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

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended December 31, 2020
or
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____
Commission file number 001-37929

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

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

Registrant's telephone number, including area code: **+44 (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 ☐

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 ☐

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. ☐

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 February 8, 2021, was 90,799,425.

MYOVANT SCIENCES LTD.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED DECEMBER 31, 2020

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	December 31, 2020	March 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 713,523	$ 76,644
Marketable securities	32,324	2,997
Prepaid expenses and other current assets	8,180	8,269
Total current assets	754,027	87,910
Property and equipment, net	2,847	2,497
Operating lease right-of-use asset	10,045	11,146
Other assets	7,295	4,373
Total assets	$ 774,214	$ 105,926
Liabilities and shareholders' deficit		
Current liabilities:		
Accounts payable	$ 12,357	$ 15,334
Interest payable (related party)	—	15
Accrued expenses	44,377	29,060
Deferred revenue	100,564	40,000
Cost share advance from collaboration partner	92,415	—
Operating lease liability	1,731	1,516
Amounts due to related parties	628	—
Total current liabilities	252,072	85,925
Deferred revenue, non-current	418,344	—
Cost share advance from collaboration partner, non-current	46,424	—
Long-term operating lease liability	9,669	10,996
Long-term debt, less current maturities (related party)	313,700	113,700
Other	4,662	3,582
Total liabilities	1,044,871	214,203
Commitments and contingencies (Note 11)		
Shareholders' deficit:		
Common shares, par value $0.000017727 per share, 564,111,242 shares authorized, 90,870,042 and 89,833,998 issued and outstanding at December 31, 2020 and March 31, 2020, respectively	2	2
Additional paid-in capital	711,411	684,381
Accumulated other comprehensive loss	(17,285)	(1,646)
Accumulated deficit	(964,785)	(791,014)
Total shareholders' deficit	(270,657)	(108,277)
Total liabilities and shareholders' deficit	$ 774,214	$ 105,926

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

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

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2020	2019	2020	2019
Revenues:				
Collaboration revenue	$ 1,379	$ —	$ 1,379	$ —
License and milestone revenue	—	—	33,333	—
Total revenues	1,379	—	34,712	—
Operating expenses:				
Research and development	30,453	48,927	115,160	150,847
Selling, general and administrative [1]	49,243	29,142	103,387	59,897
Total operating expenses	79,696	78,069	218,547	210,744
Loss from operations	(78,317)	(78,069)	(183,835)	(210,744)
Interest expense [2]	2,609	3,657	6,908	11,238
Loss on extinguishment of debt	—	4,851	—	4,851
Interest income	(32)	(597)	(178)	(2,305)
Other income, net	(5,891)	(567)	(16,178)	(1,151)
Loss before income taxes	(75,003)	(85,413)	(174,387)	(223,377)
Income tax (benefit) expense	(1,154)	191	(616)	699
Net loss	$ (73,849)	$ (85,604)	$ (173,771)	$ (224,076)
Net loss per common share — basic and diluted	$ (0.82)	$ (0.96)	$ (1.94)	$ (2.64)
Weighted average common shares outstanding — basic and diluted	90,096,557	88,893,579	89,715,160	84,750,114

[1] Includes $1,671 and $3,076 of expense (inclusive of third-party pass-through costs) for the three and nine months ended December 31, 2020, respectively, pursuant to the terms of the Company's agreements with Sumitovant Biopharma Ltd. and Sunovion Pharmaceuticals Inc. (see Note 5).

[2] Includes $2,569 and $6,868 of interest expense from related-party long-term debt with Sumitomo Dainippon Pharma for the three and nine months ended December 31, 2020, respectively, and $16 for both the three and nine months ended December 31, 2019. (see Note 5(A)).

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

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

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2020	2019	2020	2019
Net loss	$ (73,849)	$ (85,604)	$ (173,771)	$ (224,076)
Other comprehensive loss:				
Foreign currency translation adjustment	(5,745)	(792)	(15,639)	(1,330)
Total other comprehensive loss	(5,745)	(792)	(15,639)	(1,330)
Comprehensive loss	$ (79,594)	$ (86,396)	$ (189,410)	$ (225,406)

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

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

	Common Shares		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' (Deficit) Equity
	Shares	Amount				
Balance at March 31, 2020	89,833,998	$ 2	$ 684,381	$ (1,646)	$ (791,014)	$ (108,277)
Share-based compensation expense	—	—	7,812	—	—	7,812
Issuance of shares upon exercise of stock options and vesting of restricted stock units	303,014	—	2,190	—	—	2,190
Foreign currency translation adjustment	—	—	—	(3,475)	—	(3,475)
Net loss	—	—	—	—	(32,860)	(32,860)
Balance at June 30, 2020	90,137,012	2	694,383	(5,121)	(823,874)	(134,610)
Share-based compensation expense	—	—	6,924	—	—	6,924
Issuance of shares upon exercise of stock options and vesting of restricted stock units and performance share units	443,991	—	1,388	—	—	1,388
Foreign currency translation adjustment	—	—	—	(6,419)	—	(6,419)
Net loss	—	—	—	—	(67,062)	(67,062)
Balance at September 30, 2020	90,581,003	2	702,695	(11,540)	(890,936)	(199,779)
Share-based compensation expense	—	—	7,010	—	—	7,010
Issuance of shares upon exercise of stock options and vesting of restricted stock units and performance share units	289,039	—	1,706	—	—	1,706
Foreign currency translation adjustment	—	—	—	(5,745)	—	(5,745)
Net loss	—	—	—	—	(73,849)	(73,849)
Balance at December 31, 2020	90,870,042	$ 2	$ 711,411	$ (17,285)	$ (964,785)	$ (270,657)

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

	Common Shares		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' (Deficit) Equity
	Shares	Amount				
Balance at March 31, 2019	72,057,490	$ 1	$ 505,851	$ 507	$ (502,025)	$ 4,334
Issuance of shares in connection with "at-the-market" equity offering, net of commissions of $79	106,494	—	2,546	—	—	2,546
Issuance of shares in connection with public equity offering, net of commissions and offering costs of $9,229	17,424,243	1	134,537	—	—	134,538
Share-based compensation expense	—	—	6,410	—	—	6,410
Capital contribution from former controlling shareholder — share-based compensation	—	—	42	—	—	42
Capital contribution from former controlling shareholder	—	—	106	—	—	106
Foreign currency translation adjustment	—	—	—	(819)	—	(819)
Issuance of shares upon exercise of stock options and vesting of restricted stock units	34,399	—	314	—	—	314
Net loss	—	—	—	—	(67,904)	(67,904)
Balance at June 30, 2019	89,622,626	2	649,806	(312)	(569,929)	79,567
Public equity offering, additional offering costs	—	—	(80)	—	—	(80)
Share-based compensation expense	—	—	7,879	—	—	7,879
Capital contribution from former controlling shareholder — share-based compensation	—	—	52	—	—	52
Capital contribution from former controlling shareholder	—	—	123	—	—	123
Foreign currency translation adjustment	—	—	—	281	—	281
Issuance of shares upon vesting of restricted stock units	938	—	—	—	—	—
Net loss	—	—	—	—	(70,568)	(70,568)
Balance at September 30, 2019	89,623,564	2	657,780	(31)	(640,497)	17,254
Share-based compensation expense	—	—	19,740	—	—	19,740
Capital contribution from former majority shareholder — share-based compensation	—	—	55	—	—	55
Capital contribution from former majority shareholder	—	—	105	—	—	105
Foreign currency translation adjustment	—	—	—	(792)	—	(792)
Issuance of shares upon exercise of stock options and vesting of PSUs and RSUs	164,090	—	354	—	—	354
Net loss	—	—	—	—	(85,604)	(85,604)
Balance at December 31, 2019	89,787,654	$ 2	$ 678,034	$ (823)	$ (726,101)	$ (48,888)

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

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

	Nine Months Ended December 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (173,771)	$ (224,076)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Share-based compensation	21,746	34,178
Depreciation and amortization [1]	1,787	1,236
Non-cash interest expense [2]	40	1,486
Loss on extinguishment of debt	—	4,851
Foreign currency transaction gain	(16,178)	(1,151)
Other	538	(23)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	89	(1,892)
Income tax receivable	—	524
Other assets	(1,309)	(272)
Accounts payable	(2,977)	(4,402)
Interest payable	—	(1,077)
Interest payable (related party)	(15)	16
Accrued expenses	15,317	(8,521)
Deferred revenue	478,908	—
Cost share advance from collaboration partner	138,800	—
Operating lease liabilities	(1,112)	(547)
Deferred interest payable	—	(2,273)
Amounts due to related parties	628	—
Other liabilities	1,080	—
Net cash provided by (used in) operating activities	463,571	(201,943)
Cash flows from investing activities:		
Purchases of marketable securities	(47,562)	(32,076)
Maturities of marketable securities	18,235	16,440
Purchases of property and equipment	(1,036)	(824)
Net cash used in investing activities	(30,363)	(16,460)
Cash flows from financing activities:		
Proceeds from issuance of common shares in “at-the-market” equity offering, net of issuance costs paid	—	2,546
Proceeds from issuance of common shares in public equity offering, net of issuance costs	—	134,458
Proceeds from related party debt financing	200,000	113,700
Proceeds from stock option exercises	5,284	667
Payments on third party debt financings and redemption fees	—	(105,420)
Payment of annual debt administration fee to NovaQuest	—	(300)
Net cash provided by financing activities	205,284	145,651
Net change in cash, cash equivalents and restricted cash	638,492	(72,752)
Cash, cash equivalents and restricted cash, beginning of period	78,018	157,199
Cash, cash equivalents and restricted cash, end of period	$ 716,510	$ 84,447

[1] Includes amortization of operating lease right-of-use assets.
[2] Includes imputed interest on cost share advance from collaboration partner for the nine months ended December 31, 2020 and amortization of debt discount and issuance costs for the nine months ended December 31, 2019.

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

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

Note 1—Description of Business

Myovant Sciences Ltd. (together with its wholly-owned subsidiaries, the "Company") is a healthcare company focused on redefining care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. The Company's lead product candidate, relugolix, is a once-daily, oral gonadotropin-releasing hormone ("GnRH") receptor antagonist. Relugolix (120 mg) is approved by the U.S. Food and Drug Administration ("FDA") as ORGOVYX™ (relugolix) for adult patients with advanced prostate cancer. Relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) is under regulatory review in the U.S. and Europe for women with uterine fibroids and is under development for women with endometriosis. The Company is also developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, which has completed a Phase 2a study for the treatment of female infertility as part of assisted reproduction.

Since its inception, the Company has devoted substantially all of its efforts to identifying and in-licensing its product candidates, organizing and staffing the Company, raising capital, preparing for and advancing the clinical development of its product candidates, and preparing for potential regulatory approvals and commercialization of its product candidates.

The Company's majority shareholder is Sumitovant Biopharma Ltd. ("Sumitovant"), a wholly-owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo Dainippon Pharma"). As of December 31, 2020, Sumitovant directly, and Sumitomo Dainippon Pharma indirectly, own 48,641,181, or approximately 53.5%, of the Company's outstanding common shares.

Note 2—Summary of Significant Accounting Policies

(A) Basis of Presentation

The Company's fiscal year ends on March 31, and its first three fiscal quarters end on June 30, September 30 and December 31. The Company has determined that it has one operating and reporting segment as it allocates resources and assesses financial performance on a consolidated basis.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with 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. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2020, filed with the U.S. Securities and Exchange Commission (the "SEC") on May 18, 2020. The unaudited consolidated balance sheet at March 31, 2020 has been derived from the audited consolidated financial statements at that date. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary to present fairly the financial position of the Company and its results of operations and cash flows for the interim periods presented have been included. Operating results for the three and nine months ended December 31, 2020 are not necessarily indicative of the results that may be expected for the fiscal year ending March 31, 2021, for any other interim period or for any other future year. There have been no significant changes in the Company's accounting policies from those disclosed in its Annual Report on Form 10-K for the fiscal year ended March 31, 2020, filed with the SEC on May 18, 2020, except for the accounting for collaboration arrangements as described below.

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. The Company has no unconsolidated subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

(B) Liquidity and Capital Resources

Since the Company's inception, it has funded its operations primarily from the issuance and sale of its common shares, from debt financing arrangements, and more recently from upfront and milestone payments received from Gedeon Richter Plc. ("Richter") and Pfizer Inc. ("Pfizer"). As of December 31, 2020, the Company had approximately $745.8 million in cash, cash equivalents, and marketable securities. The Company currently 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 on Form 10-Q.

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 December 31, 2020, the Company has approximately $86.3 million of borrowing capacity available to it under the Sumitomo Dainippon Pharma Loan Agreement (see Note 5(A)) and is also eligible to receive up to $3.7 billion and $137.5 million of additional milestone payments from Pfizer and Richter pursuant to the Pfizer Collaboration and License Agreement (see Note 10(B)) and the Richter Development and Commercialization Agreement (see Note 10(A)), respectively, as well as potential royalty payments on net sales under each agreement.

(C) Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions in certain circumstances that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company regularly evaluates estimates and assumptions related to assets and liabilities, and disclosures of contingent assets and liabilities at the dates of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting periods. Determinations in which management uses subjective judgments include, but are not limited to, the evaluation of the Company's ability to continue as a going concern, revenue recognition, share-based compensation expenses, research and development ("R&D") expenses and accruals, leases, and income taxes. The Company bases its estimates and assumptions on historical experience and on various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities at the date of the 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 in light of changes in circumstances, facts, or experience. Changes in estimates and assumptions are reflected in reported results in the period in which they become known. Actual results could differ from those estimates.

(D) Risks and Uncertainties

The Company is subject to risks and uncertainties common to companies in the biotechnology and pharmaceutical industries, including, but not limited to, risks of failure or unsatisfactory results of nonclinical and clinical studies, the need for significant capital to fund the development of its product candidates and the commercialization of any product candidates that may obtain marketing approval, the need to obtain marketing approval for its product candidates, the need to successfully commercialize and gain market acceptance of any of its product candidates that obtain regulatory approval, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development by competitors of technological innovations, ability to transition from pilot-scale manufacturing to large-scale production of products, and dependence on third-party service providers such as contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), and third-party logistics providers.

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. Due to the COVID-19 pandemic, there has been uncertainty and disruption in the global economy and financial markets. Through February 11, 2021, the date of issuance of this Quarterly Report on Form 10-Q, the Company's results of operations and cash flows have not been significantly impacted by the COVID-19 pandemic. The Company is not aware of any specific event or circumstance that would require an update to its estimates, judgments, and assumptions or a revision of the carrying value of the Company's assets or liabilities as of February 11, 2021.

(E) Net Loss per Common Share

Basic net loss per common share is computed by dividing net loss applicable to common shareholders by the weighted-average number of common shares outstanding during the period, reduced, when applicable, for outstanding yet unvested shares of restricted common stock. The computation of diluted net loss per common share is based on the weighted-average number of common shares outstanding during the period plus, when their effect is dilutive, incremental shares consisting of shares subject to stock options, restricted stock units, restricted stock awards, performance stock units, and warrants. In periods in which the Company reports a net loss, all common share equivalents are deemed anti-dilutive such that basic net loss per common share and diluted net loss per common share are equal. Potentially dilutive common shares have been excluded from the diluted net loss per common share computations in all periods presented because such securities have an anti-dilutive effect on net loss per common share due to the Company's net loss. There are no reconciling items used to calculate the weighted-average number of total common shares outstanding for basic and diluted net loss per common share.

As of December 31, 2020, and 2019, potentially dilutive securities were as follows:

	December 31,	
	2020	2019
Stock options	8,221,197	7,744,257
Restricted stock awards (unvested)	564,111	705,137
Restricted stock units (unvested)	3,091,478	683,729
Performance stock units (unvested)	700,204	299,870
Warrants	73,710	73,710
Total	12,650,700	9,506,703

(F) Cash, Cash Equivalents, and Restricted Cash

Cash as reported on the unaudited condensed consolidated statements of cash flows includes the aggregate amounts of cash, cash equivalents, and restricted cash and consists of the following (in thousands):

	December 31,	
	2020	2019
Cash and cash equivalents	$ 713,523	$ 83,073
Restricted cash [(1)]	2,987	1,374
Total cash, cash equivalents and restricted cash	$ 716,510	$ 84,447

[(1)] Restricted cash consists of funds held or designated to satisfy the requirements of certain agreements that are restricted in their use and are included in other assets on the unaudited condensed consolidated balance sheets.

(G) Marketable Securities

Investments in marketable securities are held in a custodial account at a financial institution and managed by the Company's investment advisor based on the Company's investment guidelines. The Company considers all highly liquid investments in securities with a maturity of greater than three months at the time of purchase to be marketable securities.

The Company classifies its marketable securities as available-for-sale at the time of purchase and reevaluates such designation at each balance sheet date. Unrealized gains and losses on available-for-sale securities are excluded from earnings and are recorded in accumulated other comprehensive (loss) income until realized. Any unrealized losses are evaluated for other-than-temporary impairment at each balance sheet date. Realized gains and losses are determined based on the specific identification method and are recorded in other (income) expense, net.

The Company does not intend to sell its securities that are in an unrealized loss position, and it is unlikely that the Company will be required to sell its securities before recovery of their amortized cost basis, which may be maturity. Factors considered in determining whether a loss is temporary include the length of time and extent to which the fair value has been less than the amortized cost basis and whether the Company intends to sell the security or whether it is more likely than not that the Company would be required to sell the security before recovery of the amortized cost basis. See Note 3 for additional information.

(H) Fair Value Measurements

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

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

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

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

The Company's financial instruments include cash, cash equivalents, marketable securities, accounts payable, amounts due to related parties, debt obligations, and cost share advance from collaboration partner. Cash, cash equivalents, accounts payable, and amounts due to related parties are stated at their respective historical carrying amounts, which approximate fair value due to their short-term nature. Marketable securities and cost share advance from collaboration partner are recorded at their estimated fair value and are included in Level 2 of the fair value hierarchy.

(I) License and Collaboration Revenue

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers* (Topic 606), as subsequently amended, which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers. The core principle of the revenue model is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. The Company was required to adopt ASC 606 on April 1, 2018. As the Company did not have any effective contracts within the scope of this guidance prior to April 1, 2018, ASC 606 had no impact on the Company's consolidated financial statements and related disclosures upon adoption. ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards, such as collaboration arrangements and leases.

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements*, to determine whether such arrangements involve joint operating activities performed by the parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple units of account, the Company first determines which units of account of the collaboration are deemed to be within the scope of ASC 808 and those that are reflective of a vendor-customer relationship and, therefore, within the scope of ASC 606.

While ASC 808 defines collaboration arrangements and provides guidance on income statement presentation, classification, and disclosures related to such arrangements, it does not address recognition and measurement matters, such as (1) determining the appropriate unit of account or (2) when the recognition criteria are met. Therefore, the accounting for these arrangements is either based on an analogy to other accounting literature, such as ASC 606, or an accounting policy election by management. For units of account within collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate revenue recognition method is determined and applied consistently.

For units of account under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as the Company satisfies a performance obligation.

For units of account under ASC 606, the Company applies significant judgment when evaluating whether contractual obligations represent distinct performance obligations, allocating transaction price to performance obligations within a contract, determining when performance obligations have been met, assessing the recognition and future reversal of variable

consideration, and determining and applying appropriate methods of measuring progress for performance obligations satisfied over time. These judgments are discussed in more detail below.

- *Licenses of intellectual property*: If the licenses to intellectual property are determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are not distinct from other promises, the Company applies judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the related revenue recognition accordingly.
- *Milestone payments*: At the inception of each arrangement that includes research, development or regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative standalone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price on a cumulative catch-up basis in earnings in the period of the adjustment.
- *Royalties and sales-based milestone payments*: For arrangements that include sales-based royalties, including sales-based milestone payments based on pre-specified level of sales, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

(J) Change in Functional Currency

Prior to December 1, 2020, the functional currency of the Company's wholly-owned subsidiary in Switzerland, Myovant Sciences GmbH ("MSG"), was the local currency where the subsidiary is located, the Swiss franc. Transactions in foreign currencies were translated to the functional currency at the rate of exchange at the date of the transaction. Transaction gains and losses were recognized in other (income) expense, net in the consolidated statements of operations. The results of operations of MSG were translated to U.S. dollar, the Company's reporting currency, at the average rates of exchange during the period. The cumulative effect of these exchange rate adjustments was included in a separate component of other comprehensive income (loss) in the consolidated balance sheets.

Effective December 1, 2020, as a result of significant changes in economic facts and circumstances in the operations of MSG, the functional currency of MSG was changed from the Swiss franc to the U.S. dollar. The change in the functional currency is accounted for prospectively from December 1, 2020. Therefore, any gains or losses that were previously recorded in accumulated other comprehensive income (loss) remain unchanged.

(K) Recently Adopted Accounting Standards

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement* (Topic 820)*: Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which simplifies the fair value measurement disclosure requirements. The Company adopted the new standard on April 1, 2020. The adoption of ASU 2018-13 did not have a material impact on the Company's unaudited condensed consolidated financial statements and related disclosures.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements* (Topic 808)*: Clarifying the Interaction between Topic 808 and Topic 606* ("ASU 2018-18"). This guidance is intended to reduce diversity in practice and clarify the interaction between Topic 808, *Collaborative Arrangements*, and Topic 606, *Revenue from Contracts with Customers*. ASU 2018-18 provided guidance on whether certain transactions between collaborative arrangement participants should be accounted for with revenue under Topic 606. The Company adopted the new standard on April 1, 2020. The adoption of ASU 2018-18 did not have a material impact on the Company's unaudited condensed consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-15, *Intangibles - Goodwill and Other - Internal-Use Software* (Subtopic 350-40) ("ASU 2018-15"), which amends ASU 2015-05, *Customers Accounting for Fees in a Cloud Computing Agreement*, to help entities evaluate the accounting for fees paid by a customer in a cloud computing arrangement (hosting arrangement) by providing guidance for determining when the arrangement includes a software license. The most significant change will align

the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software and hosting arrangements that include an internal-use software license. Accordingly, the amendments in ASU 2018-15 require an entity in a hosting arrangement that is a service contract to follow the guidance in Subtopic 350-40 to determine which implementation costs to capitalize as assets related to the service contract and which costs to expense. The Company adopted ASU 2018-15 using the prospective method as of April 1, 2020. The adoption of ASU 2018-15 did not have a material impact on the Company's unaudited condensed consolidated financial statements and related disclosures.

(L) Recently Issued Accounting Standards

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 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. As of December 31, 2020, the Company has not modified its contract that will be impacted by reference rate reform. The Company will continue to assess the impact the adoption of this standard will have on its consolidated financial statements and related disclosures when its contract impacted by reference rate reform is modified.

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 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2019. Early adoption is 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 amends 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.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes* (Topic 740) ("ASU 2019-12"), that eliminates certain exceptions to the general principles in ASC 740 related to intra-period tax allocation, deferred tax liability and general methodology for calculating income taxes. ASU 2019-12 also simplifies U.S. GAAP by making other changes for matters such as, franchise taxes that are partially based on income, transactions with a government that result in a step up in the tax basis of goodwill, separate financial statements of legal entities that are not subject to tax, and enacted changes in tax laws in interim periods. ASU 2019-12 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2020. Early adoption is permitted, including adoption in any interim period. The Company is currently assessing the impact the adoption of this standard will have on its consolidated financial statements and related disclosures.

Other recent accounting pronouncements issued by the FASB, (including its Emerging Issues Task Force), the American Institute of Certified Public Accountants, and the SEC did not, or are not believed by the Company to, have a material impact on the Company's unaudited condensed consolidated financial statements and related disclosures.

Note 3—Investments and Fair Value Measurements

Fair Value Measurements

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

	Quoted Market Prices for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Fair Value
As of December 31, 2020				
Money market funds [1]	$ 3	$ —	$ —	$ 3
Commercial paper [2]	—	65,501	—	65,501
Municipal bonds [3]	—	4,499	—	4,499
Total assets	$ 3	$ 70,000	$ —	$ 70,003
As of March 31, 2020				
Money market funds [1]	$ 11,348	$ —	$ —	$ 11,348
Commercial paper [4]	—	7,042	—	7,042
Total assets	$ 11,348	$ 7,042	$ —	$ 18,390

[1] Included in cash and cash equivalents.
[2] Includes $37.7 million in cash and cash equivalents and $27.8 million in marketable securities.
[3] Included in marketable securities.
[4] Includes $4.0 million in cash and cash equivalents and $3.0 million in marketable securities.

