreement.

"**Sublicensing Income**" as used herein means any and all consideration in any form paid to Myovant by a Sublicensee for the grant of a Sublicense to the Oncology Product, including but not limited to [***] on sales of the Oncology Product; provided that Sublicensing Income shall expressly exclude [***].

Pursuant to Section 15.5.1, Canada is deemed to be a Terminated Territory for the Oncology Product under the Myovant/Pfizer Agreement. The effects of such termination-in-part are set out in Section 15.8 (Effects of Termination) of the Myovant/Pfizer Agreement.

The provisions of Sections 18.7 (Amendment), 18.8 (Notices), 18.11 (Severability), 18.12 (Waivers) and 18.15 (Counterparts) of the Myovant/Pfizer Agreement are hereby incorporated by reference as though set out in full in this Letter Agreement, provided that each reference to "this Agreement" in such incorporated provisions shall be construed as a reference to this Letter Agreement.

This Letter Agreement and the Myovant/Pfizer Agreement set forth and constitute the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises, and representations, whether written or oral, with respect thereto are superseded hereby and thereby.

This Letter Agreement shall be governed by and construed and enforced under the substantive laws of the State of New York, without giving effect to any choice of law rules that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The United Nations Convention on Contracts for the International Sale of Goods (1980) shall not apply to this Agreement.

Any controversy or claim arising out of or relating to this Letter Agreement shall constitute a "Dispute" under the Myovant/Pfizer Agreement, and Section 17.2 of the Myovant/Pfizer Agreement shall apply to any such Dispute accordingly.

[signature page follows]

This Side Letter Agreement is signed below by authorized representatives of Myovant and Pfizer, respectively indicating the Parties' acceptance of the terms and conditions of this Side Letter Agreement.

MYOVANT SCIENCES GMBH		**PFIZER Inc.**	
By:	/s/ Matt Lang	By:	/s/ John DeYoung
Name:	Matt Lang	Name:	John DeYoung
Title:	General Manager	Title:	Vice President

Exhibit 31.1

CERTIFICATION

I, David Marek, 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 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: October 26, 2022

By: /s/ David Marek
David Marek
Principal Executive Officer

Exhibit 31.2

CERTIFICATION

I, Uneek Mehra, 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 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: October 26, 2022

By: /s/ Uneek Mehra
Uneek Mehra
Principal Financial Officer

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Myovant Sciences Ltd. (the "Company") for the period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, David Marek, 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 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: October 26, 2022

By: /s/ David Marek
David Marek
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 September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Uneek Mehra, 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: October 26, 2022

By: /s/ Uneek Mehra
Uneek Mehra
Principal Financial 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.