There were no liabilities measured at fair value on a recurring basis as of December 31, 2020 or March 31, 2020. During the three months ended December 31, 2020, the Company recorded the cost share advance from collaboration partner at its estimated fair value of $138.8 million as of the transaction date, which is included in level 2 of the fair value hierarchy. As discussed in Note 10(B), the cost share advance from collaboration partner has been discounted to fair value using the Company's estimated incremental borrowing rate over the period in which the cost share advance is expected to be utilized. There were no nonrecurring fair value liabilities as of March 31, 2020.

Note 4—Accrued Expenses

As of December 31, 2020, and March 31, 2020, accrued expenses consisted of the following (in thousands):

	December 31, 2020	March 31, 2020
Accrued R&D expenses	$ 19,294	$ 15,500
Accrued compensation-related expenses	13,016	9,309
Accrued commercial expenses	7,889	818
Accrued professional service fees	1,334	1,126
Accrued other expenses	2,844	2,307
Total accrued expenses	$ 44,377	$ 29,060

Note 5—Related Party Transactions

(A) Sumitomo Dainippon Pharma Co., Ltd.

On December 27, 2019, the Company's former controlling shareholder, Roivant Sciences Ltd. ("Roivant"), completed a transaction (the "Sumitomo-Roivant Transaction") in which all of the Company's outstanding common shares held directly or indirectly by Roivant and not already held by Sumitovant were transferred to Sumitovant, and Roivant transferred all of the outstanding equity of Sumitovant to Sumitomo Dainippon Pharma, resulting in Sumitovant directly, and Sumitomo Dainippon Pharma indirectly, owning 45,008,604, or approximately 50.2%, of the Company's outstanding common shares on December 27, 2019. As of December 31, 2020, Sumitovant directly, and Sumitomo Dainippon Pharma indirectly, own 48,641,181, or approximately 53.5%, of the Company's outstanding common shares.

Sumitomo Dainippon Pharma Loan Agreement

On December 27, 2019, the Company and its subsidiary, MSG, entered into a Loan Agreement with Sumitomo Dainippon Pharma (the "Sumitomo Dainippon Pharma Loan Agreement"). Pursuant to the Sumitomo Dainippon Pharma Loan Agreement, Sumitomo Dainippon Pharma agreed to make revolving loans to the Company in an aggregate principal amount of up to $400.0 million. On December 30, 2019, the Company borrowed an initial amount of $113.7 million under the Sumitomo Dainippon Pharma Loan Agreement, the proceeds of which were used to repay all outstanding obligations of the Company to NovaQuest Capital Management ("NovaQuest") and Hercules Capital, Inc. ("Hercules") and to satisfy certain other fees and expenses. Additional 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. In addition, if Sumitomo Dainippon Pharma fails to own at least a majority of the Company's outstanding common shares, it may become unlawful under Japanese law for Sumitomo Dainippon Pharma to fund loans to the Company, in which case the Company would not be able to continue to borrow under the Sumitomo Dainippon 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 Dainippon Pharma Loan Agreement. Loans under the Sumitomo Dainippon Pharma Loan Agreement are prepayable at any time without premium or penalty upon 10 business days' prior written notice.

Loans under the Sumitomo Dainippon Pharma Loan Agreement bear interest at a rate per annum equal to 3-month LIBOR plus a margin of 3% payable on the last day of each calendar quarter. LIBOR is currently expected to be phased out by the end of 2021, and if it becomes unavailable, the Company and Sumitomo Dainippon 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 Dainippon 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 guarantees. The Sumitomo Dainippon Pharma Loan Agreement includes customary representations and warranties and affirmative and negative covenants.

The Sumitomo Dainippon 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 Dainippon 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 Dainippon Pharma may take such other actions as set forth in the Sumitomo Dainippon Pharma Loan Agreement. Upon the occurrence of certain bankruptcy and insolvency events, the obligations of Sumitomo Dainippon 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 Dainippon Pharma to maintain the loans under the Sumitomo Dainippon 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 December 31, 2020, approximately $86.3 million of borrowing capacity remains available to the Company, subject to the terms of the Sumitomo Dainippon Pharma Loan Agreement, and the outstanding loan balance of $313.7 million is classified as a long-term liability on the accompanying unaudited condensed consolidated balance sheets under the caption long-term debt, less current maturities (related party). Interest expense under the Sumitomo Dainippon Pharma Loan Agreement was $2.6 million and $6.9 million for the three and nine months ended December 31, 2020, respectively, and is included in interest expense in the accompanying unaudited condensed consolidated statements of operations. Interest expense under the Sumitomo Dainippon Pharma Loan Agreement was less than $0.1 million for both the three and nine months ended December 31, 2019.

Sumitomo Dainippon Pharma Loan Commitment

On August 5, 2020, the Company obtained a debt commitment letter from Sumitomo Dainippon Pharma, as amended by a letter dated September 29, 2020, and then further amended by a letter dated December 22, 2020 (the "2020 Commitment Letter"), pursuant to which, subject to the terms and conditions set forth therein, Sumitomo Dainippon Pharma committed to enter into a new $200.0 million unsecured, low-interest, five-year term loan facility. The 2020 Commitment Letter expires in March 2021.

Investor Rights Agreement

On December 27, 2019, the Company entered into an Investor Rights Agreement with Sumitomo Dainippon 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 Dainippon 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 their 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 Dainippon Pharma or certain of its affiliates that would increase Sumitomo Dainippon 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 Dainippon 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 Dainippon Pharma beneficially owns more than 50% of the Company's common shares, Sumitomo Dainippon 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.

(B) Sumitovant

On May 18, 2020, the Company and Sumitovant entered into a consulting agreement, as amended on November 9, 2020, pursuant to which Sumitovant provides consulting services to the Company to support the Company in commercial planning, commercial launch activities and implementation. Adele Gulfo, Sumitovant's Chief Business and Commercial Development Officer and a member of the Company's board of directors, provides services to the Company on behalf of Sumitovant under this agreement. For the three and nine months ended December 31, 2020, the Company incurred $0.2 million and $0.5 million, respectively, of expense under this consulting agreement, which is included in selling, general and administrative ("SG&A") expenses in the accompanying unaudited condensed consolidated statements of operations. As of December 31, 2020, the Company's outstanding obligation pursuant to the consulting agreement is $0.1 million and is included in amounts due to related parties on the accompanying unaudited condensed consolidated balance sheet.

(C) Sunovion Pharmaceuticals Inc.

Market Access Services Agreement

On August 1, 2020, the Company's subsidiary, MSG, entered into the Market Access Services Agreement, as amended, with Sunovion Pharmaceuticals Inc. ("Sunovion"), a subsidiary of Sumitomo Dainippon Pharma. Pursuant to the Market Access Services Agreement, among other things, Sunovion agreed to provide to MSG certain market access services with respect to the distribution and sale of ORGOVYX ("Prostate Cancer Product") and relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg and norethindrone acetate 0.5 mg) ("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 MSG with price reporting metrics and other information required to allow the Company to comply with applicable government price reporting requirements; (viii) coordinating with MSG 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.

MSG, 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 United States, including all of its territories and possessions.

In order to facilitate Sunovion's provision of these services, MSG agreed, among other things, to: (i) grant Sunovion a non-exclusive license under all intellectual property owned or controlled by MSG, 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 MSG'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, MSG 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, MSG 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 when managing any rebates, chargebacks and similar fees. As of December 31, 2020, this escrow fund is included in restricted cash under the caption other assets on the accompanying unaudited condensed consolidated balance sheet. For the three and nine months ended December 31, 2020, the Company incurred $1.4 million and $2.5 million, respectively, of expense under this agreement (inclusive of third-party pass-through costs billed to the Company), which is included in SG&A expense in the accompanying unaudited condensed consolidated statements of operations. As of December 31, 2020, the Company's outstanding obligation pursuant to this agreement is $0.6 million and is included in amounts due to related parties on the accompanying unaudited condensed consolidated balance sheet.

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. MSG 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.

(D) Roivant Sciences Ltd.

As a result of the closing of the Sumitomo-Roivant Transaction described above, on December 27, 2019 all of the Company's outstanding common shares held directly or indirectly by Roivant and not already held by Sumitovant were transferred to Sumitovant, and Roivant transferred all of the outstanding equity of Sumitovant to Sumitomo Dainippon Pharma. As a result of the transfer of these common shares, Roivant no longer beneficially owns any common shares of the Company. On December 27, 2019, the then existing Information Sharing and Cooperation Agreement between the Company and Roivant, the then existing Services Agreements between the Company and certain of its subsidiaries and Roivant and certain of its subsidiaries, and the then existing Option Agreement between the Company and Roivant were terminated. For three and nine months ended December 31, 2019, the Company paid or reimbursed Roivant approximately $0.2 million and $0.6 million, respectively, under the terms of the then existing Services Agreements. In addition, the Company recorded share-based compensation expense allocated from Roivant of $0.1 million and $0.2 million for the three and nine months ended December 31, 2019, respectively. No amounts were incurred during the three and nine months ended December 31, 2020.

Roivant purchased 2,424,242 of the Company's common shares in the Company's June 4, 2019 underwritten public equity offering at the same price offered to the public of $8.25 per common share, for a total purchase price of $20.0 million (see Note 8).

Note 6—Extinguishment of Debt

The Company used the initial $113.7 million of proceeds from the Sumitomo Dainippon Pharma Loan Agreement (see Note 5(A)) to repay all outstanding obligations with Hercules and NovaQuest and to satisfy certain other fees and expenses. The repayments resulted in a loss on extinguishment of debt of $4.9 million, which is included under the caption loss on extinguishment of debt in the accompanying unaudited condensed consolidated statements of operations for the three and nine months ended December 31, 2019. The loss on extinguishment of debt was calculated as the difference between the carrying amount of the debt and the amounts paid to retire the debt.

Note 7—Income Taxes

The Company is not subject to taxation under the laws of Bermuda since it was organized as a Bermuda Exempted Limited Company, for which there is no current tax regime. The Company's income tax expense is primarily based on income taxes in the U.S. for federal, state and local taxes. The Company's effective tax rate for the three months ended December 31, 2020 and 2019 was 1.54% and (0.22)%, respectively. The Company's effective tax rate for the nine months ended December 31, 2020 and 2019 was 0.35% and (0.31)%, respectively. The Company's effective tax rate is driven by the Company's jurisdictional earnings by location and a valuation allowance that eliminates the Company's global net deferred tax assets.

The Company assesses the realizability of the 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, and includes a review of all available positive and negative evidence. Factors reviewed include projections of pre-tax book income for the foreseeable future, determining of cumulative pre-tax book income after permanent differences, earnings history, and reliability of forecasting. The Company will continue to assess the need for a valuation allowance on its deferred tax assets by evaluating both positive and negative evidence that may exist. Any adjustment to the net deferred tax asset valuation allowance would be recorded in the consolidated statement of operations for the period that the adjustment is determined to be required.

In response to the COVID-19 pandemic, many governments have enacted or are contemplating measures to provide aid and economic stimulus. These measures include 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 is having 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 December 31, 2020, the Company has deferred $1.8 million of employer payroll taxes, of which 50% are required to be deposited by December 2021 and the remaining 50% by December 2022. The current portion of the deferred payroll tax liability of $0.9 million is included in accrued expenses and the non-current portion of the deferred payroll tax liability of $0.9 million is included in other liabilities on the accompanying unaudited condensed consolidated balance sheet.

Note 8—Shareholders' Deficit

(A) At-the-Market Equity Offering Program

In April 2018, the Company entered into a sales agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen"), to sell its common shares having an aggregate offering price of up to $100.0 million from time to time through an "at-the-market" equity offering program under which Cowen acts as the Company's agent. During the nine months ended December 31, 2019, the Company issued and sold 106,494 of its common shares under the Sales Agreement. The common shares were sold at a weighted-average price of $24.65 per common share for aggregate net proceeds to the Company of approximately $2.5 million after deducting underwriting commissions paid by the Company. No shares were sold under the Sales Agreement during the three and nine months ended December 31, 2020 and the three months ended December 31, 2019. As of December 31, 2020, the Company had approximately $10.4 million of capacity available to it under its "at-the-market" equity offering program (the "ATM Program"). Given the Company's financial position of approximately $745.8 million of cash, cash equivalents, and marketable securities as of December 31, 2020, it currently does not expect to sell additional common shares pursuant to this ATM Program prior to its scheduled expiration in March 2021.

(B) Underwritten Public Equity Offering of Common Shares

On June 4, 2019, the Company completed an underwritten public equity offering of 17,424,243 of its common shares at a public offering price of $8.25 per common share. After deducting the underwriting discounts and commissions and offering costs paid by the Company, the net proceeds to the Company in connection with the underwritten public equity offering, including from the exercise of the underwriters' option to purchase additional common shares, were approximately $134.5 million.

Note 9—Share-Based Compensation

The Company has two share-based compensation plans, the Myovant Sciences Ltd. 2020 Inducement Plan and the Myovant Sciences Ltd. 2016 Equity Incentive Plan (collectively, the "Equity Plans").

(A) 2020 Inducement Plan

In November 2020, the compensation committee of the Company's board of directors adopted the Myovant Sciences Ltd. 2020 Inducement Plan (the "2020 Inducement Plan"), which, subject to the adjustment provisions thereof, reserved 1.0 million shares of the Company's common shares for issuance. The 2020 Inducement Plan was adopted without shareholder approval pursuant to the Listed Company Manual Rule 303A.08 ("Rule 303A.08") of the New York Stock Exchange (the "NYSE"). The 2020 Inducement Plan provides for the grant of restricted stock units and non-qualified stock options, and contains terms and conditions intended to comply with the inducement award exception under the NYSE rules. In accordance with Rule 303A.08, awards under the 2020 Inducement Plan may only be made to individuals not previously employees of the Company, or being rehired following a bona fide period of interruption of employment, as an inducement material to such individuals' entering into employment with the Company. An award is a right to receive the Company's common shares pursuant to the 2020 Inducement Plan pursuant to a restricted stock unit award or a non-qualified stock option award. As of December 31, 2020, a total of 0.7 million common shares were available for future issuance under the 2020 Inducement Plan.

(B) 2016 Equity Incentive Plan

In June 2016, the Company adopted its 2016 Equity Incentive Plan, as amended (the "2016 Plan"), under which 4.5 million common shares were originally reserved for issuance. Pursuant to the "evergreen" provision contained in the 2016 Plan, the number of common shares reserved for issuance under the 2016 Plan automatically increases on April 1 of each year, commencing on (and including) April 1, 2017 and ending on (and including) April 1, 2026, in an amount equal to 4% of the total number of shares of the Company's capital stock outstanding on March 31 of the preceding fiscal year, or a lesser number of shares as determined by the Company's board of directors. On April 1, 2020, the number of common shares authorized for issuance under the 2016 Plan increased automatically by 3.6 million shares in accordance with the evergreen provision. As of December 31, 2020, a total of 1.0 million common shares were available for future issuance under the 2016 Plan.

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

(C) Stock Options

A summary of stock option activity under the Company's Equity Plans are as follows:

	Number of Options
Options outstanding at March 31, 2020	7,723,302
Granted	1,679,338
Exercised	(729,024)
Forfeited	(452,419)
Options outstanding at December 31, 2020	8,221,197
Options vested and expected to vest at December 31, 2020	8,221,197
Options exercisable at December 31, 2020	4,456,746

(D) Restricted Stock Awards and Restricted Stock Units

A summary of restricted stock award and restricted stock unit activity under the Company's Equity Plans are as follows:

	Number of Shares
Unvested balance at March 31, 2020	1,280,312
Granted	2,947,939
Vested	(246,305)
Forfeited	(326,357)
Unvested balance at December 31, 2020	3,655,589

(E) Performance Stock Units

A summary of performance stock unit activity under the Company's Equity Plans are as follows:

	Number of Shares
Unvested balance at March 31, 2020	299,870
Granted	568,976
Vested	(131,227)
Forfeited	(37,415)
Unvested balance at December 31, 2020	700,204

The vesting of performance stock units requires that certain performance conditions are achieved during the performance period and is subject to the employee's continued service requirements.

(F) Share-Based Compensation Expense

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

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2020	2019	2020	2019
Share-based compensation expense recognized as:				
R&D expenses	$ 3,311	$ 5,399	$ 11,060	$ 11,565
SG&A expenses	3,699	14,396	10,686	22,613
Total	$ 7,010	$ 19,795	$ 21,746	$ 34,178

Share-based compensation expense is included in R&D and SG&A expenses in the accompanying unaudited condensed consolidated statements of operations consistent with the grantee's salary. Total unrecognized share-based compensation expense was approximately $66.6 million as of December 31, 2020 and is expected to be recognized over a weighted-average period of approximately 2.8 years. Share-based compensation expense included in R&D and SG&A expense for the three and nine months ended December 31, 2019 includes $1.8 million and $10.2 million, respectively, related to the accelerated vesting of certain share-based payment awards as a result of the change in control of the Company described in Note 5(A).

On January 3, 2021, Dr. Lynn Seely and Myovant Sciences, Inc. entered into a Separation Agreement and General Release pursuant to which, among other things, all of Dr. Seely's equity incentive awards granted under the 2016 Plan that are then outstanding and unvested on the Separation Date shall become fully vested and, if applicable, exercisable. The vesting of these awards is expected to result in the recognition of approximately $12.0 million of previously unrecognized share-based compensation expense as well as incremental share-based compensation as a result of the modification of these awards (see Note 12(B)).

Note 10—Collaboration and License Agreements

(A) Richter Development and Commercialization Agreement

On March 30, 2020, the Company entered into an exclusive license agreement 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 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 $10.0 million was received in April 2020), $107.5 million in sales-related milestones, and tiered royalties on net sales following regulatory approval. Under the terms of the agreement, the Company will continue to lead global development of relugolix combination tablet. The Company has also agreed to assist Richter in transferring manufacturing technology from the Company's CMOs to Richter to enable Richter to manufacture relugolix combination tablet. If requested by Richter, the Company has agreed to supply Richter with quantities of relugolix combination tablet for its territories pursuant to the Company's agreements with its CMOs. Richter will be 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 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 to evaluate the accounting under the Richter Development and Commercialization Agreement. In accordance with this guidance, 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 therapy, 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 therapy. 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 evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. Based upon the Company's assessment of its progress toward delivering relugolix combination therapy clinical and regulatory data packages to Richter, the Company concluded that as of December 31, 2020, it had satisfied approximately two-thirds of the combined performance obligation. As a result, the Company recognized $33.3 million of the transaction price as license and milestone revenue during the nine months ended December 31, 2020. There were no amounts recognized in the three months ended December 31, 2020 or the comparable prior year periods. As the Company currently expects to deliver the remaining substantive relugolix combination therapy data packages to Richter in the first quarter of the fiscal year ending March 31, 2022, the Company has recorded the remaining $16.7 million of the transaction price as deferred revenue, a current liability, on the unaudited condensed consolidated balance sheet as of December 31, 2020.

(B) Pfizer Collaboration and License Agreement

On December 26, 2020, the Company's subsidiary, MSG, and Pfizer, entered into a collaboration and license agreement (the "Pfizer Collaboration and License Agreement"), pursuant to which the Company and Pfizer will collaborate to jointly develop and commercialize relugolix in oncology and women's health in the U.S. and Canada (the "Co-Promotion Territory"). 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").

In the Co-Promotion Territory, the Company and Pfizer will 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 will remain responsible for regulatory interactions and drug supply and will continue to lead clinical development for relugolix combination tablet in the women's health indications, while development for ORGOVYX will be shared equally among the parties.

In the Co-Promotion Territory, the Company will be the principal on all sales transactions with third parties and will recognize 100% of product sales to third parties as revenue from contracts with customers. The Company concluded that based on the principal vs. 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, and is eligible to receive up to $3.7 billion of additional milestone payments, including two regulatory milestones of $100.0 million upon each FDA approval for relugolix combination tablet 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 addition, if Pfizer exercises its option to acquire exclusive commercialization and development rights to relugolix in oncology in the Pfizer Territory, the Company will receive an option exercise fee of $50.0 million and will also be eligible to receive double-digit royalties on net sales of relugolix in the Pfizer Territory. Pfizer will bear 100% of costs incurred in the Pfizer Territory.

Pursuant to the terms of the Pfizer Collaboration and License Agreement, the Company will 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 will carry over into the subsequent calendar years until the Company has assumed in aggregate $150.0 million of Pfizer's share of the Allowable Expenses.

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 and, in the case that Pfizer exercises its option for relugolix in the Pfizer Territory, on the last to expire royalty term with respect to a country in the Pfizer 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 according to the nature of the expense (e.g., collaboration expense (included as a component of cost of sales), 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 is Pfizer's advanced reimbursement for Pfizer's share of Allowable Expenses (up to $100.0 million for calendar year 2021 and up to $50.0 million for calendar year 2022). The Company concluded that the prepayment by Pfizer of its share of Allowable Expenses represents 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 based on the Company's incremental borrowing rate that was derived based on the Sumitomo Dainippon Pharma Loan Agreement, and recorded the discounted value of $146.4 million on the unaudited condensed consolidated balance sheet as a deposit liability (cost share advance from collaboration partner), split between a current and a non-current portion, based on the expected timing of Allowable Expenses subject to cost share. The financing component will be accreted to interest expense utilizing a method that approximates the effective yield method over the period in which the cost share advance is expected to be used. The remainder of the upfront payment of $503.6 million is recorded as deferred revenue and is being recognized as 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 regulatory milestones is outside of the Company's control and therefore is not deemed probable at contract inception. Amounts associated with the regulatory milestones will not initially be recognized. Upon achievement of the related regulatory milestone, cumulative catch-up revenue will be recorded in the period in which the respective regulatory milestone is achieved, and the remainder will be recognized over the remaining contract term. The Company determined that, conceptually, the 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 development milestones, sales-based milestone payments will not initially be recognized due to the uncertainty associated with the future commercial outcomes of relugolix and relugolix combination tablet. 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 Company determined that the $50.0 million option for an exclusive license in the Pfizer Territory does not give rise to a material right since the option fee, coupled with the net royalty payments, reflects its standalone selling price. As such, the option is not considered a unit of account under the present arrangement and will be assessed for accounting purposes if and when exercised.

See Note 10(C) for a description of the Company's contract liabilities and changes in these contract liabilities for the nine months ended December 31, 2020.

(C) Contract Balances

The Company records contract liabilities when cash payments are received or due in advance of the Company's performance pursuant to license and collaboration agreements. The Company's contract liabilities consist of deferred revenue and a cost share advance from its collaboration partner, Pfizer. The following table presents changes in the Company's contract liabilities during the nine months ended December 31, 2020 (in thousands):

	Balance at March 31, 2020	Additions	Imputed Interest	Deductions	Balance at December 31, 2020
Contract liabilities:					
Deferred revenue, current	$ 40,000	$ 93,897	$ —	$ (33,333)	$ 100,564
Cost share advance from collaboration partner, current	$ —	$ 100,000	$ —	$ (7,585)	$ 92,415
Deferred revenue, non-current	$ —	$ 419,723	$ —	$ (1,379)	$ 418,344
Cost share advance from collaboration partner, non-current	$ —	$ 46,384	$ 40	$ —	$ 46,424

The Company had no contract assets as of December 31, 2020 or March 31, 2020.

During the nine months ended December 31, 2020, current and non-current deferred revenue increased by $478.9 million. The increase was the net result of a $503.6 million upfront payment received from Pfizer (see Note 10(B)) and a $10.0 million regulatory milestone payment received from Richter (see Note 10(A)), partially offset by the recognition of $33.3 million of license and milestone revenue related to the Richter Development and Commercialization Agreement and the recognition of $1.4 million of collaboration revenue related to the Pfizer Collaboration and License Agreement.

During the nine months ended December 31, 2020, current and non-current cost share advance from collaboration partner increased by $138.8 million. The increase was the net result of the cost share advance of $150.0 million (discounted to a present value of $146.4 million) received from Pfizer (see Note 10(B)), partially offset by the application $7.6 million of shared Allowable Expenses. Accretion of the implied financing costs related to the cost share advance was less than $0.1 million.

Note 11—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 Dainippon Pharma against certain losses, claims, liabilities and related expenses incurred by Sumitomo Dainippon Pharma, subject to the terms of the Sumitomo Dainippon 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

Under the Company's license agreement (the "Takeda License Agreement") with Takeda, the Company will pay Takeda a fixed, high single-digit royalty on net sales of relugolix and MVT-602 products in the Company's territory, subject to certain agreed reductions. Takeda will pay the Company a royalty at the same rate 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. As the amount and timing of any potential future payments under the Takeda License Agreement are not probable and estimable, no such potential commitments have been included in the unaudited condensed consolidated balance sheet.

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.

Pursuant to a Commercial Manufacturing and Supply Agreement entered into with Takeda (the "Takeda Commercial Supply Agreement"), 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. For relugolix drug substance manufactured or delivered on or after December 31, 2019, the Company will pay Takeda a price per kilogram of relugolix drug substance to be agreed upon between the parties at the beginning of each fiscal year.

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 12—Subsequent Events

(A) Sumitomo Dainippon Pharma Loan Agreement

Pursuant to the terms of the Sumitomo Dainippon Pharma Loan Agreement (see Note 5(A)), the Company is permitted to draw down funds once per calendar quarter, subject to certain conditions. In January 2021, the Company borrowed $45.0 million under the Sumitomo Dainippon Pharma Loan Agreement. Subsequent to this draw, approximately $41.3 million of borrowing capacity remains available to the Company.

(B) Appointment of New Principal Executive Officer and Changes to Board of Directors

On January 4, 2021, David Marek was appointed as chief executive officer of Myovant Sciences, Inc. Mr. Marek will also serve as Principal Executive Officer of Myovant Sciences Ltd. and as a member of its board of directors. Mr. Marek succeeds Dr. Lynn Seely, who previously held these positions until her resignation on January 3, 2021.

Employment Agreement between Myovant Sciences, Inc. and David Marek

Mr. Marek and Myovant Sciences, Inc. entered into an Employment Agreement on January 4, 2021, pursuant to which, Mr. Marek was granted 306,427 stock options and 223,076 restricted stock units in January 2021. These awards will vest with respect to 1/4 of the shares covered by the awards on the first anniversary of the grant date and 1/16 of the shares covered by the awards quarterly thereafter.

Separation Agreement and General Release by and between Lynn Seely, M.D. and Myovant Sciences, Inc.

On January 3, 2021, Dr. Seely and Myovant Sciences, Inc. entered into a Separation Agreement and General Release pursuant to which, among other things, Dr. Seely will receive severance benefits of approximately $1.9 million, which the Company will record as SG&A expenses during the three months ended March 31, 2021.

Pursuant to the terms of the Separation and General Release Agreement, Dr. Seely will also receive full vesting of her then-outstanding and unvested equity awards. In addition, the post-termination period during which Dr. Seely may exercise her outstanding stock options will be extended to 12 months, and Dr. Seely has granted Sumitovant or any Sumitovant affiliate a right of first refusal to purchase her common shares of the Company under certain circumstances and provide the Company and its affiliates a general release of claims. The Company expects to recognize share-based compensation expense within SG&A expenses during the three months ended March 31, 2021 of approximately $28.0 million, consisting of share-based compensation expense related to the accelerated vesting of these equity awards, incremental share-based compensation expense related to the modification of the post-exercise termination period, and the reclassification and remeasurement of the awards from equity to liabilities following the modification of these awards to include a repurchase feature described above.

The share-based compensation liabilities will be remeasured at fair value each reporting period, with the change in fair value recorded as share-based compensation expense within SG&A expenses until the underlying equity awards are exercised and sold to Sumitovant or to the market or Dr. Seely has held the unsold shares for a period of at least six months. The fair value of the shares held for less than six months will be remeasured based on the Company’s closing stock price at each reporting period and the fair value of the outstanding stock options will be remeasured at each reporting period by utilizing the Black-Scholes option-pricing model.

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

The following discussion and analysis of our financial condition, results of operations and cash flows should be read in conjunction with (1) the unaudited condensed consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q, and (2) the audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the fiscal year ended March 31, 2020 included in our Annual Report on Form 10-K, filed with the SEC on May 18, 2020. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "Myovant," the "Company," "we," "us," and "our" refer to Myovant Sciences Ltd. and its wholly-owned subsidiaries.

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, (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 on Form 10-Q include, but are not limited to, statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things:

- the impact of pandemics, epidemics or outbreaks of infectious diseases, including the effect that the COVID-19 pandemic and related "shelter-in-place" orders and other measures will have on our business operations, financial conditions and results of operations;
- 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;
- our and our collaboration partners' ability to successfully plan for and commercialize ORGOVYX, as well as any other product candidates, such as relugolix combination tablet, if approved;
- our ability to procure sufficient quantities of commercial relugolix drug substance and drug product from approved third party 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 payors 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;
- 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 Richter under the Richter Development and Commercialization Agreement and Pfizer under the Pfizer Collaboration and License Agreement;
- our ability to borrow under the Sumitomo Dainippon Pharma Loan Agreement;

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

All brand names or trademarks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

Business Overview

We are a healthcare company focused on redefining care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. Our lead product candidate, relugolix, is a once-daily, oral GnRH receptor antagonist. Relugolix (120 mg) is approved by the FDA as ORGOVYX™ (relugolix) for adult patients with advanced prostate cancer. Relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) is under regulatory review in the U.S. and Europe for women with uterine fibroids and is under development for women with endometriosis. We are also developing MVT-602, an 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 devoted substantially all of our efforts to identifying and in-licensing our product candidates, organizing and staffing our company, raising capital, preparing for and advancing the clinical development of our product candidates and preparing for potential regulatory approvals and commercialization of our product candidates.

Our majority shareholder is Sumitovant, a wholly-owned subsidiary of Sumitomo Dainippon Pharma. As of December 31, 2020, Sumitovant directly, and Sumitomo Dainippon Pharma indirectly, own 48,641,181, or approximately 53.5%, of our outstanding common shares.

Third Fiscal Quarter Ended December 31, 2020 and Recent Corporate Updates

The following summarizes our third fiscal quarter ended December 31, 2020 and recent corporate updates.

Key Developments and Trends in Liquidity and Capital Resources

As of December 31, 2020, we had cash, cash equivalents and marketable securities of approximately $745.8 million. We currently 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 on Form 10-Q. See Note 2(B) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Pfizer Collaboration and License Agreement

On December 26, 2020, our subsidiary, MSG, and Pfizer, entered into a collaboration and license agreement (the "Pfizer Collaboration and License Agreement"), pursuant to which we and Pfizer will collaborate to jointly develop and commercialize relugolix in oncology and women's health in the U.S. and Canada (the "Co-Promotion Territory"). 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").

In the Co-Promotion Territory, we and Pfizer will equally share profits and certain expenses, including certain pre-launch inventory costs incurred by us prior to the effective date of the Pfizer Collaboration and License Agreement (the "Allowable Expenses"). We will remain responsible for regulatory interactions and drug supply and will continue to lead clinical development for relugolix combination tablet in the women's health indications, while development for ORGOVYX will be shared equally among the parties. In the Co-Promotion Territory, we will be the principal on all sales transactions with third parties and will recognize 100% of product sales to third parties as revenue from contracts with customers.

Pursuant to the terms of the Pfizer Collaboration and License Agreement, we received an upfront payment of $650.0 million in December 2020, and are eligible to receive up to $3.7 billion of additional milestone payments, including two regulatory milestones of $100.0 million upon each FDA approval for relugolix combination tablet 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 addition, if Pfizer exercises its option to acquire exclusive commercialization and development rights to relugolix in oncology in the Pfizer Territory, we will receive an option exercise fee of $50.0 million and will also be eligible to receive double-digit royalties on net sales of relugolix in the Pfizer Territory. Pfizer will bear 100% of costs incurred in the Pfizer Territory. See Note 10(B) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional information about the Pfizer Collaboration and License Agreement.

FDA Approval of ORGOVYX

On December 18, 2020, the FDA approved ORGOVYX for the treatment of adult patients with advanced prostate cancer. ORGOVYX, which was granted Priority Review by the FDA, is the first and only oral GnRH receptor antagonist for men with advanced prostate cancer. The approval was based on the efficacy and safety data from the Phase 3 HERO study of ORGOVYX in men with advanced prostate cancer. ORGOVYX became available through authorized specialty distributors in the U.S. in early January 2021. Additional information about ORGOVYX is included below in the section titled "—Our Approved Product and Product Candidates—ORGOVYX."

Relugolix Combination Tablet Clinical and Regulatory Updates

In this section, we summarize certain of our third fiscal quarter ended December 31, 2020 and recent relugolix combination tablet clinical and regulatory updates. Additional information about relugolix combination tablet is included in the section below titled "—Our Approved Product and Product Candidates—Relugolix Combination Tablet."

- ***Uterine Fibroids***
  - In October 2020, we presented the following data for relugolix combination therapy in women with uterine fibroids at the American Society for Reproductive Medicine ("ASRM") 2020 Virtual Congress:
    - One-year efficacy and safety data from the LIBERTY long-term extension study (Scientific Congress Prize Paper Session 1).
    - A validated exposure-response model simulating long-term effects of relugolix combination therapy on bone mineral density at the lumbar spine.
    - A poster describing the improvement of pain associated with uterine fibroids in the LIBERTY Phase 3 program (1st Place in Poster Competition).
- ***Endometriosis***
  - In October 2020, data from the replicate Phase 3 SPIRIT 1 and SPIRIT 2 studies were presented at the ASRM 2020 Virtual Congress in an oral presentation named the Prize Paper by the Endometriosis Special Interest Group.
  - In January 2021, we and Pfizer announced positive one-year data from the Phase 3 SPIRIT extension study of once-daily relugolix combination therapy in women with endometriosis.
- ***Ovulation Inhibition Study***
  - In October 2020, we presented additional data from the Phase 1 ovulation inhibition study at the ASRM 2020 Virtual Congress.

Appointment of New Principal Executive Officer and Changes to Board of Directors

On January 4, 2021, David Marek was appointed as chief executive officer of Myovant Sciences, Inc. Concurrent with this appointment, Mr. Marek was also appointed as Principal Executive Officer of Myovant Sciences Ltd. and a member of its board of directors. Mr. Marek succeeds Dr. Lynn Seely, who previously held these positions until her resignation on January 3, 2021.

Expected Upcoming Clinical and Regulatory Milestones

In this section, we summarize certain of our expected upcoming clinical and regulatory milestones.

- Data from the LIBERTY randomized withdrawal study, including efficacy and safety data of relugolix combination therapy in women with uterine fibroids for up to 2 years, is expected in the first quarter of calendar year 2021.
- Marketing Authorization Application ("MAA") submission to the European Medicines Agency ("EMA") for relugolix monotherapy for advanced prostate cancer expected in the first quarter of calendar year 2021.
- Myovant and Pfizer plan to initiate in the first half of calendar year 2021 a Phase 3 open label clinical study in the U.S. to assess the contraceptive efficacy of relugolix combination tablet. The SERENE study will enroll sexually active, healthy premenopausal women ages 18-35 years with presumed normal fertility. Women will receive once-daily relugolix combination tablet for thirteen 28-day cycles. The primary efficacy endpoint will be the Pearl Index, defined as the number of on-treatment pregnancies per 100 women-years of treatment. Positive data from the SERENE study would further differentiate relugolix combination tablet by potentially adding the benefit of prevention of pregnancy for women taking relugolix combination tablet for the treatment of uterine fibroids and endometriosis, if approved for these indications.
- FDA decision for relugolix combination tablet for the treatment of uterine fibroids expected by the June 1, 2021 target action date.
- NDA submission to the FDA for relugolix combination tablet for the treatment of women with endometriosis-associated pain expected in the first half of calendar year 2021.
- European Commission decision on the uterine fibroids MAA expected in mid-calendar year 2021. If approved, this launch will be executed by Richter, our commercialization partner for relugolix combination tablet for the uterine fibroids and endometriosis indications in Europe and certain other international markets.
- MAA submission to the EMA for relugolix combination tablet for the treatment of women with endometriosis-associated pain expected in calendar year 2021. Richter will be the MAA sponsor.

Related Party Agreements

Sunovion Market Access Services Agreement

On August 1, 2020, our subsidiary, MSG, entered into the Market Access Services Agreement, as amended, with Sunovion, a subsidiary of Sumitomo Dainippon Pharma, pursuant to which, among other things, Sunovion agreed to provide to MSG certain market access services with respect to the distribution and sale of ORGOVYX and relugolix combination tablet. MSG, in turn, appointed Sunovion as the exclusive distributor of relugolix combination tablet and a non-exclusive distributor of ORGOVYX, each in the United States, including all of its territories and possessions. For the three and nine months ended December 31, 2020, we incurred $1.4 million and $2.5 million, respectively, of expense under this agreement (inclusive of third-party pass-through costs billed to us), which is included in SG&A expenses in the accompanying unaudited condensed consolidated statements of operations included elsewhere in this Quarterly Report on Form 10-Q. Additional information is included in Note 5(C) to our unaudited condensed consolidated statements of operations included elsewhere in this Quarterly Report on Form 10-Q.

Sumitovant Consulting Agreement

On May 18, 2020, we and Sumitovant entered into a consulting agreement, as amended, pursuant to which Sumitovant provides consulting services to us to support us in commercial planning, commercial launch activities and implementation. Adele Gulfo, Sumitovant's Chief Business and Commercial Development Officer and a member of our board of directors, provides services to us on behalf of Sumitovant under this agreement. For the three and nine months ended December 31, 2020, we incurred $0.2 million and $0.5 million, respectively, of expense under this consulting agreement, which is included in SG&A expenses in the

accompanying unaudited condensed consolidated statements of operations included elsewhere in this Quarterly Report on Form 10-Q.

Sumitomo Dainippon Pharma Loan Commitment

On August 5, 2020, we obtained a debt commitment letter from Sumitomo Dainippon Pharma, as amended (the "2020 Commitment Letter"), pursuant to which, subject to the terms and conditions set forth therein, Sumitomo Dainippon Pharma committed to enter into a new $200.0 million unsecured, low-interest, five-year term loan facility. The 2020 Commitment Letter expires in March 2021.

Manufacturing Update

In June 2020, the FDA issued a warning letter to Takeda following a routine inspection of aseptic finished pharmaceuticals (drug product) manufacturing at Takeda's manufacturing facility located at Takeda 4720, Mitsui, Hikari, Yamaguchi (the "Hikari Facility"). The warning letter indicated that the FDA was not satisfied with Takeda's response to an FDA Form 483 issued to Takeda following the inspection and cited significant violations of current good manufacturing practice ("cGMP") for finished pharmaceuticals. The Hikari Facility is one of two contract manufacturing organizations included in our initial regulatory filings for the manufacture of relugolix drug substance, with Excella GmbH & Co. KG ("Excella") being the other. We have removed the Hikari Facility as a manufacturing site from our NDA submissions and may remove it from other regulatory filings if required until Takeda corrects the violations noted in the warning letter to the satisfaction of the regulatory authorities. We believe we have procured from Excella sufficient quantities of commercial relugolix drug substance to support our U.S. ORGOVYX commercial launch plans and U.S. commercial launch plans for relugolix combination tablet, if approved. We have not experienced any supply constraints to date. We currently do not expect that the issues relating to the Hikari Facility will have an effect on the June 1, 2021 FDA target action date for relugolix combination tablet for uterine fibroids or the European Commission decision on the uterine fibroids MAA anticipated in mid-calendar year 2021, or any other of our currently planned regulatory submissions.

Impact of COVID-19

In December 2019, an outbreak of a novel strain of coronavirus, or COVID-19, was identified. Due to the rapid and global spread of the virus, in March 2020, the World Health Organization categorized COVID-19 as a pandemic and it continues to spread throughout the U.S. and other countries across the world. To limit the spread of COVID-19, governments have taken various actions including the issuance of stay-at-home orders, closing schools, restricting travel, and social distancing guidelines and causing some businesses to suspend operations. It remains unclear how long these measures will remain in place and whether these measures will be effective. Further, recently it has been reported that the rate of the reported number of COVID-19 cases in the United States is increasing, and new more virulent variants of the coronavirus have been identified, which may further impact the effects that the COVID-19 pandemic may have on us.

Our priorities during the COVID-19 pandemic are protecting the health and safety of our employees and patients while continuing our mission to redefine care for women and for men. We believe the safety measures we are taking in response to the COVID-19 pandemic meet or exceed the guidelines established by government and public health officials. Beginning in mid-March 2020, substantially all of our workforce began working from home and we curtailed employee travel. We have adopted remote working tools to minimize the disruption to our business activities. At this time, we have not identified a material change to our productivity as a result of these measures, but this could change, particularly if restricted travel, closed schools, and shelter-in-place orders are not removed or significantly eased.

To date, the impact of the COVID-19 pandemic on our ability to advance our clinical studies, our regulatory activities, our U.S. commercial launch activities for ORGOVYX, and our preparations for the potential commercialization of relugolix combination tablet has been limited and all of our publicly announced milestones remain on track. The FDA approved ORGOVYX for the treatment of adult patients with advanced prostate cancer on December 18, 2020. In May 2020, we submitted our NDA to the FDA for relugolix combination tablet for the treatment of women with heavy menstrual bleeding associated with uterine fibroids, which has been accepted by the FDA with a target action date of June 1, 2021. Regulatory agency pre-approval inspections are limited, and it is not clear if virtual inspections will be required and acceptable due to COVID-19 and this may impact the FDA's review process and timing of potential approval of this product candidate. We commercially launched ORGOVYX in the U.S. in early January 2021, and may launch other approved product candidates in the COVID-19 environment. In response to the COVID-19 pandemic, health professionals may reduce staffing and reduce or postpone appointments with patients, or patients may cancel or miss appointments, resulting in fewer prescriptions. In addition, multiple medical conferences have been cancelled, postponed or moved to virtual formats, resulting in fewer opportunities to present our scientific data. In addition, our sales teams have been and would likely have to continue to make presentations to physicians and the medical community in many cases by virtual means instead of in-person, which could reduce the number of medical professionals we are able to present to, and these virtual meetings may not be as successful as in-person meetings.

Reduced access to healthcare providers as a result of social distancing protocols may impact or require adjustments to our planned commercialization activities, including the manner in which our field teams engage with healthcare providers and facilities. At this time, we do not believe that the COVID-19 pandemic has disproportionately impacted us relative to other companies in our industry and the medical community appears to be highly engaged with our field team. To date, we have not experienced supply constraints, and we believe we have procured sufficient quantities of relugolix drug substance to meet our U.S. ORGOVYX launch plans and U.S. launch plans for relugolix combination tablet, if approved.

However, the ultimate impact of the COVID-19 pandemic is highly uncertain and we do not yet know the full extent of potential delays or impacts on our business, our financial results, our clinical trials, our supply chains, our commercial launch for ORGOVYX, and pre-launch commercial readiness activities for relugolix combination tablet, end user demand for our products, if approved, healthcare systems or the global economy as a whole. The extent to which the COVID-19 pandemic impacts us will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. As such, it is uncertain as to the full magnitude that the pandemic will have on our financial condition, liquidity, and future results of operations. Refer to the risk factor titled "Business interruptions resulting from effects of pandemics or epidemics such as the novel strain of the coronavirus known as COVID-19, 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.

On March 27, 2020, the CARES Act was enacted in response to the COVID-19 pandemic and the negative impacts that it is having on the global economy and U.S. companies. The CARES Act includes various financial measures to assist companies, including temporary changes to income and non-income-based tax laws. We have implemented certain provisions of the CARES Act, such as deferring employer payroll taxes through the end of calendar year 2020. As of December 31, 2020, we have deferred $1.8 million of employer payroll taxes, of which 50% are required to be deposited by December 2021 and the remaining 50% by December 2022. The current portion of the deferred payroll tax liability of $0.9 million is included in accrued expenses and the non-current portion of the deferred payroll tax liability of $0.9 million is included in other liabilities on the accompanying unaudited condensed consolidated balance sheet included elsewhere in this Quarterly Report on Form 10-Q.

Our Approved Product and Product Candidates

Relugolix in General

Relugolix is an oral, once-daily, small molecule that acts as a GnRH receptor antagonist that binds to and inhibits GnRH receptors in the anterior pituitary gland. Inhibition of GnRH receptors decreases the release of gonadotropins (luteinizing hormone ("LH") and follicle-stimulating hormone ("FSH")), thereby decreasing the downstream production of estrogen and progesterone by the ovaries in women and testosterone by the testes in men.

As a GnRH receptor antagonist, relugolix has a clinically-validated mechanism of action in each of our three targeted indications: heavy menstrual bleeding associated with uterine fibroids; pain associated with endometriosis; and advanced prostate cancer. The direct and rapid action of relugolix on the pituitary-gonadal axis is distinct from approved luteinizing hormone-releasing hormone ("LHRH") agonists which are administered as depot injections and result in an initial surge in levels of gonadotropins, and estrogen and progesterone or testosterone, before resulting in pituitary desensitization and a fall in hormone levels over weeks. Approved LHRH agonist injections such as leuprolide acetate are used in women to treat the symptoms of uterine fibroids and endometriosis, but the adoption and duration of use is limited due to bone mineral density ("BMD") loss and vasomotor symptoms.

ORGOVYX

On December 18, 2020, the FDA approved ORGOVYX for the treatment of adult patients with advanced prostate cancer. ORGOVYX, which was granted Priority Review by the FDA, is the first and only oral GnRH receptor antagonist for men with advanced prostate cancer. The approval is based on efficacy and safety data from the Phase 3 HERO study of ORGOVYX in men with advanced prostate cancer. ORGOVYX became available through authorized specialty distributors in the U.S. in early January 2021.

In the Phase 3 HERO study, ORGOVYX met the primary endpoint and achieved sustained testosterone suppression to castrate levels (< 50 ng/dL) through 48 weeks in 96.7% (95% confidence interval [CI]: 94.9-97.9) of men, compared with 88.8% (95% CI: 84.6-91.8) of men receiving leuprolide acetate injections, the current standard of care. ORGOVYX also achieved several key secondary endpoints compared to leuprolide acetate, including suppression of testosterone to castrate levels at Day 4 and Day 15 (56% versus 0% and 99% versus 12%, respectively) and profound suppression of testosterone (< 20 ng/dL) at Day 15 (78% versus 1%). ORGOVYX lowered prostate-specific antigen ("PSA"), on average, by 65% at Day 15 and by 83% at Day 29. In a substudy, 55% of men treated with ORGOVYX achieved normal testosterone levels (> 280 ng/dL) or returned to

baseline within 90 days of treatment discontinuation. The most frequent adverse events reported in at least 10% of men in the ORGOVYX group, were hot flush, musculoskeletal pain, fatigue, constipation, and mild to moderate diarrhea.

In May 2020, efficacy and safety data from the Phase 3 HERO study were simultaneously published online in the *New England Journal of Medicine* and presented at the American Society of Clinical Oncology ("ASCO")'s ASCO20 Virtual Scientific Program. In July 2020, these data were also presented in an oral presentation during the American Urological Association 2020 Virtual Experience.

On October 19, 2020, we presented an economic analysis of the Phase 3 HERO data at the Academy of Managed Care Pharmacy ("AMCP") Nexus 2020 Virtual Meeting, demonstrating that treatment with relugolix may prevent one major adverse cardiovascular event for every 31 patients treated versus patients receiving leuprolide injections.

We currently expect to submit a MAA to the EMA for relugolix monotherapy for advanced prostate cancer in the first quarter of calendar year 2021. We and our collaboration partner, Pfizer, may conduct additional clinical studies to support the commercial potential of relugolix monotherapy in the U.S. and other major markets.

Relugolix Combination Tablet

We are developing relugolix combination tablet administered orally once-daily, with the goal of maintaining estrogen levels in the low normal range to achieve the long-term benefit of relugolix on symptoms of uterine fibroids and endometriosis, while maintaining bone health and mitigating side effects from a low-estrogen state, such as vasomotor symptoms. We have successfully completed a bioequivalence study, which demonstrated the bioequivalence of our relugolix combination tablet with relugolix combination therapy, the co-administered regimen used in the LIBERTY and SPIRIT clinical programs (one relugolix 40 mg tablet plus one tablet containing estradiol 1.0 mg and norethindrone acetate 0.5 mg). We expect to launch in the women's health indications with our single-tablet regimen.

Lowering estrogen and progesterone levels has been demonstrated, including in our two replicate Phase 3 LIBERTY studies, to effectively decrease heavy menstrual bleeding and pain in women with uterine fibroids. Similarly, relugolix combination therapy has been demonstrated in our two replicate Phase 3 SPIRIT studies to reduce pelvic pain associated with endometriosis. Relugolix combination therapy achieved these results while maintaining a generally well-tolerated safety profile. We believe our combination approach has the potential to have a better safety and tolerability profile than the currently approved LHRH agonist therapies and has the potential to be used longer-term. We further believe our single tablet combination approach also has certain benefits over other oral GnRH antagonist therapies that are currently approved or in development. The goal of our relugolix combination tablet is to provide women with uterine fibroids and endometriosis a once-daily oral medical alternative to hysterectomy and other invasive procedures often recommended to treat these conditions that is suitable for long-term use.

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

We initiated a Phase 3 clinical program in January 2017, evaluating relugolix combination therapy in women with heavy menstrual bleeding associated with uterine fibroids. The program consisted of two multinational, replicate pivotal clinical studies (LIBERTY 1 and LIBERTY 2). Women in the LIBERTY 1 and LIBERTY 2 studies underwent a screening period requiring up to two menstrual cycles to document heavy menstrual bleeding and were randomized in a 1:1:1 ratio to one of three groups. Women received treatment either with relugolix combination therapy for 24 weeks, relugolix 40 mg once-daily monotherapy for 12 weeks followed by relugolix combination therapy once-daily for an additional 12 weeks, or placebo once-daily for 24 weeks.

We enrolled 388 women in LIBERTY 1 and 382 women in LIBERTY 2. To be enrolled, women must have had a monthly menstrual blood loss volume of at least 80 mL in two consecutive cycles or 160 mL in one cycle, measured by the alkaline hematin method, a quantitative measure of menstrual blood loss from an assessment of collected menstrual products.

Eligible women who completed the LIBERTY 1 or LIBERTY 2 studies were offered the opportunity to enroll in an active treatment extension study in which all women received relugolix combination therapy for an additional 28-week period for a total treatment period of 52 weeks, designed to evaluate the safety and sustained efficacy of longer-term treatment. Upon completion of this 52-week total treatment period, eligible women could elect to participate in a second 52-week randomized withdrawal study designed to provide two-year safety and efficacy data on relugolix combination therapy, and to evaluate the need for maintenance therapy. We currently expect to present data from the LIBERTY randomized withdrawal study, including efficacy and safety data of relugolix combination therapy in women with uterine fibroids for up to 2 years, in the first quarter of calendar year 2021.

The primary efficacy endpoint for LIBERTY 1 and LIBERTY 2 was the proportion of all women enrolled who achieved a menstrual blood loss volume of less than 80 mL and at least a 50% reduction in menstrual blood loss volume from baseline

during the last 35 days of the 24-week treatment period as measured by the alkaline hematin method. The secondary endpoints included the proportion of women who achieved amenorrhea (defined as no or negligible blood loss) during the last 35 days of treatment, reduction in pelvic pain, reduction in fibroid volume, reduction in uterine volume, percent change from baseline to week 24 in menstrual blood loss, increase in hemoglobin, and an assessment of the impact of therapy on quality-of-life. Safety, including BMD changes as measured by dual-energy x-ray absorptiometry ("DXA"), was also assessed.

On May 14, 2019 and July 23, 2019, we announced positive top-line results for the LIBERTY 1 and LIBERTY 2 studies, respectively. On February 10, 2020, we announced positive safety and efficacy data from the Phase 3 LIBERTY long-term extension study. On September 14, 2020, we announced additional data on BMD in women with uterine fibroids from the LIBERTY program and from a prospective observational study and on October 21, 2020, we presented one-year efficacy and safety data from the LIBERTY long-term extension study at the ASRM 2020 Virtual Congress.

On March 9, 2020, we announced the submission of a MAA to the EMA for relugolix combination tablet for the treatment of women with moderate to severe symptoms associated with uterine fibroids. This application has completed validation and is now under evaluation by the EMA. We currently expect the European Commission decision on this application in mid-calendar year 2021. If approved, this launch would be executed by Richter, our commercialization partner for relugolix combination tablet for the uterine fibroids and endometriosis indications in Europe and certain other international markets. In May 2020, we submitted an NDA to the FDA for relugolix combination tablet for the treatment of women with heavy menstrual bleeding associated with uterine fibroids, which has been accepted by the FDA with a target action date of June 1, 2021.

LIBERTY 1

On May 14, 2019, we announced that LIBERTY 1 met its primary efficacy endpoint and six key secondary endpoints. The distribution of the change in BMD, including outliers, was similar for the relugolix combination therapy and placebo groups at 24 weeks, as assessed by DXA.

In the primary endpoint analysis, 73.4% of women receiving relugolix combination therapy achieved the responder criteria compared with 18.9% of women receiving placebo ($p < 0.0001$). On average, women receiving relugolix combination therapy experienced an 84.3% reduction in menstrual blood loss from baseline, a clinically relevant secondary endpoint. A significantly greater proportion of women suffering from moderate-to-severe pain from uterine fibroids at baseline experienced no pain or minimal pain during the last 35 days of treatment with relugolix combination therapy compared with women on placebo ($p < 0.0001$).

LIBERTY 1 achieved six key secondary endpoints with statistical significance compared to placebo, including mean change in menstrual blood loss from baseline to week 24, reduction in pain in women with pain at baseline, improvement in quality of life, amenorrhea (defined as no or negligible blood loss), improvement in anemia in those women with anemia at baseline, and reduction in uterine volume. The seventh key secondary endpoint, reduction in uterine fibroid volume, did not achieve statistical significance.

The overall incidence of adverse events in the relugolix combination therapy and placebo groups was comparable (62% vs. 66%). In the relugolix combination therapy group, 5% of women discontinued treatment early due to adverse events compared with 4% in the placebo group. The only adverse event in the relugolix combination therapy arm occurring in at least 10% of women and more frequently than in the placebo arm was hot flash (11% vs. 8%). There were no pregnancies in the relugolix combination therapy group and one in the placebo group. There were two serious adverse events related to the study drug: one fibroid expulsion and one for pelvic pain.

LIBERTY 2

On July 23, 2019, we announced that LIBERTY 2 met its primary efficacy endpoint and the same six key secondary endpoints as were achieved in LIBERTY 1. Changes in BMD were comparable between the relugolix combination therapy and placebo groups at the end of treatment as was the distribution of the change in BMD, including outliers.

In the primary endpoint analysis, 71.2% of women receiving relugolix combination therapy achieved the responder criteria compared with 14.7% of women receiving placebo ($p < 0.0001$). On average, women receiving relugolix combination therapy experienced a highly significant 84.3% reduction in menstrual blood loss from baseline to week 24 ($p < 0.0001$). In addition, a significantly greater proportion of women suffering from moderate-to-severe pain from uterine fibroids at baseline experienced no pain or minimal pain during the last 35 days of treatment with relugolix combination therapy compared with women on placebo ($p < 0.0001$).

LIBERTY 2 achieved six key secondary endpoints with statistical significance compared to placebo, including mean change in menstrual blood loss from baseline to week 24, reduction in pain in women with pain at baseline, improvement in quality of

life, amenorrhea (defined as no or negligible blood loss), improvement in anemia in those women with anemia at baseline, and reduction in uterine volume. The seventh key secondary endpoint, reduction in uterine fibroid volume, did not achieve statistical significance.

The overall incidence of adverse events in the relugolix combination therapy and placebo groups was comparable (60.3% vs. 58.9%). In the relugolix combination therapy group, 1.6% of women discontinued treatment early due to adverse events compared with 4.7% in the placebo group. There were no adverse events in the relugolix combination therapy group reported by at least 10% of women and more frequently than in the placebo group. The incidence of hot flashes in the relugolix combination therapy group was similar to placebo (5.6% vs. 3.9%). There were no pregnancies in the relugolix combination therapy group and one in the placebo group. There were no serious adverse events related to study drug reported in this study.

LIBERTY Long-Term Extension Study

On February 10, 2020, we announced positive one-year safety and efficacy data from the Phase 3 LIBERTY long-term extension study of relugolix combination therapy in women with heavy menstrual bleeding associated with uterine fibroids.

In the primary endpoint analysis, 87.7% of women achieved the responder criteria. The primary endpoint result in the one-year Phase 3 LIBERTY long-term extension study was consistent with the 24-week primary endpoint data from the pivotal LIBERTY 1 and LIBERTY 2 studies, demonstrating a durability of response through one year. In addition, women experienced, on average, an 89.9% reduction in menstrual blood loss from baseline at one year.

Changes in BMD through one year, as assessed by DXA every three months, demonstrated maintenance of bone density and were consistent with those in LIBERTY 1 and LIBERTY 2. The adverse events over one year were consistent with those observed in LIBERTY 1 and LIBERTY 2, with no new safety signals. Adverse events reported in more than 10% of women treated with relugolix combination therapy for one-year and more frequently than those reported in the placebo group after 6 months included only hot flashes (11% vs. 6%). There were no pregnancies reported in the relugolix combination therapy group.

In October 2020, we presented a poster at the ASRM 2020 Virtual Congress describing a validated exposure-response model simulating long-term effects of relugolix combination therapy on BMD at the lumbar spine. Simulations from this model were well correlated with the effect of relugolix combination therapy observed in the Phase 3 LIBERTY program and projected maintenance of BMD for at least three years.

Observational Bone Mineral Density Study

This prospective observational study was designed to characterize the longitudinal natural history of BMD in 262 premenopausal women with uterine fibroids over 52 weeks. Women with documented uterine fibroids by imaging who were not receiving treatment with GnRH agonists or antagonists were enrolled contemporaneously from U.S. centers that participated in the LIBERTY studies. BMD was assessed by DXA at baseline, week 24 and week 52. Mean BMD at the lumbar spine showed minimal changes over the 52-week observational period (0% at week 24 and -0.41% at week 52) and did not appear to be influenced by race or body mass index.

Phase 3 Program for the Treatment of Pain Associated with Endometriosis

We initiated a Phase 3 clinical program in June 2017, evaluating relugolix combination therapy in women with pain associated with endometriosis. The program consisted of two multinational, replicate pivotal clinical studies (SPIRIT 1 and SPIRIT 2). Each study randomized women 1:1:1 to one of three treatment arms. Women received treatment either with relugolix combination therapy for 24 weeks, relugolix 40 mg once-daily monotherapy for 12 weeks followed by relugolix combination therapy once-daily for an additional 12 weeks, or placebo once-daily for 24 weeks.

We enrolled 623 and 638 patients in the SPIRIT 2 and SPIRIT 1 studies, respectively. To be enrolled, women must have had a surgical diagnosis of endometriosis in the last 10 years and moderate-to-severe dysmenorrhea (menstrual pelvic pain) and non-menstrual pelvic pain.

Eligible women who completed the SPIRIT 1 or SPIRIT 2 studies were offered the opportunity to enroll in an active treatment long-term extension study in which all women receive relugolix combination therapy for an additional 80-week period, resulting in a total treatment period of up to 104 weeks, designed to evaluate the safety and sustained efficacy of longer-term treatment. In January 2021, we and Pfizer announced positive data from the Phase 3 SPIRIT long-term extension study.

The co-primary efficacy endpoints for the SPIRIT 1 and SPIRIT 2 studies were the proportion of all women enrolled with reductions in both dysmenorrhea and non-menstrual pelvic pain, as assessed by an endometriosis-specific patient questionnaire based on the Numerical Rating Scale (“NRS”) completed daily on an electronic patient diary, with no increase in background

pain medication. The NRS is an 11-point scale with 0 representing “no pain” and 10 representing “the worst pain you can imagine.” Secondary endpoints included additional questionnaires assessing functional changes associated with endometriosis-specific pain and quality of life, and the use of pain medications to treat endometriosis, including opioid medications. Safety, including BMD changes as measured by DXA, was also assessed.

On April 22, 2020 and June 23, 2020, we announced positive top-line results from the SPIRIT 2 and SPIRIT 1 studies, respectively. We currently expect to submit an NDA with the FDA for relugolix combination tablet for the treatment of women with endometriosis-associated pain in the first half of calendar year 2021. We currently expect to submit an MAA to the EMA for relugolix combination tablet for the treatment of women with endometriosis-associated pain in calendar year 2021. Richter will be the MAA sponsor. Data from these Phase 3 studies were presented at the ASRM 2020 Virtual Congress on October 20, 2020 and the presentation was named the Prize Paper by the Endometriosis Special Interest Group.

SPIRIT 1

On June 23, 2020, we announced that SPIRIT 1 met its co-primary efficacy endpoints and all seven key secondary endpoints. In addition, relugolix combination therapy was generally well-tolerated and resulted in minimal BMD loss over 24 weeks.

Relugolix combination therapy achieved both co-primary endpoints by demonstrating clinically meaningful pain reductions for 74.5% of women with dysmenorrhea (menstrual pain) and 58.5% of women with non-menstrual pelvic pain, compared to 26.9% and 39.6% of women in the placebo group, respectively ($p < 0.0001$). On average, women receiving relugolix combination therapy had a 73.3% reduction on the 11-point (0 to 10) NRS for dysmenorrhea from 7.3 (severe pain) to 1.8 (mild pain).

All seven key secondary endpoints measured at week 24 and compared to placebo achieved statistical significance, including changes in mean dysmenorrhea and overall pelvic pain, impact of pain on daily activities as measured by the EHP-30 pain domain, greater proportions of women not using analgesics (p-values < 0.0001), changes in mean non-menstrual pelvic pain ($p = 0.0002$), greater proportions of women not using opioids ($p = 0.0005$), and changes in mean dyspareunia (painful intercourse) ($p = 0.0149$).

The overall incidence of adverse events in the relugolix combination and placebo groups was similar (71.2% vs. 66.0%). In the relugolix combination therapy group, 3.8% of women had adverse events leading to discontinuation of treatment versus 1.9% in the placebo group. The only reported adverse events in at least 10% of women in the relugolix combination group were headache and hot flashes. There was one pregnancy in the relugolix combination group and three in the placebo group.

SPIRIT 2

On April 22, 2020, we announced that SPIRIT 2 met its co-primary efficacy endpoints and six key secondary endpoints. In addition, relugolix combination therapy was generally well-tolerated and resulted in minimal BMD loss over 24 weeks.

In the co-primary endpoint analysis, 75.2% of women achieved a clinically meaningful reduction in dysmenorrhea versus 30.4% of women in the placebo group ($p < 0.0001$). For non-menstrual pelvic pain, relugolix combination therapy achieved a clinically meaningful reduction in 66.0% of women versus 42.6% of women in the placebo group ($p < 0.0001$). On average, women receiving relugolix combination therapy had a 75.1% reduction on the 11-point (0 to 10) NRS for dysmenorrhea from 7.2 (severe pain) to 1.7 (mild pain).

Six key secondary endpoints measured at week 24 and compared to placebo achieved statistical significance, including changes in mean dysmenorrhea and overall pelvic pain, impact of pain on daily activities as measured by the EHP-30 pain domain, a greater proportion of women not using opioids (all p-values < 0.0001), changes in non-menstrual pelvic pain ($p = 0.0012$), and dyspareunia (painful intercourse) ($p = 0.0489$). An endpoint evaluating change in analgesic use did not achieve statistical significance.

The overall incidence of adverse events in the relugolix combination therapy and placebo groups was similar (80.6% vs. 75.0%). In the relugolix combination therapy group, 5.3% of women discontinued treatment early due to adverse events versus 3.9% in the placebo group. The most frequently reported adverse events, reported in at least 10% of women in the relugolix combination therapy group, were headache, nasopharyngitis, and hot flashes. There were three pregnancies in the relugolix combination therapy group and five in the placebo group.

SPIRIT Long-Term Extension Study

On January 26, 2021, we and Pfizer announced positive one-year safety and efficacy data from the Phase 3 SPIRIT long-term extension study of relugolix combination therapy in women with endometriosis. Another analysis will be conducted at week

104. A total of 802 women enrolled in the extension study, all of whom receive relugolix combination therapy regardless of their treatment assignment in SPIRIT 1 and SPIRIT 2.

In the primary endpoint analysis, 84.8% and 73.3% of women receiving relugolix combination therapy over one year achieved clinically meaningful pain reductions in dysmenorrhea and non-menstrual pelvic pain, respectively. On average, women reported an 82.8% reduction on the 11-point Numerical Rating Scale (0-10) for dysmenorrhea from 7.4 (severe pain) to 1.3 (mild pain) over one year.

BMD remained stable through week 52 in women treated with relugolix combination therapy after minimal, non-clinically meaningful bone loss through week 24. The incidence of adverse events over one year was consistent with that observed in the SPIRIT 1 and SPIRIT 2 studies, with no new safety signals observed. The most commonly reported adverse events in at least 10% of women treated with relugolix combination therapy were headache, nasopharyngitis, and hot flashes. There was one pregnancy reported in the relugolix combination therapy group (n = 278).

We currently expect that results from the Phase 3 SPIRIT long-term extension study will be included in the NDA for relugolix combination tablet for the treatment of women with endometriosis, anticipated to be submitted to the FDA in the first half of calendar year 2021. Results from the 52-week analysis of the Phase 3 SPIRIT long-term extension study are expected to be submitted for presentation at a future scientific meeting and publication in a medical journal.

Bioequivalence Study of Relugolix Combination Therapy and Relugolix Combination Tablet

On July 23, 2019, we announced that a separate clinical study of relugolix combination tablet met all required and pre-specified criteria for bioequivalence to the two tablets (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) used in our Phase 3 uterine fibroid and endometriosis clinical studies, providing data necessary to include the once-daily dosing regimen of relugolix combination tablet in our NDA and MAA submissions for the treatment of heavy menstrual bleeding associated with uterine fibroids and endometriosis. In December 2019, we successfully completed one-year stability studies, which are required for FDA approval of relugolix combination tablet.

Ovulation Inhibition Study

On April 22, 2020, we announced results from an open-label, single-arm ovulation inhibition study consisting of a pre-treatment period to confirm ovulatory status, an 84-day treatment period (three cycles) to assess the effects of relugolix combination therapy on ovulation inhibition, and a post-treatment follow-up period to determine the time to the return of ovulation. Ovulation inhibition was based on the Hoogland-Skouby scale. In this study, relugolix combination therapy achieved 100% ovulation inhibition in 67 healthy women with no women ovulating during the 84-day treatment period, as evaluated by the Hoogland-Skouby assessment scale (score < 5). Furthermore, 100% of women resumed ovulation or menses upon discontinuation of treatment with an average time to ovulation of 23.5 days.

In July 2020, we presented data from the ovulation inhibition study and additional data from the LIBERTY program showing improvement in patient-reported outcomes and in hemoglobin levels in women with anemia during the European Society of Human Reproduction and Embryology (“ESHRE”) virtual 36th Annual Meeting. Additional data from the ovulation inhibition study were also presented at the ASRM 2020 Virtual Congress in October 2020.

Planned Phase 3 SERENE Study

Myovant and Pfizer plan to initiate in the first half of calendar year 2021 a Phase 3 open label clinical study in the U.S. to assess the contraceptive efficacy of relugolix combination tablet. The SERENE study will enroll sexually active, healthy premenopausal women ages 18-35 years with presumed normal fertility. Women will receive once-daily relugolix combination tablet for thirteen 28-day cycles. The primary efficacy endpoint will be the Pearl Index, defined as the number of on-treatment pregnancies per 100 women-years of treatment. Positive data from the SERENE study would further differentiate relugolix combination tablet by potentially adding the benefit of prevention of pregnancy for women taking relugolix combination tablet for the treatment of uterine fibroids and endometriosis, if approved for these indications.

MVT-602

As part of our license agreement with Takeda, we acquired the worldwide rights to MVT-602, our second product candidate, which previously had been evaluated in over 150 men. MVT-602 is an oligopeptide kisspeptin-1 receptor agonist. Kisspeptin, the ligand, is a naturally occurring peptide that stimulates GnRH release and is required for puberty and maintenance of normal reproductive function, including production of sperm, follicular maturation and ovulation, and production of estrogen and progesterone in women and testosterone in men. MVT-602 is being developed as a potential treatment for female infertility in women as part of assisted reproduction, such as in vitro fertilization.

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

Further assessment of the exposure-response profile of MVT-602 was conducted in a Phase 2a study during the pre-ovulatory phase in 75 fertile women following a minimal controlled ovarian stimulation protocol. After ovarian stimulation, women were randomized to one of four MVT-602 dose groups (0.1 µg, 0.3 µg, 1 µg or 3 µg), to triptorelin, 0.2 mg, or to placebo. Top-line results from this Phase 2a study were presented at the European Society of Human Reproduction and Embryology in Vienna, Austria in June 2019. The study demonstrated that MVT-602 was generally well-tolerated and produced the desired LH surge associated with high and dose-dependent rates of ovulation in healthy women following a minimal controlled ovarian stimulation protocol. This study provides information for dose selection for a future study of MVT-602 in infertile women seeking pregnancy.

Components of Operating Results

Revenue

Through December 31, 2020, we have not generated any product revenue. Our revenue has been derived solely from the upfront and regulatory milestone payments we received from Richter under the Richter Development and Commercialization Agreement and collaboration revenue under the Pfizer Collaboration and License Agreement.

Research and Development Expenses

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.

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 manufacturing activities in connection with preparations for our anticipated commercial launches and regulatory submissions, and other third-party expenses directly attributable to the development of our product candidates.

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.

R&D activities have been, and will continue to be, central to our business model. We currently expect R&D expenses over the next several quarters to be at similar levels to our third quarter 2020 R&D expenses as declining spend on our Phase 3 HERO, LIBERTY, and SPIRIT clinical programs, which are winding down, as well as our sharing of certain R&D expenses with Pfizer, are expected to be offset by incremental expenses associated with life-cycle management activities, such as the planned Phase 3 SERENE study, including clinical manufacturing expenses, the further build out of our medical affairs function and potential new investments in our pipeline. We also expect to incur additional regulatory expenses which may result in an increase in our R&D expense in periods where potential regulatory submissions for our product candidates occur.

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, 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. As a result, we are unable to determine with certainty to what extent we will generate product revenue from commercialization and sale of any of our product candidates that receive regulatory approval. Our R&D activities may be subject to change from time to time as we evaluate our priorities and available resources.

We expect that certain R&D expenses will be shared equally with Pfizer pursuant to the Pfizer Collaboration and License Agreement discussed previously.

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 expenses for our executive, finance, human resources, legal, information technology, commercial operations, marketing, market access, sales, and other administrative functions. SG&A expenses also include marketing programs, advertising, conferences, congresses, travel expenses, professional fees for legal, accounting, auditing and tax services, and costs related to rent and facilities, insurance, information technology, commercial operations, and general overhead. SG&A expenses also include costs incurred under our Market Access Services Agreement with Sunovion and our consulting agreement with Sumitovant.

We expect SG&A expenses to increase in future periods as we continue to expand our sales and marketing infrastructure and general administrative functions. These increases will likely include salaries, sales incentive compensation, share-based compensation and travel expenses associated with our oncology sales force which began promoting ORGOVYX in the U.S. in January 2021, as well as expected costs associated with the further build out of our commercial operations functions and the hiring of our women's health sales force in advance of the potential FDA approval of relugolix combination tablet. SG&A expenses in future periods are also expected to include certain expenses related to our patient support programs such as free trial drug and patient assistance for qualified uninsured patients. The timing of these increased expenditures and their magnitude are primarily dependent on our commercial success and sales growth of ORGOVYX, as well as the timing of any new product launches and other potential business and operational activities. In addition, we expect to record incremental share-based compensation expense of approximately $28.0 million in the three months ended March 31, 2021 as a result of the Separation and General Release we entered into with our former Principal Executive Officer as discussed in Note 12(B) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

We expect that certain SG&A expenses will be shared equally with Pfizer pursuant to the Pfizer Collaboration and License Agreement discussed previously.

Interest Expense

Interest expense consists of interest expense related to our previously outstanding debt with Hercules and NovaQuest, which we repaid on December 31, 2019, as well as the associated non-cash amortization of debt discounts and issuance costs. Subsequently, interest expense consists of related party interest expense pursuant to the Sumitomo Dainippon Pharma Loan Agreement, which bears interest at a rate per annum equal to 3-month LIBOR plus a margin of 3% payable on the last day of each calendar quarter.

Loss on Extinguishment of Debt

Loss on extinguishment of debt represents the difference between the carrying amount of our previously outstanding debt with Hercules and NovaQuest and the amounts we paid to retire the outstanding debt obligations on December 31, 2019.

Interest Income

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

Other Income, Net

Other income, net consists primarily of the impact of changes in foreign currency exchange rates on our foreign exchange denominated liabilities, relative to the U.S. dollar. The impact of foreign currency exchange rates on our results of operations fluctuates period over period based on our foreign currency exposures resulting from changes in applicable exchange rates associated with our foreign denominated liabilities. Our primary foreign currency exposure has historically been the exchange rate between the Swiss franc and the U.S. dollar.

In December 2020, we changed the functional currency of our wholly-owned subsidiary in Switzerland, MSG, from the Swiss franc to U.S. dollar. This change in functional currency is accounted for prospectively. As a result of this change, we currently expect that future impacts of changes in foreign currency exchange rates on our results of operations will not be significant. See Note 2(J) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Results of Operations

The following table summarizes our results of operations for the three and nine months ended December 31, 2020 and 2019 (in thousands):

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2020	2019	2020	2019
Revenues:				
Collaboration revenue	$ 1,379	$ —	$ 1,379	$ —
License and milestone revenue	—	—	33,333	—
Total revenues	1,379	—	34,712	—
Operating expenses:				
Research and development	30,453	48,927	115,160	150,847
Selling, general and administrative	49,243	29,142	103,387	59,897
Total operating expenses	79,696	78,069	218,547	210,744
Loss from operations	(78,317)	(78,069)	(183,835)	(210,744)
Interest expense	2,609	3,657	6,908	11,238
Loss on extinguishment of debt	—	4,851	—	4,851
Interest income	(32)	(597)	(178)	(2,305)
Other income, net	(5,891)	(567)	(16,178)	(1,151)
Loss before income taxes	(75,003)	(85,413)	(174,387)	(223,377)
Income tax (benefit) expense	(1,154)	191	(616)	699
Net loss	$ (73,849)	$ (85,604)	$ (173,771)	$ (224,076)

Collaboration Revenue

Collaboration revenue for both the three and nine months ended December 31, 2020 was $1.4 million and represents the partial amortization of the upfront payment received from Pfizer pursuant to the terms of the Pfizer Collaboration and License Agreement. There were no such amounts recognized in the comparable prior year periods. See Note 10(B) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional information about the Pfizer Collaboration and License Agreement.

License and Milestone Revenue

License and milestone revenue for the nine months ended December 31, 2020 was $33.3 million and represents the partial recognition of previously deferred revenue associated with upfront and regulatory milestone payments we received from Richter pursuant to the terms of the Richter Development and Commercialization Agreement. We recognize revenue as we satisfy our combined performance obligation to Richter. There were no such amounts recognized in the three months ended December 31, 2020 or the comparable prior year periods. See Note 10(A) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional information about the Richter Development and Commercialization Agreement.

Research and Development Expenses

For the three months ended December 31, 2020 and 2019, our R&D expenses consisted of the following (in thousands):

	Three Months Ended December 31,		
	2020	2019	Change
Program-specific costs:			
Relugolix	$ 11,574	$ 29,708	$ (18,134)
MVT-602	—	486	(486)
Unallocated costs:			
Share-based compensation	3,311	5,399	(2,088)
Personnel expense	11,669	9,230	2,439
Other expense	3,899	4,104	(205)
Total R&D expenses	$ 30,453	$ 48,927	$ (18,474)

For the nine months ended December 31, 2020 and 2019, our R&D expenses consisted of the following (in thousands):

	Nine Months Ended December 31,		
	2020	2019	Change
Program-specific costs:			
Relugolix	$ 57,260	$ 105,047	$ (47,787)
MVT-602	239	1,561	(1,322)
Unallocated costs:			
Share-based compensation	11,060	11,565	(505)
Personnel expense	35,332	24,280	11,052
Other expense	11,269	8,394	2,875
Total R&D expenses	$ 115,160	$ 150,847	$ (35,687)

R&D expenses decreased by $18.5 million, to $30.5 million, in the three months ended December 31, 2020 compared to $48.9 million in the three months ended December 31, 2019. The decrease reflects a reduction in clinical study costs as a result of the completion and continued wind down of our Phase 3 LIBERTY, HERO, and SPIRIT studies, cost reimbursements from Pfizer for certain R&D expenses (See Note 10(B) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q), and a reduction in share-based compensation expenses as the prior year period included incremental expense related to the accelerated vesting of certain equity awards as a result of the change in control of Myovant. This decrease was partially offset by an increase in personnel expenses, mainly driven by the continued expansion of our medical affairs organization, in preparation for the U.S. commercial launch of ORGOVYX and the potential U.S. commercial launches of relugolix combination tablet, if approved.

R&D expenses for the three months ended December 31, 2020 consisted primarily of program-specific costs composed of CRO, drug supply and other study, regulatory, and manufacturing related costs of $11.6 million (net of $7.6 million of cost reimbursements from Pfizer), personnel expenses of $11.7 million, share-based compensation expense of $3.3 million, and other R&D expenses of $3.9 million, which primarily includes contractors, consultants, and information technology costs and other unallocated nonclinical research costs.

R&D expenses in the three months ended December 31, 2019 consisted primarily of program-specific costs composed of CRO, drug supply and other study and manufacturing related costs of $30.2 million, personnel expenses of $9.2 million, share-based compensation expense of $5.4 million, and other R&D costs of $4.1 million, which primarily includes contractors, consultants, and information technology costs. The share-based compensation expense includes $1.8 million related to the accelerated vesting of certain equity awards as a result of a change in control of Myovant in connection with the closing of the Sumitomo-Roivant Transaction (see Note 5(A) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q).

R&D expenses decreased by $35.7 million, to $115.2 million, in the nine months ended December 31, 2020 compared to $150.8 million in the nine months ended December 31, 2019. The decrease reflects a reduction in clinical study costs as a result of the completion and continued wind down of our Phase 3 LIBERTY, HERO, and SPIRIT studies and cost reimbursements from Pfizer for certain R&D expenses (See Note 10(B) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q). This decrease was partially offset by an increase in personnel expenses, including in our medical affairs organization, in preparation for the U.S. commercial launch of ORGOVYX and the potential U.S. commercial launches of relugolix combination tablet, if approved, as well as regulatory expenses and NDA submission fees.

R&D expenses for the nine months ended December 31, 2020 consisted primarily of program-specific costs composed of CRO, drug supply and other study, regulatory, and manufacturing related costs of $57.5 million (net of $7.6 million of cost reimbursements from Pfizer), which includes fees related to our NDA submissions for ORGOVYX and relugolix combination tablet for uterine fibroids of $5.8 million, personnel expenses of $35.3 million, share-based compensation expense of $11.1 million, and other R&D costs of $11.3 million, which primarily includes contractors, consultants, and information technology costs and other unallocated nonclinical research costs.

R&D expenses in the nine months ended December 31, 2019 consisted primarily of program-specific costs composed of CRO, drug supply and other study and manufacturing related costs of $106.6 million, personnel expenses of $24.3 million, share-based compensation expense of $11.6 million, and other R&D costs of $8.4 million, which primarily includes contractors, consultants, and information technology costs. The share-based compensation expense includes $1.8 million related to the accelerated vesting of certain equity awards as a result of a change in control of Myovant in connection with the closing of the Sumitomo-Roivant Transaction (see Note 5(A) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q).

Selling, General and Administrative Expenses

SG&A expenses increased by $20.1 million, to $49.2 million, in the three months ended December 31, 2020 compared to $29.1 million in the three months ended December 31, 2019, primarily due to higher expenses related to commercial readiness activities to support the ORGOVYX U.S. commercial launch and the potential U.S. commercial launches of relugolix combination tablet as well as higher personnel-related costs primarily due to the hiring of our commercial operations, marketing, market access teams, and our oncology sales force, and general overhead expenses to support our organizational growth. These items were partially offset by lower share-based compensation expenses in the three months ended December 31, 2020, as the prior year period included incremental expense related to the accelerated vesting of certain equity awards as a result of the change in control of Myovant.

SG&A expenses in the three months ended December 31, 2020 consisted primarily of commercial operations expenses of $16.6 million, personnel expenses of $15.0 million, general overhead, administrative and information technology expenses of $8.4 million, share-based compensation expense of $3.7 million, professional service fees of $3.0 million, and rent and other facilities-related costs of $0.8 million. For the three months ended December 31, 2020, SG&A expenses also include $0.2 million of expense under a consulting agreement with Sumitovant and $1.5 million of expense (inclusive of third-party pass-through costs billed to us) under our agreement with Sunovion. For additional information about these related party expenses, see Note 5 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

SG&A expenses in the three months ended December 31, 2019 consisted primarily of share-based compensation expense of $14.4 million, personnel expenses of $6.0 million, commercial operations expenses of $3.9 million, general overhead, administrative and information technology expenses of $2.2 million, professional service fees of $1.9 million, and rent and other facilities-related costs of $0.8 million. The share-based compensation expense includes $10.2 million related to the accelerated vesting of certain equity awards as a result of a change in control of Myovant in connection with the closing of the Sumitomo-Roivant Transaction (see Note 5(A) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q).

SG&A expenses increased by $43.5 million, to $103.4 million, in the nine months ended December 31, 2020 compared to $59.9 million in the nine months ended December 31, 2019, primarily due to higher expenses related to commercial readiness activities to support the ORGOVYX U.S. commercial launch and the potential U.S. commercial launches of relugolix combination tablet as well as higher personnel-related expenses primarily due to the hiring of our commercial operations, marketing, market access teams, and our oncology sales force, and general overhead expenses to support our organizational growth. These items were partially offset by lower share-based compensation expenses in the nine months ended December 31, 2020, as the prior year period included incremental expense related to the accelerated vesting of certain equity awards as a result of the change in control of Myovant.

SG&A expenses in the nine months ended December 31, 2020 consisted primarily of personnel expenses of $31.2 million, commercial operations expenses of $32.2 million, general overhead, administrative and information technology expenses of $17.4 million, shared-based compensation expense of $10.7 million, professional service fees of $6.3 million, and rent and other facilities-related costs of $2.5 million. For the nine months ended December 31, 2020, we incurred $0.5 million of expense under a consulting agreement with Sumitovant and $2.5 million of expense (inclusive of third-party pass-through costs billed to us) under our agreement with Sunovion. For additional information about these related party expenses, see Note 5 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

SG&A expenses in the nine months ended December 31, 2019 consisted primarily of share-based compensation expense of $22.6 million, personnel expenses of $14.4 million, commercial operations expenses of $7.5 million, general overhead, administrative and information technology expenses of $9.2 million, professional service fees of $4.4 million, and rent and other facilities-related costs of $1.9 million. The share-based compensation expense includes $10.2 million related to the accelerated vesting of certain equity awards as a result of a change in control of Myovant in connection with the closing of the Sumitomo-Roivant Transaction (see Note 5(A) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q).

Interest Expense

Interest expense was $2.6 million and $6.9 million in the three and nine months ended December 31, 2020, respectively, primarily related to the Sumitomo Dainippon Pharma Loan Agreement, compared to $3.7 million and $11.2 million in the three and nine months ended December 31, 2019, respectively, primarily related to our previously outstanding financing arrangements with NovaQuest and Hercules. The decrease in interest expense, despite higher outstanding loan balances, was driven by the significantly lower interest rates associated with the Sumitomo Dainippon Pharma Loan Agreement as compared to the previously outstanding debt obligations to NovaQuest and Hercules, which were repaid in December 2019.

Loss on Extinguishment of Debt

In the three and nine months ended December 31, 2019, we incurred a $4.9 million loss on extinguishment of debt associated with the write-off of unamortized debt issuance costs and debt discounts, prepayment penalties and early redemption fees in connection with the repayment of our outstanding obligations to NovaQuest and Hercules. There are no such losses in the three and nine months ended December 31, 2020.

Interest Income

Interest income was less than $0.1 million for the three months ended December 31, 2020, approximately $0.2 million for the nine months ended December 31, 2020, and $0.6 million and $2.3 million for the three and nine months ended December 31, 2019, respectively. The decreases were primarily due to decreases in interest rates and lower balances in cash equivalents and marketable securities for most of the current year periods relative to the prior year periods.

Other Income, Net

For the three months ended December 31, 2020 and 2019, we recorded a foreign exchange gain of $5.9 million and $0.6 million, respectively, and for the nine months ended December 31, 2020 and 2019, we recorded a foreign exchange gain of $16.2 million and $1.2 million, respectively. The foreign exchange gains in the three and nine months ended December 31, 2020 were primarily the result of foreign currency exchange gains on our outstanding balance under the Sumitomo Dainippon Pharma Loan Agreement.

Income Tax (Benefit) Expense

Our income tax benefit was $1.2 million and $0.6 million for the three and nine months ended December 31, 2020, respectively. Our income tax expense was $0.2 million and $0.7 million for the three and nine months ended December 31, 2019, respectively. Our effective tax rate was 1.54% and (0.22)% for the three months ended December 31, 2020 and 2019, respectively, and for the nine months ended December 31, 2020 and 2019 was 0.35% and (0.31)%, respectively, and are driven by our jurisdictional earnings by location and a valuation allowance that eliminates our global net deferred tax assets.

Liquidity and Capital Resources

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 received from Richter and Pfizer.

As of December 31, 2020, we had cash, cash equivalents, marketable securities, and amounts available to us under the Sumitomo Dainippon Pharma Loan Agreement of $832.1 million, consisting of $745.8 million of cash, cash equivalents, and marketable securities and $86.3 million of borrowing capacity available to us under the Sumitomo Dainippon Pharma Loan Agreement, as compared to cash, cash equivalents, marketable securities, and amounts available to us under the Sumitomo Dainippon Pharma Loan Agreement of $365.9 million, consisting of $79.6 million of cash, cash equivalents, and marketable securities and $286.3 million of borrowing capacity available to us under the Sumitomo Dainippon Pharma Loan Agreement as of March 31, 2020.

Additional funds under the Sumitomo Dainippon 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. In January 2021, we borrowed an additional $45.0 million under the Sumitomo Dainippon Pharma Loan Agreement and $41.3 million of borrowing capacity currently remains available to us.

Pursuant to the Pfizer Collaboration and License Agreement, we are eligible to receive up to $3.7 billion of additional milestone payments, including two regulatory milestones of $100.0 million upon each FDA approval for relugolix combination tablet 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. We and Pfizer will equally share profits and certain expenses in the Co-Promotion Territory. In addition, if Pfizer exercises its option to acquire exclusive commercialization and development rights to relugolix in oncology in the Pfizer Territory, we will receive an option exercise fee of $50.0 million and will also be eligible to receive double-digit royalties on net sales of relugolix in the Pfizer Territory.

Pursuant to the Richter Development and Commercialization Agreement, we are eligible to receive up to $137.5 million of additional milestone payments, including regulatory milestones of up $30.0 million and tiered sales milestones of up to $107.5 million upon reaching certain thresholds of annual net sales for relugolix combination tablet in Richter's territory, and tiered royalties on net sales following regulatory approval for relugolix combination tablet in Richter's territory.

Capital Requirements

For the nine months ended December 31, 2020 and 2019, we had net losses of $173.8 million and $224.1 million, respectively. As of December 31, 2020, we had an accumulated deficit of $964.8 million. As of December 31, 2020, we had approximately $745.8 million in cash, cash equivalents, and marketable securities. We currently 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 on Form 10-Q. 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 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 Dainippon 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.

We expect that 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 commercialize ORGOVYX in the U.S., prepare for the potential regulatory approvals and commercialization of relugolix combination tablet, initiate life cycle management activities for our relugolix franchise, continue to develop our other product candidates and potentially expand our pipeline. We expect our net cash burn to gradually decrease as our net revenues increase but our future capital requirements and operating expenses are expected to continue 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 revenues generated from commercial sales of ORGOVYX and for any other product candidates that may receive marketing approval;
- the achievement of regulatory milestones, sales milestones, and royalties that we are eligible to earn pursuant to the Richter Development and Commercialization Agreement and the Pfizer Collaboration and License Agreement;

- the timing, shared costs, and level of investment in our and our collaboration partners' activities related to sales, marketing, market access, manufacturing, and distribution for ORGOVYX and for any other 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, relugolix combination tablet, and any other 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 intellectual property portfolio;
- costs to hire additional commercial operations, sales, scientific, clinical, regulatory, quality, and other personnel to support our commercialization, regulatory, and clinical development efforts;
- costs to implement or enhance operational, accounting, finance, quality, commercial, and management information systems and;
- costs to service our debt obligations and associated interest payments; and
- costs to operate as a public company.

Until such time, if ever, as we can generate substantial net product revenue from sales of ORGOVYX, relugolix combination tablet, MVT-602, or any future 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 Dainippon Pharma Loan Agreement, subject to the consent of our board of directors, as well as potential payments we are eligible to receive from Pfizer and Richter pursuant to the terms of our agreements with them.

Cash Flows

The following table sets forth a summary of our cash flows for the nine months ended December 31, 2020 and 2019 (in thousands):

	Nine Months Ended December 31,	
	2020	2019
Net cash provided by (used in) operating activities	$ 463,571	$ (201,943)
Net cash used in investing activities	$ (30,363)	$ (16,460)
Net cash provided by financing activities	$ 205,284	$ 145,651

Operating Activities

For the nine months ended December 31, 2020, $463.6 million of cash was provided by operating activities, which was primarily driven by a net increase in deferred revenue of $478.9 million and a net increase in cost share advance from collaboration partner of $138.8 million, both of which were largely driven by the upfront payment received from Pfizer in December 2020 discussed previously. For the nine months ended December 31, 2020, net cash provided by operating activities also included an increase in accrued expenses of $15.3 million primarily due to an increase in accrued commercial, compensation, and R&D expenses, as well as $21.7 million of non-cash share-based compensation expense. These items were partially offset by a net loss for the period of $173.8 million primarily due to our ongoing development and clinical studies, and activities related to our preparation for potential regulatory approvals and commercialization of our product candidates, and a non-cash foreign currency transaction gain of $16.2 million primarily related to amounts outstanding under the Sumitomo Dainippon Pharma Agreement.

For the nine months ended December 31, 2019, we used $201.9 million in operating activities primarily due to our ongoing development and clinical studies, activities related to our preparation for potential regulatory approvals and commercialization of our product candidates, and the expansion of our company. This was primarily attributable to a net loss for the period of $224.1 million along with a decrease of $8.5 million in accrued expenses resulting primarily from a decrease in accrued R&D expenses and a decrease of $4.4 million in accounts payable due to the timing of vendor invoice payments, along with decreases of $2.3 million and $1.1 million in deferred interest payable and interest payable, respectively, related to our previously outstanding debt that was repaid in full on December 31, 2019. These amounts were partially offset by $34.2 million of non-

cash share-based compensation expense, including $12.0 million related to the accelerated vesting of certain equity awards as a result of the change in control of Myovant in connection with the closing of the Sumitomo-Roivant Transaction and the remainder as a result of an increase in headcount, $2.7 million of total depreciation and amortization expense, and a $4.9 million loss on extinguishment of debt associated with the write-off of unamortized debt issuance costs and debt discounts, prepayment penalties and early redemption fees in connection with the repayment of outstanding obligations to NovaQuest and Hercules on December 31, 2019.

Investing Activities

For the nine months ended December 31, 2020, we used $30.4 million in investing activities, of which $29.3 million was for the purchase of marketable securities, net of maturities, and $1.0 million was for the purchase of property and equipment.

For the nine months ended December 31, 2019, we used $16.5 million in investing activities, of which $15.6 million was for the purchase of marketable securities, net of maturities, and $0.8 million was for the purchase of property and equipment.

Financing Activities

For the nine months ended December 31, 2020, $205.3 million was provided by financing activities. This was primarily due to proceeds of $200.0 million borrowed under the Sumitomo Dainippon Pharma Loan Agreement and proceeds of $5.3 million from the exercise of stock options under our 2016 Equity Incentive Plan.

For the nine months ended December 31, 2019, $145.7 million was provided by financing activities. This was primarily due to the net proceeds of $134.5 million we received from the issuance and sale of 17,424,243 common shares in our underwritten public equity offering, proceeds of $113.7 million borrowed under the Sumitomo Dainippon Pharma Loan Agreement and $2.5 million we received from the sale of 106,494 common shares through our "at-the-market" equity offering program. In addition, we received proceeds of $0.7 million from the exercise of stock options under our 2016 Equity Incentive Plan. These amounts were partially offset by the repayment of our financing obligations and redemption fees to NovaQuest and Hercules, including payments to NovaQuest of $60.0 million for repayment of principal, an early redemption fee of $2.4 million, and an annual debt administration fee of $0.3 million, and payments to Hercules of $40.0 million for repayment of principal, a prepayment penalty of $0.4 million, and an end of term charge of $2.6 million.

Contractual Obligations

During the nine months ended December 31, 2020, there were no material changes to our contractual obligations and commitments described under Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended March 31, 2020, other than additional draws under the Sumitomo Dainippon Pharma Loan Agreement (see Note 5(A) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q).

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, and disclosures of contingent assets and liabilities as of the dates of the unaudited condensed consolidated financial statements, and the reported amounts of revenues and expenses during the reporting periods. We base our estimates on historical experience and on various other information available to us at the time we make the estimates and judgments that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts, or experience. Changes in estimates and assumptions are reflected in reported results in the period in which they become known.

We define our critical accounting policies as those under U.S. GAAP that require us to make subjective estimates and judgments about matters that are inherently uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles.

Our critical accounting policies are more fully described in "Critical Accounting Policies and Significant Judgments and Estimates" in Part II. Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended March 31, 2020, filed with the SEC on May 18, 2020. We believe there have been no material changes to our critical accounting policies and use of estimates as disclosed in our Annual Report on Form 10-K, except for the accounting for collaboration arrangements described below.

Collaboration Arrangements

We analyze our collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements*, to determine whether such arrangements involve joint operating activities performed by the parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple units of account, we first determine which units of account of the collaboration are deemed to be within the scope of ASC 808 and those that are reflective of a vendor-customer relationship and, therefore, within the scope of ASC 606, *Revenue from Contracts with Customers*.

While ASC 808 defines collaborative arrangements and provides guidance on the income statement presentation, classification, and disclosures related to such arrangements, it does not address recognition and measurement matters, such as (1) determining the appropriate unit of account or (2) when the recognition criteria are met. Therefore, the accounting for these arrangements is either based on an analogy to other accounting literature, such as ASC 606, or an accounting policy election by management. For units of account within the collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate revenue recognition method is determined and applied consistently.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue on the consolidated balance sheets. If the related efforts underlying the deferred revenue are expected to be satisfied within the next twelve months, the deferred revenue is classified in current liabilities, otherwise it is classified as a non-current liability.

For collaboration arrangements that are within the scope of ASC 808, the recognition of collaboration revenue (expense) requires management judgement due to the fact that the terms of collaboration arrangements may be complicated, and the nature of the collaborative activities may change over time. Management judgement is exercised in determining the units of account within a collaboration arrangement and in allocating consideration to those units, estimating the collaboration revenue to be recognized, including estimating an appropriate term over which the collaboration revenue is expected to be recognized, as well as in determining the amortization method. For example, judgement is required in identifying material rights and performance obligations, and in estimating the stand-alone selling price of identified performance obligations and material rights, the estimates of which may include forecasted revenue, development timelines, discount rates and probabilities of technical and regulatory success.

There is also judgement involved in the identification of costs that we incur related to the collaboration activities, evaluating the nature of these costs (for example, whether the costs relate to a particular geography or territory or whether the costs relate to clinical or commercial activities), and applying the terms of the respective collaborative arrangement to determine the portion of such costs that are the responsibility of the collaboration partner, which in certain circumstances requires significant judgement.

In addition, we are dependent on collaborative partners to provide us with information in a timely and accurate manner for use in preparing our consolidated financial statements and related disclosures. Certain of this information may also be subject to estimates. Should our collaborative partners fail to provide us with any such information in a timely manner, or should any estimates upon which such financial information was based, prove to be inaccurate, we could be require to record such adjustments in future periods.

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 2 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Under SEC rules and regulations, because we are considered to be a "smaller reporting company," we are not required to provide information in this Item 3.

Item 4. 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 on Form 10-Q, have concluded that, based on such evaluation, our disclosure controls and procedures were effective at the reasonable assurance level. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

We continually seek to improve the efficiency and effectiveness of our internal control over financial reporting. No changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended December 31, 2020 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, including the section of this report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our unaudited condensed consolidated financial statements and related notes. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. If any of the events described in the following risk factors and the risks described elsewhere in this Quarterly Report on Form 10-Q occurs, our business, operating results and financial condition could be seriously harmed and the trading price of our common shares could decline and you could lose all or part of your investment in our common shares.

Summary Risk Factors

Our business is subject to a number of risks that our shareholders should be aware of before making a decision to invest in our common shares. These risks are more fully described below. These risks include, among others, the following:

- Our success depends in part on the successful commercialization of ORGOVYX, which received approval in December 2020 from the U.S. Food and Drug Administration (the "FDA"), for the treatment of adult patients with advanced prostate cancer. To the extent ORGOVYX is not commercially successful, our business, financial condition and results of operations will be materially harmed.
- ORGOVYX may fail to achieve the degree of market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success, which would negatively impact our business.
- If we and Pfizer are unable to effectively market and sell ORGOVYX, the commercialization of ORGOVYX will not be successful and our business will be harmed.
- Failure to successfully obtain coverage and reimbursement for ORGOVYX in the United States, or the availability of coverage only at limited levels, would diminish our ability to generate product revenue.
- We face substantial competition in the commercialization of ORGOVYX, and our operating results will suffer if we fail to compete effectively.
- If manufacturers obtain approval for generic versions of ORGOVYX, or of products with which we compete, our business may suffer.
- If patient safety issues were to arise for ORGOVYX, our future sales of ORGOVYX may be reduced, adversely affecting our results of operations.
- If we or our collaboration partner, Pfizer, are found to have improperly promoted unapproved uses of ORGOVYX, we may be subject to restrictions on the sale or marketing of ORGOVYX and significant fines, penalties, sanctions and product liability claims, and our image and reputation within the industry and marketplace could be harmed.
- 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.
- Business interruptions resulting from effects of pandemics or epidemics such as the novel strain of the coronavirus known as COVID-19, may materially and adversely affect our business and financial condition.
- If we do not have adequate funds to cover our development and commercial 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 are required to meet certain terms and conditions to draw down funds under the Sumitomo Dainippon Pharma Loan Agreement or obtain additional funds under the 2020 Commitment Letter. If we are unable to meet such terms and conditions, we may not be able to access funding from the Sumitomo Dainippon Pharma Loan Agreement or under the 2020 Commitment Letter. The terms of the Sumitomo Dainippon 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 delay in our ability to develop and commercialize our products.
- 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.
- 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.
- 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.
- Reported data or other clinical development announcements by Takeda, its partners or sublicensees, or by our collaboration partners, including Pfizer and Richter may adversely affect our commercialization of ORGOVYX and our clinical development plans.
- 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, we will not be able to commercialize relugolix combination tablet, relugolix monotherapy tablet, or MVT-602, and our ability to generate product revenue will be materially impaired.
- ORGOVYX, relugolix combination therapy, relugolix monotherapy and MVT-602 may cause adverse effects or have other properties that could halt, delay or prevent their commercialization, regulatory approval or limit the scope of any approved label or market acceptance.
- 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.
- We are dependent upon our collaborative relationships with collaboration partners to further develop, fund, manufacture and commercialize ORGOVYX, relugolix combination tablet and our other product candidates. If such relationships are unsuccessful, or if a collaboration partner terminates its collaboration agreement with us, it could negatively impact our ability to conduct our business and generate product revenue.
- 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.
- 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.
- We have agreements with Sumitovant, our majority shareholder, and with Sumitovant's parent, Sumitomo Dainippon Pharma, and their affiliates, including Sunovion, that may be perceived to create conflicts of interest which, if other investors perceive that Sumitovant or Sumitomo Dainippon 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.

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

Risks Related to Commercialization of ORGOVYX™ (relugolix) for the treatment of adult patients with advanced prostate cancer

Our success depends in part on the successful commercialization of ORGOVYX, which received approval in December 2020 from the FDA for the treatment of adult patients with advanced prostate cancer. To the extent ORGOVYX is not commercially successful, our business, financial condition and results of operations will be materially harmed.

We have invested and continue to invest a significant portion of our efforts and financial resources in the development, approval and now commercialization in the U.S. of ORGOVYX for the treatment of advanced prostate cancer. Our and/or our collaboration partner, Pfizer's, ability to generate net product revenues from ORGOVYX will depend upon the size of the markets in the jurisdictions for which regulatory approval is obtained, the number of competitors in such markets and numerous other factors, including:

- successfully establishing effective sales, marketing, and distribution systems in the jurisdictions in which ORGOVYX is approved for sale;
- successfully establishing and maintaining commercial third-party manufacturers and having adequate commercial quantities of ORGOVYX 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 ORGOVYX by physicians, patients and the healthcare community;
- the acceptance of pricing and placement of ORGOVYX 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 ORGOVYX in comparison to competing products, including through differentiated approved labeling; and
- obtaining, maintaining, enforcing, and defending intellectual property rights and claims.

If we and/or Pfizer do not achieve one or more of these factors in a timely manner or at all, we and/or Pfizer could experience significant delays or an inability to successfully commercialize ORGOVYX, which would materially harm our business.

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

ORGOVYX may fail to gain sufficient market acceptance by physicians, patients, third-party payers, or others in the medical community. If it does not achieve an adequate level of acceptance, we may not generate significant product revenue or become profitable. The degree of market acceptance of ORGOVYX 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 ORGOVYX relative to other treatments;
- the content of the approved product label and our ability to make compelling product claims;
- the effectiveness and adequacy of our marketing efforts;
- the effectiveness of our and Pfizer's sales efforts;
- the patient out-of-pocket costs in relation to alternative treatments;
- the willingness of the potential patient population to try new therapies and of physicians 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 payor coverage or reimbursement;
- whether diagnosis and treatment rates increase in advanced prostate cancer; and
- any restrictions on the use of ORGOVYX together with other medications.

The failure of ORGOVYX to obtain market acceptance would materially harm our business.

If we and Pfizer are unable to effectively market and sell ORGOVYX, the commercialization of ORGOVYX will not be successful and our business will be harmed.

To successfully market ORGOVYX, we must continue to develop our capabilities in sales, market access, marketing, distribution, and other commercial functions, either on our own or with our third-party collaboration partners. We have made arrangements regarding some of these functions in certain markets with third-party collaboration partners. For example, on August 1, 2020, we entered into a Market Access Services Agreement, as amended, with Sunovion pursuant to which, among other things, Sunovion has agreed to provide to us certain market access services with respect to the distribution and sale of ORGOVYX for prostate cancer and relugolix combination tablet for uterine fibroids and endometriosis. On December 26, 2020, we entered into the Pfizer Collaboration and License Agreement, pursuant to which we and Pfizer will collaborate to jointly develop and commercialize relugolix in oncology and women's health in the U.S. and Canada (the "Co-Promotion Territory"). 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"). If Sunovion or Pfizer, or any other collaboration 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 ORGOVYX would be delayed or may not occur. In addition to the third-party collaboration arrangements described above, we continue to develop 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 and distribution 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 physicians to prescribe any approved drugs; (iii) the ability to negotiate with payors regarding reimbursement and formulary access for our products; and (iv) unforeseen costs and expenses associated with creating and sustaining internal sales, market access, marketing and distribution capabilities. The COVID-19 pandemic may negatively impact our ability to maintain our own commercial capabilities and may negatively impact our ability to rapidly and effectively educate potential prescribers and, if significant delays result, to commercialize ORGOVYX.

ORGOVYX is a newly marketed drug in the U.S. and is the first and only oral gonadotropin-releasing hormone ("GnRH") receptor antagonist for adult patients with advanced prostate cancer. Therefore, none of the members of our recently hired sales force and of our collaboration partner, Pfizer, has ever promoted ORGOVYX prior to its launch. We have only recently established our distribution and reimbursement capabilities in the U.S. together with Sunovion, all of which will be necessary to successfully commercialize ORGOVYX. As a result, we and/or our collaboration partners will be required to expend significant time and resources to market, sell, and distribute ORGOVYX 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 and marketing messages, or the distribution and reimbursement capabilities, that we or our collaboration partners have developed will be successful. Specifically, for distribution of ORGOVYX, we are heavily dependent on third-party logistics, pharmacy and distribution partners. If we or our collaboration partners are unable to perform effectively, our ability to realize the return on our investment in developing ORGOVYX will suffer.

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

Our and Pfizer's ability to commercialize ORGOVYX successfully in the United States will depend in part on the extent to which coverage and reimbursement for ORGOVYX will be available from third-party payors, including government health administration authorities and private health insurers. In the U.S., no uniform policy of coverage for products exists among third-party payors. Third-party payors 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. Payor 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 payor's decision to provide coverage for a drug does not imply that an affordable out-of-pocket cost for patients will be established. Each plan determines whether or not it will provide coverage for a drug, what amount it will pay the manufacturer for the drug, on what tier of its formulary the drug will be placed, and whether to require step therapy or prior authorizations. The position of a drug on a formulary generally determines the co-payment that a

patient will need to make to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Coverage from both governmental healthcare programs, such as Medicare Part D and Medicaid, and commercial payors are critical to ORGOVYX's commercial success. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or cheaper therapeutic alternatives are already available or subsequently become available.

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

We face substantial competition in the commercialization of ORGOVYX, 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 ORGOVYX. 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) and Firmagon® (Ferring Pharmaceuticals).

Many of our current and potential future competitors have significantly more experience commercializing drugs and may succeed in developing, acquiring or licensing, on an exclusive basis, drugs that are more effective or less costly than ORGOVYX or any product candidate that we may 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 and the price we are able to charge for ORGOVYX or any other product candidate we 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, or of products with which we 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 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 or products with which it competes, our business would be materially harmed.

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

The data supporting the marketing approval in the U.S. for ORGOVYX and forming the basis for our product label for ORGOVYX were obtained in controlled clinical trials of limited duration. As ORGOVYX is used over a longer period of time

by patients, including those taking other medicines, we may continue to identify new issues such as safety concerns, resistance or drug interactions of ORGOVYX, which may require us to provide additional warnings or contraindications on our label or narrow the approved indication, each of which could reduce the market acceptance of ORGOVYX.

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 product sales of ORGOVYX. Further, if serious safety, resistance or drug interaction issues arise with ORGOVYX, 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 ORGOVYX marketed by third parties that utilize the same therapeutic target or that belong to the same therapeutic class could adversely affect the commercialization of ORGOVYX.

If a safety issue emerges post-approval, we may become subject to costly product liability litigation by our customers, patients or payors. 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 ORGOVYX caused injuries, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for ORGOVYX;
- the inability to commercialize ORGOVYX;
- injury to our reputation and significant negative media attention;
- withdrawal of patients from clinical studies or cancellation of studies of relugolix;
- significant costs to defend the related litigation;
- substantial monetary awards to patients; and
- loss of 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 stock price to decline.

If we or our collaboration partner, Pfizer, are found to have improperly promoted unapproved uses of ORGOVYX, we may be subject to restrictions on the sale or marketing of ORGOVYX 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 United States, strictly regulate the marketing and promotional claims that are made about drug products, such as ORGOVYX. 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, for the treatment of adult patients with advanced prostate cancer, we cannot prevent physicians from prescribing ORGOVYX for indications or uses that are inconsistent with the approved label. If, however, we or our collaboration partner, Pfizer, 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 United States 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 stock 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.

ORGOVYX is complex to manufacture, and manufacturing disruptions may occur that could cause us to experience disruptions in the supply of ORGOVYX.

ORGOVYX is complex to manufacture. Notwithstanding the fact that our third-party manufacturers have validated our process, 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 ORGOVYX or our future product candidates, our business, financial results, or stock 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 delay in our ability to develop and commercialize our products."

Risks Related to Commercialization of Relugolix Combination Tablet and for MVT-602

Our success also depends on successful development and commercialization of relugolix combination tablet for our women's health indications of uterine fibroids and endometriosis and MVT-602, and if we are successful in obtaining regulatory approval for these products, we will be subject to the same commercialization risks as described above for ORGOVYX.

Although relugolix monotherapy has been approved in the U.S. as ORGOVYX for the treatment of adult patients with advanced prostate cancer, relugolix combination tablet has not yet been approved for our women's health indications of uterine fibroids and endometriosis, nor has MVT-602 received any regulatory approvals. If relugolix combination tablet for either of our women's health indications, or MVT-602 for the treatment of female infertility or other potential indications, receives regulatory approval in any indication, our commercialization of those products will be subject to the same or similar risks we currently face with the commercialization of ORGOVYX, as described under "Risks Related to Commercialization of ORGOVYX™ (relugolix) for the treatment of adult patients with advanced prostate cancer" above.

Risks Related to Our Financial Position and Capital Requirements

If we do not have adequate funds to cover our development and commercial 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 began to commercialize ORGOVYX in the U.S. for the treatment of adult patients with advanced prostate cancer in January 2021, and plan to commercialize relugolix combination tablet, if approved, for women with uterine fibroids later this year. 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 December 31, 2020, we had cash, cash equivalents and marketable securities of $745.8 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 on Form 10-Q. 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 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 revenues generated from commercial sales of ORGOVYX and for any other product candidates that may receive marketing approval;
- the achievement of regulatory milestones, sales milestones, and royalties that we are eligible to earn pursuant to the Richter Development and Commercialization Agreement and the Pfizer Collaboration and License Agreement;
- the timing, shared costs, and level of investment in our and our collaboration partners' activities related to sales, marketing, market access, manufacturing, and distribution for ORGOVYX and for any other 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, relugolix combination tablet, and any other 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 and timing of completion of commercial-scale manufacturing activities, including securing regulatory approval for commercial production;
- the costs to hire additional commercial operations, sales, scientific, clinical, regulatory, quality, and other personnel to support our commercialization, regulatory, and clinical development efforts; and
- the costs to implement or enhance operational, accounting, finance, quality, commercial, and management information systems.

Under the terms of the Sumitomo Dainippon Pharma Loan Agreement, we may not raise additional capital without obtaining the consent of Sumitomo Dainippon Pharma. If we do not have sufficient funds to complete the development of, seek regulatory approvals for our product candidates and commercialize ORGOVYX and, if approved, our other 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 Dainippon Pharma Loan Agreement or obtain additional funds under the 2020 Commitment Letter. If we are unable to meet such terms and conditions, we may not be able to access funding from the Sumitomo Dainippon Pharma Loan Agreement or under the 2020 Commitment Letter.

On December 27, 2019, we, one of our subsidiaries and Sumitomo Dainippon Pharma entered into the Sumitomo Dainippon Pharma Loan Agreement, pursuant to which Sumitomo Dainippon Pharma agreed to make revolving loans to us in an aggregate principal amount up to $400.0 million. As of December 31, 2020, approximately $86.3 million of borrowing capacity remained available to us under the Sumitomo Dainippon Pharma Loan Agreement. In January 2021, we borrowed an additional $45.0 million under this agreement. We may draw down additional funds under the Sumitomo Dainippon 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. In addition, if Sumitomo Dainippon Pharma fails to own at least a majority of the outstanding common shares of Myovant, it may become unlawful under Japanese law for Sumitomo Dainippon Pharma to fund loans to us, in which case we would not be able to continue to borrow under the Sumitomo Dainippon 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 Dainippon Pharma Loan Agreement. We may not be able to meet such terms and conditions in the future and may not be able to secure additional funds.

Pursuant to the 2020 Commitment Letter with Sumitomo Dainippon Pharma and subject to the terms and conditions set forth therein, Sumitomo Dainippon Pharma has agreed to negotiate with us $200.0 million in unsecured revolving commitments (the "New Credit Facility"), the proceeds of which may be used for our business operating expenditures. Such New Credit Facility would be in addition to the commitments made available to us by Sumitomo Dainippon Pharma under the existing Sumitomo Dainippon Pharma Loan Agreement. Sumitomo Dainippon Pharma will have the discretion to require certain prepayments as Sumitomo Dainippon Pharma may request and/or to not allow us to draw down any remaining funds under the New Credit Facility, upon the occurrence of certain material business development transactions, including the transaction contemplated by the Pfizer Collaboration and License Agreement. In addition, as a condition of entering into the New Credit Facility, we are required to enter into an information sharing agreement with Sumitovant which will be on terms to be agreed between Sumitovant and us. The New Credit Facility described in the 2020 Commitment Letter will not be available to us until we negotiate and enter into a definitive agreement with Sumitomo Dainippon Pharma and the New Credit Facility becomes effective. As a result, if the conditions set forth in the 2020 Commitment Letter are not met or unexpected disagreements arise in the negotiations, that may delay or prevent the entering into an agreement and the New Credit Facility may not become effective. We therefore cannot be certain that additional capital, including the potential additional capital Sumitomo Dainippon Pharma may provide to us as set forth in the 2020 Commitment Letter will be available to us on acceptable terms, or at all.

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 and negative operating cash flows. We expect to continue to incur significant operating expenses as we commercially launch ORGOVYX in the U.S., continue to develop our product candidates and prepare for potential regulatory approvals and commercialization of relugolix combination tablet. The timing and magnitude of our net income (loss) will depend on the commercial success of ORGOVYX, as well as the timing and commercial success of any other 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 the Pfizer Collaboration and License Agreement and the Richter Development and Commercialization Agreement will depend on the regulatory and commercial success of ORGOVYX and relugolix combination tablet. As a result, we may never achieve or maintain profitability.

Risks Related to Our Business Operations

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

Our obligations under the Sumitomo Dainippon Pharma Loan Agreement are senior unsecured obligations including customary representations and warranties as well as affirmative and negative covenants, that are guaranteed on a full and unconditional basis by all our subsidiaries.

The negative covenants include limitations on additional indebtedness, liens, certain corporate changes, certain restricted payments, investments 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 Dainippon 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 and Sumitomo Dainippon 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 Dainippon 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 Dainippon Pharma Loan Agreement to become immediately due and payable, and Sumitomo Dainippon Pharma may take such other actions as set forth in the Sumitomo Dainippon Pharma Loan Agreement. Upon the occurrence of certain bankruptcy and insolvency events, the obligations of Sumitomo Dainippon Pharma to make loans to us would automatically terminate and the principal amount of all outstanding loans and other obligations due under the Sumitomo Dainippon Pharma Loan Agreement would automatically become due and payable. In addition, if it becomes unlawful for Sumitomo Dainippon Pharma to maintain the loans under the Sumitomo Dainippon 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 diversifying our product development risk by identifying and acquiring or in-licensing novel product candidates. We may fail to identify and acquire or in-license product candidates, including for reasons discussed in these risk factors and also:

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

In addition, our novel product candidates may prove to be unsuccessful. Further, time and resources spent searching for, identifying, acquiring, and developing potential product candidates may distract management's attention from our primary business. 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 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 for all indications. 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 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 would be required for us to complete further Phase 2 and Phase 3 clinical studies for MVT-602. Third-party vendors may be difficult to identify for MVT-602 process and formulation development and manufacturing due to special capabilities required and they may not be able to meet our quality standards.

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. For example, if any of the drug substance 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, if approved, 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.

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 ("Hikari Facility"). We initially listed both Takeda and Excella as contract manufacturing organizations ("CMOs") in our regulatory filings for the manufacture of relugolix drug substance. We are now procuring the commercial relugolix drug substance for U.S. ORGOVYX solely from Excella. We have removed the Hikari Facility as a manufacturing site from our NDA submissions and may remove it from other regulatory filings if required until Takeda corrects the violations noted in the warning letter to the satisfaction of the regulatory authorities. We cannot predict if or when Takeda will correct the violations and deviations to the satisfaction of the FDA or any other regulatory agency or whether the regulatory agencies will be satisfied with Takeda's responses. The COVID-19 pandemic may also cause delays in the remediation and re-inspection process. We also face the risk that Excella or our other 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 ORGOVYX and our other anticipated launches, 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 ORGOVYX and any of our other 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 ORGOVYX or relugolix combination tablet;
- 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 ORGOVYX, relugolix combination tablet or MVT-602, if approved, or any future product candidate in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- 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, third-party manufacturers, principal investigators, consultants, commercial 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, including third-party manufacturers, principal investigators, consultants, commercial 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 payors, 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 commission, customer incentive programs, and other business arrangements. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical 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 novel strain of the coronavirus known as COVID-19, may materially and adversely affect our business and financial condition.

The COVID-19 pandemic may materially and adversely affect our business and financial condition. For example, the majority of our employees have been subject to "shelter-in-place" orders resulting from the COVID-19 pandemic that require our employees to work from home with limited exceptions. Employees may be less efficient given competing priorities with home-schooling or caring for sick family members, and employee engagement and productivity may decrease from the stress of the COVID-19 pandemic resulting in delays in the progress of our business. 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 ORGOVYX commercial launch, and anticipated commercial launches of relugolix combination tablet, our supply chain for raw materials, drug substance and drug product is worldwide, and the continued spread of the coronavirus and the duration of its impact on the ability of our suppliers to operate could negatively impact our manufacturing supply chain for ORGOVYX, for any other product candidates that may receive regulatory approval, or for clinical trial 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.

The COVID-19 pandemic has made it more difficult for our medical affairs team to present scientific data and for our regional medical advisors to engage potential prescribers in scientific exchange. Multiple medical conferences have been canceled, postponed or moved to virtual formats, resulting in fewer opportunities to present our scientific data and our medical affairs team members can only communicate virtually making it more difficult to educate and engage in scientific exchange.

In addition, the COVID-19 pandemic may impact the FDA's review process and timing of potential approval of our product candidates. Regulatory agency pre-approval inspections are now limited, and it is not clear if virtual inspections will be required and acceptable.

The COVID-19 pandemic may negatively impact our ability to rapidly and effectively educate potential prescribers and payers and, successfully commercialize ORGOVYX and our other product candidates, if approved. We commercially launched ORGOVYX in January 2021, and may launch other approved product candidates in the COVID-19 environment. In response to the COVID-19 pandemic, health professionals may reduce staffing and reduce or postpone appointments with patients, or patients may cancel or miss appointments, resulting in fewer prescriptions. In addition, our sales teams have been and would likely have to continue to make presentations to physicians and the medical community in many cases by virtual means instead of in-person, which could reduce the number of medical professionals we are able to present to, and these virtual meetings may not be as successful as in-person meetings. Reduced access to healthcare providers as a result of social distancing protocols may impact or require adjustment to our planned commercialization activities, including the manner in which our field teams engage with healthcare providers and facilities. Travel restrictions may make it more difficult for us to maximize the potential of our third-party market access, marketing and distribution capabilities, such as our relationships with Sunovion, Pfizer, and Richter and provide adequate collaboration and oversight.

The COVID-19 pandemic may negatively impact our ability to attract the human resources required to maintain and build out our commercial capabilities. 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.

The extent to which the coronavirus and global efforts to contain its spread will impact our operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, and include the duration, severity and scope of the outbreak and the actions taken to contain or treat the coronavirus outbreak. In addition, the current COVID-19 pandemic may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

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, payors, government officials, distributors, manufacturers and other third parties globally in case any of our product candidates is approved for marketing outside of the U.S.

Conducting business internationally involves a number of risks, including:

- multiple conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment, 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 appropriate licenses or regulatory approvals for the sale or use of our product candidates, if approved, in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing multiple payor-reimbursement, 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 and terrorism, economic weakness, inflation, political instability in particular foreign economies and markets, boycotts, curtailment of trade, 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 European Union 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 biopharmaceutical companies have found the process of marketing their products in foreign countries to be very challenging.

The withdrawal of the United Kingdom (the "U.K.") from the European Union (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. Pursuant to the formal withdrawal arrangements between the U.K. and the EU, the U.K. was subject to a transition period until December 31, 2020 (the "Transition Period") during which EU rules continued to apply. 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 on 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, Great Britain is no longer covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA, and a separate marketing authorization will be required to market our product candidates in Great Britain. It is currently unclear whether the Medicines & Healthcare products Regulatory Agency ("MHRA") in the U.K. is sufficiently prepared to handle the increased volume of marketing authorization applications that it is likely to receive. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us 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 prior to the end of the Transition Period. 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 (when compared to the position prior to the end of the Transition Period) 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 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 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 ORGOVYX 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.

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 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 implement and maintain an enterprise resource planning system could adversely affect our business and results of operations or the effectiveness of internal controls over financial reporting.

We have implemented and continue to optimize a company-wide enterprise resource planning ("ERP") system pertaining to certain business, operational, and finance processes. ERP implementations are complex 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. The implementation and optimization of the ERP system has required, and will continue to require, the investment of significant financial and human resources.

Any disruptions, delays, or deficiencies in the design or the ongoing maintenance and optimization of the ERP system 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 does not operate as intended, the effectiveness of our internal controls 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, 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 a different reference rate, may adversely affect interest rates.

On July 27, 2017, the Financial Conduct Authority (the authority that regulates LIBOR) announced that it would cease to compel banks to submit to LIBOR by the end of 2021. It is unclear whether new methods of calculating LIBOR will be established such that it continues to exist after 2021, or if alternative rates or benchmarks will be adopted. The interest rate under the Sumitomo Dainippon Pharma Loan Agreement is calculated based on LIBOR and, when LIBOR is phased out, we will need to agree with Sumitomo Dainippon Pharma to a new method of calculating the interest rate under the Sumitomo Dainippon 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 materially and adversely affect our results of operations, cash flows and liquidity. We cannot predict the effect of the potential changes to LIBOR or the establishment and use of alternative rates or benchmarks.

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. For example, the FDA or other regulatory authorities may not agree with our proposed plans for any clinical studies of relugolix combination tablet, relugolix monotherapy tablet, MVT-602, or any other potential future product candidates, which may delay the approval of an NDA or similar application. The clinical study process is also very time-consuming. The commencement and completion of clinical studies may be delayed 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;
- 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, including missed assessments or impeded access to study sites due to government or institutional stay-at-home or shelter-in-place measures during the COVID-19 pandemic;
- premature discontinuation of study participants from clinical studies or missing data, including from patients unable to come to study visits during the COVID-19 pandemic;
- 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. 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 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 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, 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 sites, the eligibility criteria for the study and the proportion of patients screened that meets those criteria, our ability to obtain and maintain patient consents, and the risk that patients enrolled in clinical studies will not comply with the protocol or will drop out of the studies before completion. In addition, unforeseen global instability, including political instability 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 Takeda may report in 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 results reported by our competitors about their drug 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 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 predetermined endpoints would likely cause us to abandon a product candidate and may delay development of any other product candidates. Any delay in, or termination of, our clinical studies will delay the submission of our NDAs to the FDA or other similar applications with other relevant foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates and generate product revenue.

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

Takeda, its partners and sublicensees and our collaboration partners, Pfizer and Richter, may be involved in the further clinical development of relugolix. Favorable announcements by Takeda, Pfizer or Richter do not guarantee that the results of our clinical studies will also be favorable as the designs of our clinical studies differ from those of Takeda, Pfizer or Richter. 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 ORGOVYX 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 FDA's (or other regulatory authority) evaluation. 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, we will not be able to commercialize relugolix combination tablet, relugolix monotherapy tablet, or MVT-602, and our ability to generate 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 are not permitted to market our product candidates in the U.S. until we receive approval of NDAs or in any foreign country until we receive the requisite approvals from the appropriate regulatory authorities in such countries. Obtaining approval of an NDA or similar 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 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 from the FDA or a regulatory approval from a regulatory authority outside the U.S. is an expensive process. The submission of NDAs is subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA 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 NDA 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. For example, GnRH receptor antagonists, like relugolix, when taken alone, may cause loss of bone mineral density due to the induced hypoestrogenic state that may limit duration of use. This risk, and a related risk of hot flash or vasomotor symptoms, may be mitigated by the co-

administration of relugolix in combination with low-dose estradiol and a progestin. A key part of our relugolix clinical development strategy has been to formulate a single-tablet fixed-dose combination of relugolix with low-dose estradiol and a progestin (relugolix combination tablet) to maintain bone health and mitigate side effects of a low-estrogen state such as vasomotor symptoms, and to facilitate patient convenience and compliance. If the FDA or another regulatory authority concludes that the data from these studies are insufficient to support regulatory approvals, we may be required to conduct further studies and we could face delays and increased expenses associated with our development programs and our commercial opportunity could be limited. If we are not able to obtain required regulatory approvals for relugolix combination tablet or if our competitors obtain regulatory approval of a fixed-dose combination with hormonal therapy before we do, we would be at a competitive disadvantage and this could limit our commercial opportunity.

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 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. For example, in June 2020, the FDA issued a warning letter to Takeda following a routine inspection of aseptic finished pharmaceuticals (drug product) manufacturing at the Hikari Facility. The Hikari Facility is one of two CMOs included in our initial regulatory filings for the manufacture of relugolix drug substance ("API"). The warning letter indicated that the FDA was not satisfied with Takeda's response to an FDA Form 483 issued to Takeda following the inspection and cited significant violations of cGMP for finished pharmaceuticals. Although API manufacturing was not included in the scope of the FDA's inspection that led to the warning letter, the Hikari Facility is classified under one FDA Establishment Identifier and the facility has a common quality system. We are now procuring the commercial relugolix drug substance for U.S. ORGOVYX solely from Excella, pursuant to the Commercial Manufacturing and Supply Agreement we have with Excella. Due to the warning letter, we have removed the Hikari Facility as a manufacturing site from our NDA submissions and may remove it from other regulatory filings if required until Takeda corrects the violations noted in the warning letter to the satisfaction of the regulatory authorities. We cannot predict if or when Takeda will correct the violations and deviations to the satisfaction of the FDA or any other regulatory agency or whether the regulatory agencies will be satisfied with Takeda's responses. The COVID-19 pandemic may also cause delays in the remediation and re-inspection process. We also face the risk that Excella or our other 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 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. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval. We are reliant, in part, upon the regulatory expertise of Richter to gain approval for relugolix combination tablet in the licensed territories to Richter and are completely reliant on Richter to generate revenue in the licensed territories to Richter. If we or Richter fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

ORGOVYX, relugolix combination therapy, relugolix monotherapy and MVT-602 may cause adverse effects or have other properties that could halt, delay or prevent their commercialization, regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events associated with ORGOVYX could cause U.S. regulatory authorities to interrupt, delay or halt commercialization of ORGOVYX. Further, adverse events associated with relugolix combination therapy, relugolix monotherapy, or MVT-602 could cause us, other reviewing entities, clinical study sites or regulatory authorities 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 relugolix combination therapy, relugolix monotherapy or MVT-602 or any future 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.

In addition, if post-marketing adverse events related to Relumina® are reported, it could negatively impact our clinical development plans for relugolix.

If ORGOVYX causes, 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 ORGOVYX and our other product candidates.

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

ORGOVYX, 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, "ORGOVYX, relugolix combination therapy, relugolix monotherapy and MVT-602 may cause adverse effects or have other properties that could halt, delay or prevent their commercialization, regulatory approval or limit the scope of any approved label or market acceptance."

Our current and future relationships with investigators, healthcare professionals, consultants, third-party payors, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient support channels, charitable organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws regulate the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our products for which we obtain marketing approval. Such laws include, among others, the federal Anti-Kickback Statute, the federal false claims laws, the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 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 relugolix combination tablet, relugolix monotherapy tablet or MVT-602 and affect the prices we may obtain.

In the U.S. and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of relugolix combination tablet, relugolix monotherapy tablet or MVT-602, 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. Such scrutiny has resulted in several Congressional inquiries and proposed and enacted federal and state

legislation designed to, among other things, bring more transparency to drug product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.

At the 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 regulations, guidance, or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. It is also possible that additional governmental action is taken to address the COVID-19 pandemic.

Risks Related to Our Dependence on Third Parties

We are dependent upon our collaborative relationships with collaboration partners to further develop, fund, manufacture and commercialize ORGOVYX, relugolix combination tablet and our other product candidates. If such relationships are unsuccessful, or if a collaboration partner terminates its collaboration agreement with us, it could negatively impact our ability to conduct our business and generate product revenue.

On December 26, 2020, we entered into the Pfizer Collaboration and License Agreement, pursuant to which we and Pfizer will collaborate to jointly develop and commercialize relugolix in oncology and women's health in the Co-Promotion Territory. Pfizer also received an option to acquire exclusive commercialization and development rights to relugolix in oncology in the Pfizer Territory. We and Pfizer will equally share profits and certain expenses for ORGOVYX and relugolix combination tablet. In the Co-Promotion Territory, we will be the principal on all sales transactions with third parties and will recognize 100% of product sales to third parties as revenue from contracts with customers. In addition to the Pfizer Collaboration and License Agreement, we have entered into collaboration arrangements with other collaboration partners. On August 1, 2020, we entered into a Market Access Services Agreement, as amended, with Sunovion pursuant to which, among other things, Sunovion has agreed to provide to us certain market access services with respect to the distribution and sale of ORGOVYX for prostate cancer and relugolix combination tablet for uterine fibroids and endometriosis. On March 30, 2020, we entered into the Richter Development and Commercialization Agreement pursuant to which, among other things, Richter will be responsible for all commercialization activities for relugolix combination tablet for uterine fibroids and endometriosis in certain territories outside of the U.S.

We are subject to a number of risks associated with our dependence on our collaborative relationship with our collaboration partners, including:

- our collaboration partners may terminate their collaboration agreements with us for reasons specified in the collaboration 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 partners in the event that a collaboration partner was to terminate its collaboration with us;
- adverse decisions by a collaboration partner regarding the amount and timing of resource expenditures for the commercialization, distribution and sale of ORGOVYX or relugolix combination tablet;
- failure by a collaboration partner to perform its duties under its collaboration agreement with us;
- decisions by a collaboration partner to prioritize other of its present or future products more highly than ORGOVYX or our other product candidates when it performs its duties;
- possible disagreements with a collaboration partner as to the timing, nature and extent of our development plans or distribution and sale plans;
- the financial returns to us, if any, under our collaboration agreements with Pfizer and Richter, depend in large part on the achievement of milestones and generation of product sales, and if Pfizer or Richter fail to perform or satisfy their obligations under the collaboration agreements, the development and commercialization of ORGOVYX and relugolix

combination tablet 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 partners, we may be delayed or prevented from further developing, manufacturing or commercializing ORGOVYX, relugolix combination tablet or our other product candidates or we may become involved in litigation or arbitration, which would be time consuming and expensive.

If any collaboration partner were to terminate our collaborative relationship with it unilaterally, we would need to undertake development, commercialization or distribution or sale activities for ORGOVYX, relugolix combination tablet and other 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 ORGOVYX, relugolix combination tablet and our product candidates and could prevent us from effectively commercializing ORGOVYX, relugolix combination tablet and our other 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 relationship with our current collaboration 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. For example, the receipt by Takeda of the warning letter described in 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 delay in our ability to develop and commercialize our products" has caused us to rely on our Commercial Manufacturing and Supply Agreement with Excella to a greater extent than we had intended, and may require us to remove the Hikari Facility from our regulatory filings until Takeda corrects the violations noted in the warning letter to the satisfaction of the regulatory authorities. We cannot predict if or when Takeda will correct the violations and deviations to the satisfaction of the FDA or any other regulatory agency or whether the regulatory agencies will be satisfied with Takeda's responses. The COVID-19 pandemic may also cause delays in the remediation and re-inspection process. 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 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, principal investigators, 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 GLP nonclinical studies and GCP 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 or our CROs 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 and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries with respect to relugolix, MVT-602, and any future product candidates. We seek to protect our proprietary position by filing patent applications in the U.S. and abroad related to our development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

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

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

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

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

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

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

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

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

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

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution.

Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the U.S., in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

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

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

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

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

might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

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

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

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

Because we expect to rely on third parties to manufacture ORGOVYX and other clinical trial 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 R&D programs that may require us to share trade secrets under the terms of our R&D 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 Dainippon Pharma, and their affiliates, including Sunovion, that may be perceived to create conflicts of interest which, if other investors perceive that Sumitovant or Sumitomo Dainippon 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 Dainippon 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 a loan agreement with Sumitomo Dainippon Pharma 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 Dainippon Pharma that, although designed in part to provide protections for our minority shareholders, also provides rights to Sumitovant and Sumitomo Dainippon Pharma, such as the ability of Sumitomo Dainippon Pharma to appoint directors on our board, to maintain their share ownership percentage in our company, and provide Sumitomo Dainippon Pharma with certain information and give them access to certain of our records. We also entered into a consulting agreement with Sumitovant pursuant to which Sumitovant provides consulting services to us to support us in commercial planning, commercial launch activities and implementation, pursuant to which Adele Gulfo, Sumitovant's Chief Business and Commercial Development Officer and a member of our board of directors, provides services to us on behalf of Sumitovant. Further, we are a party to a Market Access Services Agreement with Sunovion, a subsidiary of Sumitomo Dainippon Pharma, pursuant to which Sunovion provides certain market access services with respect to the distribution and sale of our product candidates. We may enter into additional agreements with Sumitovant or Sumitomo Dainippon Pharma or their affiliates in the future. Sumitovant and Sumitomo Dainippon 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 Dainippon 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 comprised 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 Dainippon 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. Further, we are a party to a Market Access Services Agreement with Sunovion, a subsidiary of Sumitomo Dainippon Pharma, pursuant to which Sunovion provides certain market access services with respect to the distribution and sale of our product candidates.

We are a "controlled company" within the meaning of the applicable rules of the NYSE and, as a result, qualify for exemptions from certain corporate governance requirements. If we rely on these exemptions, 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 must approve all issues and transfers of shares of a Bermuda exempted company. However, the Bermuda Monetary Authority has, pursuant to its statement of June 1, 2005, given its general permission under the Exchange Control Act 1972 and related regulations for the issue and free transfer of our common shares to and among persons who are non-residents of Bermuda for exchange control purposes as long as the shares are listed on an appointed stock exchange, which includes the NYSE. Additionally, we have sought and have obtained a specific permission from the Bermuda Monetary Authority for the issue and transfer of our common shares up to the amount of our authorized capital from time to time, and options, warrants, depository receipts, rights, loan notes, debt instruments, and our other securities to persons resident and non-resident for exchange control purposes with the need for prior approval of such issue or transfer. The general permission or the specific permission would cease to apply if we were to cease to be listed on the NYSE or another appointed stock exchange.

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 are incorporated under the laws of Bermuda, where we are not subject to any income or withholding taxes. We are centrally managed and controlled in the U.K., and under current 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, except when an exemption applies. We may be treated as a dual resident company for U.K. tax purposes. As a result, our right to claim certain reliefs from U.K. tax may be restricted, and changes in law or practice in the U.K. could result in the imposition of further restrictions on our right to claim U.K. tax reliefs. We may also become subject to income, withholding or other taxes in certain jurisdictions by reason of our activities and operations, and it is also possible that taxing authorities in any such jurisdictions could assert that we are subject to greater taxation than we currently anticipate. Any such additional tax liability could adversely affect our results of operations.

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

We are incorporated under the laws of Bermuda. 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 various countries and tax jurisdictions, in part through intercompany service agreements between our subsidiaries and us. In that case, our corporate structure and intercompany transactions, including the manner in which we develop and use our intellectual property, will be organized so that we can achieve our business objectives in a tax-efficient manner and in compliance with applicable transfer pricing rules and regulations. If two or more affiliated companies are located in different countries or tax jurisdictions, the tax laws and regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arm's length and that appropriate documentation be maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities.

Significant judgment is required in evaluating our tax positions and determining our provision for income taxes. During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. For example, our effective tax rates could be adversely affected by changes in foreign currency exchange rates or by changes in the relevant tax, accounting, and other laws, regulations, principles, and interpretations. In addition, our effective tax rate could be adversely affected if we do not obtain favorable tax rulings from certain taxing authorities. As we intend to operate in numerous countries and taxing jurisdictions, the application of tax laws can be subject to diverging and sometimes conflicting interpretations by tax authorities of these jurisdictions. It is not uncommon for taxing authorities in different countries to have conflicting views, for instance, with respect to, among other things, the manner in which the arm's length standard is applied for transfer pricing purposes, or with respect to the valuation of intellectual property. If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arm's length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, potentially resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations, and cash flows.

In addition, tax laws are dynamic and subject to change as new laws are passed and new interpretations of the law are issued or applied. We continue to assess the impact of such changes in tax laws on our business and may determine that changes to our structure, practice, tax positions or the manner in which we conduct our business are necessary in light of such changes and developments in the tax laws of other jurisdictions in which we operate. Such changes may nevertheless be ineffective in avoiding an increase in our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

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

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

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

U.S. holders that own 10 percent or more of the vote or value of our common shares may suffer adverse tax consequences because we and 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 percent of (1) the total combined voting power of all classes of stock of such corporation entitled to vote, or (2) the total value of the stock of such corporation, is owned, or is considered as owned by applying certain constructive ownership rules, by U.S. shareholders (U.S. persons who own stock representing 10% or more of the vote or 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 will be classified as CFCs in the current taxable year as a result of certain constructive ownership rules. 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. Any such U.S. holder who is an individual generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a U.S. corporation. If you are a U.S. holder who holds 10% or more of the vote or value of our common shares, you should consult your own tax advisors regarding the U.S. tax consequences of acquiring, owning, or disposing our common shares.

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, 2020, we believe that we were not a PFIC; however, with respect to the current taxable year and foreseeable future taxable years, because the PFIC tests are based upon the value of our assets, including any goodwill and going concern value, and the nature and composition of our income and assets, which cannot be known at this time, we cannot predict whether we will or will not be classified as a PFIC. 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 cannot provide any assurances regarding our PFIC status for the current or future taxable years.

We have implemented structures and arrangements intended to mitigate the possibility that we will be classified as a PFIC. There can be no assurance that the IRS will not successfully challenge these structures and arrangements, which may result in an adverse impact on the determination of whether we are classified as a PFIC. In addition, recently proposed U.S. Treasury Regulations, which we are continuing to assess the impact of, may also adversely affect the treatment of these structures and arrangements with respect to our PFIC status.

General Risk Factors

Raising additional funds may cause dilution to existing shareholders and/or may restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital 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, including in our commercial department. 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 biopharmaceutical 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 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 expand our organization and hire additional employees. Our management is expected to have increasing responsibilities to identify, recruit, maintain, motivate, and integrate additional employees, consultants and contractors which may divert a disproportionate amount of its time and attention away from our day-to-day activities. The expected growth may also require significant capital expenditures and divert financial resources from other projects. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate or grow revenue could be adversely affected, and we may not be able to implement our business strategy. As a result, our future financial performance and our ability to complete clinical development, obtain regulatory approval, and commercialize our product candidates or any potential future product candidate may be adversely affected.

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

- inability to commercialize our products or any future product candidates;
- 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 product candidate, if approved for commercial sale; and
- loss of 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 a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for any of our product candidates, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our common share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization of any product candidates we develop.

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 candidate, which could result in reporting obligations. In addition, there is a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us or our product candidates on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face restrictive regulatory actions or incur other harm to our business.

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 ORGOVYX and any other product candidates that receive marketing approval. Any future regulatory milestones, sales milestones and royalty payments we are eligible to earn from Pfizer under terms of the Pfizer Collaboration and License Agreement and from Richter under the terms of the Richter Development and Commercialization Agreement, 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 extent to which reimbursement and coverage is available from government and private payors such as Medicare Part D, Medicaid, insurance companies, health maintenance organizations and other plan administrators with respect to ORGOVYX and our other product candidates, if approved, and the competitive response from existing and potential future therapeutic approaches that compete with 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 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 current or future product candidates, or the inability to do so at acceptable prices;
- inability to maintain or hire 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;
- 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 Dainippon Pharma, Sunovion, Pfizer, and/or Richter;
- 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 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;
- issuance of additional shares of our common shares, or the perception that such issuances may occur, including through our "at-the-market" equity offering program;
- negative coverage in the media or analyst reports, whether accurate or not;
- any changes in our relationships with Sumitomo Dainippon Pharma, Sumitovant, Sunovion and/or their respective affiliates, or actions taken or omission of actions with respect to the Sumitomo Dainippon Pharma Loan Agreement, the Investor Rights Agreement, the Market Access Services Agreement or under the other agreements we entered with Sumitomo Dainippon 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;
- general political, economic, industry, and market conditions;
- 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 financial 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 market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated operating results and/or earnings guidance that we may provide.

Volatility in our 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 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 Dainippon 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

Not applicable.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

On February 8, 2021, Myovant Sciences, Inc. entered into an incentive bonus letter with each of: Frank Karbe, our Principal Financial and Accounting Officer; Matthew Lang, our General Counsel and Corporate Secretary; and Juan Camilo Arjona Ferreira, our Chief Medical Officer (each, an "executive officer").

The amount of the incentive bonus opportunity awarded to each executive officer equals a percentage of his base salary for the fiscal year ending on March 31, 2021, as follows: 175% with respect to Mr. Karbe and Mr. Lang; and 125% with respect to Mr. Arjona Ferreira. The incentive bonus will be paid within 30 days following June 30, 2022 (the "Vesting Date"), subject to such executive officer's continued employment through the Vesting Date, his performance of his duties at a satisfactory level, as determined by us in our sole discretion, and his execution of a release of claims in a customary form to be provided by us.

If an executive officer's employment is involuntarily terminated by us without cause or due to his death or disability, before the Vesting Date, the incentive bonus will become payable and will be made within 30 calendar days after his termination date. However, if before the Vesting Date, the executive officer voluntarily resigns, except for "good reason," or if his employment is terminated by us for "cause," such bonus will not vest and will be forfeited. The definitions of "cause" and "good reason" are set forth in each executive officer's respective individual employment agreement.

Item 6. Exhibits

Exhibit Number	Description of Document	Schedule / Form	File No.	Exhibit No.	Filing Date
3.1	Certificate of Incorporation.	S-1	333-213891	3.1	09/30/2016
3.2	Memorandum of Association.	S-1	333-213891	3.2	09/30/2016
3.3	Fifth Amended and Restated Bye-laws.	10-Q	001-37929	3.3	02/10/2020
10.1†*	Amendment to Consulting Agreement, dated November 11, 2020, by and between the Registrant and Sumitovant BioPharma, Inc.				
10.2†*	Amendment No. 3 to License Agreement, dated December 15, 2020, by and between the Registrant and Takeda Pharmaceuticals International AG.				
10.3†	Commitment Letter Amendment Letter, dated December 22, 2020, by and between Sumitomo Dainippon Pharma Co., Ltd. and the Registrant.				
10.4†*	Amendment No.1 to Market Access Services Agreement, dated as of December 14, 2020, by and between Sunovion Pharmaceuticals Inc. and Myovant Sciences GmbH.				
10.5†*	Collaboration and License Agreement, dated December 26, 2020, by and between Myovant Sciences GmbH and Pfizer Inc.				
31.1†	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2†	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1††**	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2††**	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	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.

* Portions of this exhibit have been omitted from this exhibit (indicated by asterisks) as such portions are both not material and would likely cause competitive harm to the Registrant if publicly disclosed.

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

SIGNATURES

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

MYOVANT SCIENCES LTD.

By: /s/ Frank Karbe
Frank Karbe
(Duly Authorized Officer and Principal Financial and Accounting Officer)

Date: February 11, 2021

Exhibit 10.1

CERTAIN INFORMATION IDENTIFIED BY "[***]" HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

AMENDMENT NO.1 TO CONSULTING AGREEMENT

This Amendment No.1 (this "**Amendment**") to the Consulting Agreement (the "**Consulting Agreement**") dated May 18, 2020, effective as of May 11, 2020, by and between Myovant Sciences GmbH**,** having a registered office at Viaduktstrasse 8, 4051 Basel, Switzerland ("**Myovant**"), and Sumitovant Biopharma, Inc., having an office at 151 W. 42nd Street, 15th Floor, New York NY 10036 ("**Sumitovant**" or "**Consultant**"), is being entered into effective as of November 11, 2020, by and between Myovant and Sumitovant.

All capitalized terms used but not otherwise defined in this Amendment have the meanings given to them in the Consulting Agreement. The Consulting Agreement is hereby amended as follows:

1. Section 2.1 is hereby amended and restated in its entirety to the following:

   Subject to the terms and provisions set forth below in this Section 2, the term of Consultant's engagement will begin on May 11, 2020 and continue until March 31, 2021 or such earlier time when Myovant notifies Consultant that it has hired a permanent Chief Commercial Officer and the Individual Consultant has completed its transitioned all responsibilities to such permanent Chief Commercial Officer.

2. Section 3.1 is hereby amended and restated in its entirety to the following:

   In consideration of the Services provided by Consultant, Myovant shall provide Consultant with $[***]/hour (the "**Fee**").

All other provisions of the Consulting Agreement shall continue in full force and effect. The provisions of 5-17 of the Consulting Agreement shall apply to this Amendment as if included in this Amendment.

[Remainder of this page intentionally left blank]

IN WITNESS WHEREOF, the duly authorized representatives of the parties hereto have caused this Agreement to be duly executed as of the date set forth.

Myovant Sciences GmbH ("Myovant")		**Sumitovant Biopharma, Inc. "Consultant")**	
By:	/s/ Elke Hunsche	By:	/s/ Tara Soni
Name:	Elke Hunsche	Name	Tara Soni
Title	VP, Global Market Access & HEOR	Title	Head of Legal
Date:	11/9/2020	Date:	11/6/2020

Exhibit 10.2

CERTAIN INFORMATION IDENTIFIED BY "[***]" HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

Amendment No. 2 to License Agreement

This Amendment No. 2 (this "**Amendment**") to the License Agreement, dated April 29, 2016, as previously amended effective November 19, 2019 (the "**License Agreement**") by and between Takeda Pharmaceuticals International AG, a company incorporated wider the laws of Switzerland having its principal place of business at Thurgauerstrasse 130, 8152 Glattpark-Opfikon Zurich, Switzerland ("**Takeda**" or "**TPI**") and Myovant Sciences Ltd. (formally with the name "Roivant Endocrinology Ltd."), an exempted limited company incorporated under the laws of Bermuda, and having its Granted office at 2 Church Street, Hamilton, Bermuda (the "**Former Licensee**") is being entered into as of **December 15, 2020** (the "**Amendment Effective Date**"), by and between Takeda and Myovant Sciences GmbH, a Switzerland limited liability company with an address of Viaduktstrasse 8, 4051 Basel, Switzerland (the "**Licensee**") in accordance with Section 16.12 of the License Agreement.

For clarification purpose, the Former Licensee assigned all of its rights and obligations under the License Agreement to the Licensee pursuant to that certain Asset and Contribution Agreement, dated as of November 11, 2016, by and between the Former Licensee and the Licensee, in accordance with Section 16.3 of the License Agreement.

All capitalized terms used but not otherwise defined in this Amendment have the meanings given to them in the License Agreement.

Takeda and Licensee wish to further amend the License Agreement to, among other things, reflect ownership by an Affiliate of TPI of certain intellectual property rights, which TPI sublicensed to Licensee pursuant to the License Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, the License Agreement is hereby amended as follows:

1. Schedule 1.151 of the License Agreement is hereby deleted and replaced in its entirety with the Schedule 1.151 attached hereto as Exhibit A, which includes only Patents that are solely owned by Takeda or one of its Affiliates.

2. Section 1.71 (Joint Patent Rights) of the License Agreement is hereby deleted and replace with the following:

> "**1.71** "Joint Patent Rights" means all Patent Rights Covering Joint Inventions, including those Patent Rights set forth on Schedule 1.71."

3. A new Schedule 1.71, attached hereto as Exhibit B, is hereby added to the License Agreement.

4. Section 11.2.2 is hereby deleted and replaced with the following:

> "Takeda or one of its Affiliates is the sole and exclusive owner of the entire right, title, and interest in the Takeda Patent Rights set forth on Schedule 1.151 (Takeda Patent Rights) free of any encumbrance, lien, or claim of ownership by any Third Party."

5. Section 11.2.11(b) is hereby deleted and replaced with the following:

"*Ownership of Takeda Patent Rights*. Except for the obligations under the [***], Takeda or one of its Affiliates is the sole and exclusive owner of the entire right, title, and interest in the Added Patents set forth on Schedule 1.151 free of any encumbrance, lien, or claim of ownership by any Third Party."

6. Section 11.2 of the License Agreement is amended to add the following:

11.2.12 Takeda In-License. With respect to that certain License Agreement (Non-Core Pipeline Assets) between Takeda Pharmaceutical Company Ltd. ("**TPC**") and Takeda effective February 1, 2016 as amended (the "**TPC-TPI Exclusive License Agreement**") Takeda hereby represents and warrants that:

(a) *Disclosure.* Takeda has disclosed to Licensee a full and complete copy of the TPC-TPI Exclusive License Agreement, including any and all amendments or supplements thereto that are material to Licensee's rights under this Agreement, subject only to redactions with respect to terms and conditions that are not material to Licensee's rights under this Agreement.

(b) *Effectiveness*. The TPC-TPI Exclusive License Agreement is in full force and effect according to its terms and neither Takeda nor TPC is in material breach thereof.

7. Section 11.3 of the License Agreement is amended to add the following:

11.3.5 Takeda In-License. With respect to the TPC-TPI Exclusive License Agreement (defined in Section 11.2.12), and only with respect to any right sublicensed or otherwise conveyed to Licensee under this Agreement, including rights related to the prosecution, maintenance, enforcement or defense of any Takeda Technology, Takeda hereby covenants that it shall not (a) terminate the TPC-TPI Exclusive License Agreement, (b) act, or fail to act, in any manner that would cause TPC to have the right to terminate the TPC-TPI Exclusive License Agreement, or (c) assign or otherwise transfer ownership of its rights under the TPC-TPI Exclusive License Agreement except in conjunction with the concurrent assignment to the same entity of all of Takeda's rights and obligations this Agreement in accordance with Section 16.3 (Assignment). Nothing in this Section 11.3.5 shall be construed to waive or release any rights or obligations that either Party may have under any other provision of this Agreement.

8. All other provisions of the License Agreement shall continue in full force and effect. The provisions in Article 16 (Miscellaneous) of the License Agreement shall apply to this Amendment as if included in this Amendment.

[*Remainder of this page intentionally left blank*]

IN WITNESS WHEREOF, each of Takeda Pharmaceuticals International AG and Myovant Sciences GmbH have caused this Amendment to be executed by their respective duly authorized officers as of the date first above written, each copy of which will for all purposes be deemed to be an original.

TAKEDA PHARMACEUTICAL INTERNATIONAL AG		**MYOVANT SCIENCES GMBH**	
By:		By:	/s/ Dr. Slava Rakov
Name:		Name:	Dr. Slava Rakov
Title:		Title:	Director and VP Medical Affairs
Date:		Date:	14/24/2020
By:			
Name:			
Title:			
Date:			

IN WITNESS WHEREOF, each of Takeda Pharmaceuticals International AG and Myovant Sciences GmbH have caused this Amendment to be executed by their respective duly authorized officers as of the date first above written, each copy of which will for all purposes be deemed to be an original.

TAKEDA PHARMACEUTICAL INTERNATIONAL AG

By:	/s/ Charles Alexander
Name:	Charles Alexander
Title:	Head International BD
Date:	16/12/2020

By:	/s/ Antonio Raffaele Toma
Name:	Antonio Raffaele Toma
Title:	Authorized signatory
Date:	16 December 2020

MYOVANT SCIENCES GMBH

By:	
Name:	
Title:	
Date:	

Exhibit 10.3

Sumitomo Dainippon Pharma	Sumitomo Dainippon Pharma Co., Ltd. 3-1, Kyobashi 1-chome, Chuo-ku, Tokyo 104-8356, Japan

December 22, 2020

Myovant Sciences Ltd.
Suite 1, 3rd Floor, 11-12 St. James's Square,
London, SW1Y 4LB, United Kingdom
c/o Myovant Sciences, Inc.
2000 Sierra Point Parkway, 9th Floor
Brisbane, CA 94005, the United States of America

Re: $200,000,000 Credit Facility

Ladies and Gentlemen:

Reference is made to the commitment letter dated as of August 5, 2020 (the "Commitment Letter"), from Sumitomo Dainippon Pharma Co., Ltd., a company (Kabushiki Kaisha) incorporated under the laws of Japan (the "Lender"), to Myovant Sciences Ltd., an exempted company organized under the laws of Bermuda (the "Borrower"), with respect to a proposed $200,000,000 credit facility (the "Credit Facility"), the Summary of Principal Terms and Conditions attached thereto (the "Summary of Terms"), and the letter dated as of September 29, 2020, from the Lender to the Borrower, with respect to the extension of the expiration date in the Commitment Letter.

The Lender's undertaking and commitment under the Commitment Letter expires on December 31, 2020, unless definitive documentation of the Credit Facility is executed and delivered prior to such date. The Lender hereby extends the December 31, 2020, expiration date in the Commitment Letter to March 31, 2021.

The Borrower reaffirms its agreements set forth in the Commitment Letter. Except as specifically provided herein, all terms and conditions of the Commitment Letter and the Summary of Terms remain in full force and effect, without waiver or modification.

Very truly yours,

SUMITOMO DAINIPPON PHARMA CO., LTD.

By: /s/ Shigeyuki Nishinaka

Name: Shigeyuki Nishinaka

Title: Senior Executive Officer

ACCEPTED AND AGREED TO
AS OF THE DATE FIRST ABOVE WRITTEN:

MYOVANT SCIENCES LTD.

By: /s/ Marianne Romeo
Name: Marianne Romeo
Title: Head, Global Transactions & Risk Management

Exhibit 10.4

CERTAIN INFORMATION IDENTIFIED BY "[***]" HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

EXECUTION COPY

AMENDMENT NO. 1 TO MARKET ACCESS SERVICES AGREEMENT

This Amendment No. 1 (this "Amendment") is entered into as of December 14, 2020 (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");

B. Sunovion and Myovant desire to amend certain rights and obligations of the Parties under the Agreement to address updated timelines with respect to the launch of the Products and the addition of certain rights and obligations; and

C. Sunovion and Myovant desire to amend certain rights and obligations under the Agreement regarding Sunovion's contractual obligation to carry product liability insurance.

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 The following defined terms shall be added to Article 1 of the Agreement:

"State Transparency Reporting Services" means the Sunovion activities related to provision of certain support with regard to Myovant's compliance with the State Transparency Reporting Laws, as further described on Exhibit K."

"State Transparency Reporting Laws" means (a) with respect to California, Cal. Health & Safety Code Div. 107 Part 2. Ch. 9 § 127677, § 127679, and § 127681; (b) with respect to Colorado, Col. Rev. Stat. § 12-42.5-308 and § 12-280-308; (c) with respect to Connecticut, Conn. Gen. Stat. § 19a-754b and § 38a-479ppp; (d) with respect to Louisiana, LA. R. S. § 2255.11; (e) with respect to Maine, 22 MRSA § 8703; (f) with respect to Maryland, MD. Health-General Code § 21-2C-08 and 21-2C-09; (g) with respect to New Mexico, NM Stat § 27-2E-1; (h) with respect to Nevada, Nev. Rev. Stat. § 439B.635, 439B.640, and 439B.645, (i) with respect to Oregon, House Bill 4005, (j) with respect to Texas, Tex. Health & Safety Code § 441.0002, (k) with respect to Vermont, 18 V.S.A. § 4635, and (l) with respect to Washington, House Bill 1224."

1.2 Section 1.51 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) (a) $[***] per calendar month through [***], and (b) $[***] per calendar month from [***], (ii) $[***] for the [***], and (iii) an adjusted amount for each year after the second year of the Term 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."

1.3 Section 1.73 of the Agreement is hereby deleted in its entirety and replaced as follows:

"Pass-Through Expenses" means (a) the Market Access Customer Fees, (b) the DS Fees, (c) the GPO/IDN Fees, (d) the out-of-pocket costs and expenses incurred by or on behalf of Sunovion in connection with the 3PL Services, (e) the out-of-pocket costs and expenses incurred by or on behalf of Sunovion in connection with Sunovion's provision to Myovant of reports other than the Sunovion Reports and that are specific to, and customized by Sunovion for, the Products, (f) the costs and expenses paid to a third-party recall vendor that arise in connection with the Regulatory Services, (g) reasonable travel expenses that are incurred by Sunovion, its Affiliates or a third-party service provider in connection with the performance of the Services that are incurred in accordance with a travel policy to be agreed upon in writing by the Parties, (h) software license fees, costs and expenses reasonably incurred by Sunovion or its Affiliates in connection with modification of the information technology systems reasonable necessary or useful for Sunovion to perform the Services and that have been pre-approved by Myovant in writing; provided that any costs expressly set forth herein shall be deemed to be approved by Myovant, and (i) any additional costs and expenses incurred by Sunovion in connection with the Services as agreed by the Parties in writing; in each case, (a) through (i), to the extent such amounts are not paid from the Escrow Fund in accordance with Section 8.1.3 and to the extent incurred in accordance with Section 8.2.5."

1.4 Section 4.3.2 of the Agreement is hereby deleted in its entirety and replaced as follows:

"Sunovion shall, subject to Section 4.1, configure, or cause to be configured, the [***] software by [***] to enable Sunovion to perform its obligations under this Agreement with respect to the Prostate Cancer Product, provided that (a) Sunovion shall not be obligated to perform any obligations under this Agreement that requires such configured software until such software configuration is complete, and (b) the reasonable, out-of-pocket costs and expenses incurred by or on behalf of Sunovion in connection therewith shall be deemed to be Pass-Through Expense to the extent such amounts are not in excess of amounts permitted in accordance with Section 8.2.5. Sunovion shall provide Myovant regular updates on the progress of such configuration activities and, if Sunovion anticipates that such software configuration will be delayed after [***], then it shall promptly notify Myovant of such potential delay and the projected length of such delay, and discuss with Myovant the potential actions to minimize such delay."

1.5 Section 4.5.1 of the Agreement is hereby deleted in its entirety and replaced as follows:

"Sunovion shall, subject to Section 4.1, configure, or cause to be configured, the [***] by [***] to enable Sunovion to perform its obligations under this Agreement, provided that (a) Sunovion shall not be obligated to perform any obligations under this Agreement that requires such configured software until such software configuration is complete, and (b) the reasonable, out-of-pocket costs and expenses incurred by or on behalf of Sunovion in connection therewith shall be deemed to be Pass-Through Expense to the extent such amounts are not in excess of the amounts permitted in accordance with Section 8.2.5. Sunovion shall provide Myovant regular updates on the progress of

such configuration activities and, if Sunovion anticipates that such software configuration will be delayed after [***], then it shall promptly notify Myovant of such potential delay and the projected length of such delay, and discuss with Myovant the potential actions to minimize such delay."

1.6 A new Section 4.8 (State Transparency Reporting Support Services) shall be added to the Agreement as follows:

"State Transparency Reporting Services. Sunovion shall provide the State Transparency Reporting Services."

1.7 Section 5.2.3 of the Agreement is hereby deleted in its entirety and replaced as follows:

"In connection with the 3PL Services, Myovant shall, subject to Section 5.1, (a) cause the Products to be consigned to Sunovion upon receipt by a 3PL Provider; (b) use Commercially Reasonable Efforts to enter into a quality agreement with each 3PL Provider and Sunovion prior to consignment of any Product to Sunovion; (c) provide to Sunovion an evidence of property certificate evidencing its cargo and/or transit insurance and static inventory insurance relevant to the applicable logistics line(s); and (d) refrain from actions which would cause Sunovion to be in material breach of any covenant, representation, or warranty contained in any agreement by and between Sunovion and a 3PL Provider to which a Product has been consigned, provided that a copy of such agreement, or a copy or summary of the applicable provisions in such agreement, has been provided to Myovant in advance for review."

1.8 A new Section 5.8 (State Transparency Reporting Support Services) shall be added to the Agreement as follows:

"State Transparency Reporting Services. Myovant hereby acknowledges and agrees that certain State Transparency Reporting Laws require reporting of information to applicable states that is related to activities with respect to which Sunovion will not have knowledge. Accordingly, (a) Myovant shall be solely responsible for notifying Sunovion of any activity that requires a report or data to be submitted or transmitted pursuant to the State Transparency Reporting Laws, and (b) Sunovion shall bear no responsibility to identify to Myovant new or additional State Transparency Reporting Laws in any state. Myovant shall be solely responsible for (x) submitting or transmitting reports or data required to be submitted or transmitted to applicable states or third parties in accordance with the State Transparency Reporting Laws, and (y) certifying such reports and data, if applicable. Such reports and data are deemed to be the Confidential Information of Myovant."

1.9 Section 12.1 (Indemnification by Myovant) of the Agreement is hereby deleted in its entirety and replaced as follows:

"Indemnification by Myovant. Myovant agrees to indemnify, defend and hold Sunovion, its Affiliates, and its and their respective officers, directors, employees, permitted subcontractors and permitted agents (collectively, the "Sunovion Indemnitees") harmless from and against any and all Losses resulting from any Claims by a Third Party to the extent such Claim results from, arises from or out of, relates to, is in the nature of, or is caused by (a) death of, or bodily injury to, any person on account of the use of any Product, (b) disputes that arise between Myovant and a Market Access Customer, Government Entity, Specialty Distributor or a GPO or IDN that is not a Sunovion GPO or Sunovion IDN that relate to a Myovant Market Access Contract, Myovant Government Contract, Myovant Specialty Distributor Contract or a Myovant GPO/IDN Contract, respectively, (c) disputes that result from Myovant exercising its final decision-making authority set forth in Section 7.2(c); provided that if such dispute results from the JGC's final decision-making authority set forth in Section 7.2(b), then the Parties shall negotiate in good faith an

appropriate allocation of responsibility under the circumstances; (d) any recall, quarantine, warning or withdrawal of any Product not solely caused by Sunovion's performance of the Services, (e) government pricing calculations performed by Sunovion on behalf of Myovant in connection with the GPR Services; provided that such calculations were performed by Sunovion in accordance with Sunovion's government price calculation methodologies approved in writing by Myovant, (f) any report submitted or transmitted (or any report not submitted or transmitted or not properly submitted or transmitted) by or on behalf of Myovant to an applicable state or third party pursuant to the State Transparency Reporting Laws or any other comparable statute, rule or regulation in the same states or other states, (g) a breach of any representation, warranty or covenant of Myovant set forth in this Agreement, and (h) the negligence, gross negligence or willful misconduct of Myovant in connection with this Agreement; except, in each case (clauses (a) through (h)), to the extent that such Losses (or part thereof) results from a Claim that is an indemnifiable event pursuant to Section 12.1, in which case Sunovion shall indemnify the Myovant Indemnitees for such Losses (or part thereof) in accordance with Section 12.1."

1.10 Section 12.4.3 of the Agreement is hereby deleted in its entirety and replaced as follows:

NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, (A) SUNOVION SHALL HAVE NO LIABILITY FOR THIRD PARTY CLAIMS ARISING OUT OF (I) GOVERNMENT PRICING CALCULATIONS PERFORMED BY SUNOVION ON BEHALF OF MYOVANT UNDER THIS AGREEMENT; PROVIDED THAT SUCH CALCULATIONS WERE PERFORMED BY SUNOVION IN ACCORDANCE WITH SUNOVION'S GOVERNMENT PRICE CALCULATION METHODOLOGIES APPROVED IN WRITING BY MYOVANT, OR (II) any report submitted OR TRANSMITTED (or any report not submitted OR TRANSMITTED or not properly submitted OR TRANSMITTED) by or on behalf of Myovant to an applicable state OR THIRD PARTY pursuant to the State Transparency Reporting Laws or any other comparable statute, rule or regulation in the same states or other states, AND (B) TO THE EXTENT ANY PRODUCTS ARE LOST OR DAMAGED WHILE IN THE CUSTODY OF A 3PL PROVIDER, THE TERMS OF SECTION 6.1 SHALL APPLY AND MYOVANT HEREBY AGREES TO THE LOSS AND DAMAGE LIMITATIONS SET FORTH IN THE APPLICABLE CONTRACT BETWEEN SUNOVION AND SUCH 3PL PROVIDER.

1.11 Section 14.6.2 of the Agreement is hereby deleted in its entirety and replaced as follows:

"Upon written notice to Sunovion, Myovant may terminate this Agreement if (a) [***] provide feedback to Sunovion that the [***] definitively cannot be added to the Material Wholesaler Contracts [***], (b) Sunovion has failed to [***], or (c) the [***] software configurations required by Sections 4.3.2 and 4.5.1 are not completed by [***] and, as a result, Sunovion is unable to perform the related Services; provided that prior to any such termination by Myovant, the Parties will cooperate in good faith to identify and negotiate in good faith the execution of alternative services that may be provided to Myovant by Sunovion in lieu of such termination at the discretion of Myovant; provided, further, that if Sunovion (i) [***], or (ii) substantially completes the [***] software configurations, as applicable, such that Sunovion is able to perform the related Services, in either case, before Myovant terminates this Agreement pursuant to this Section 14.6.2, then Myovant shall no longer have the right to terminate this Agreement pursuant to this Section 14.6.2."

1.12 Exhibit A of the Agreement is hereby deleted in its entirety and replaced with Attachment 1 of this Amendment.

1.13 Attachment 2 of this Amendment is hereby added to the Agreement as Exhibit K.

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/ Slava Rakov
Name:	Thomas Gibbs	Name:	Slava Rakov
Title:	SVP and Chief Commercial Officer	Title:	VP Medical-Clinical

Attachment 1

EXHIBIT A - 3PL SERVICES

To the extent that Sunovion is able to add a Product to the 3PL Contract(s), 3PL Services shall include the following obligations:

1. Freight Activities from Contract Packaging Organization(s) (CPO) to 3PL Provider(s): Sunovion shall be responsible for the coordination and management of shipments of Product at times, modes, and conditions as determined by Myovant. Sunovion, as a function of transportation management, will incur transportation costs from transport service provider(s). On an agreed frequency, Sunovion will invoice Myovant for all transport costs and expenses on a pass through basis. Myovant will retain all liabilities of Product ownership including loss or damage in transit. Where transport timing permits, Myovant and Sunovion Product may be co-loaded on same conveyance. Where applicable, Myovant will be responsible for any temperature tracking devices, GPS tracking devices, and/or security seals.

2. Communication Activities. Upon request by a 3PL Provider, Sunovion shall facilitate communication between Myovant and such 3PL Provider to which Products have been consigned.

3. Additional 3PL Service Activities. Sunovion shall perform any other services (which may result in additional fees being added to this Agreement, subject to customary, good faith negotiation) that are agreed upon in writing by the Parties from time to time.

Attachment 2

EXHIBIT K

STATE TRANSPARENCY REPORTING SERVICES

With respect to the Products, the State Transparency Reporting Services shall include the following obligations:

1. State Transparency Reporting Support. Sunovion shall provide reasonable support to Myovant to enable Myovant to comply with its obligation under the State Transparency Reporting Laws, which shall include, (a) supporting Myovant in its registration with each applicable state, (b) consulting with Myovant to assist Myovant in its fulfillment of its obligations under the State Transparency Reporting Laws, and (c) preparing and/or reviewing reports or data required to be submitted or transmitted to applicable states or third parties in accordance with the State Transparency Reporting Laws. For purposes of clarity, Myovant shall be responsible for, and Sunovion shall not be responsible for, submitting or transmitting to applicable states or third parties any reports or data required to be submitted or transmitted under State Transparency Reporting Laws. Further, nothing herein shall be construed to create any obligation on Sunovion to identify new or additional laws that may be similar to the State Transparency Reporting Laws.

2. Additional State Transparency Reporting Services. Any other services (which may result in additional fees being added to this Agreement, subject to customary, good faith negotiation) that are agreed upon in writing by the Parties from time to time.

Exhibit 10.5

CERTAIN INFORMATION IDENTIFIED BY "[***]" HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

EXECUTION VERSION

COLLABORATION AND LICENSE AGREEMENT

by and between

MYOVANT SCIENCES GMBH

and

PFIZER INC.

Dated as of December 26, 2020

TABLE OF CONTENTS

EXHIBITS

This **COLLABORATION AND LICENSE AGREEMENT** (this "**Agreement**") is made and entered into as of December 26, 2020 (the "**Effective Date**") by and between MYOVANT SCIENCES GMBH, a Swiss company, having a principal place of business at **Viaduktstrasse 8, 4051 Basel Switzerland** ("**Myovant**"), and PFIZER INC., a Delaware company, having a principal place of business at 235 East 42nd Street, New York, New York 10017 ("**Pfizer**"). Each of Myovant and Pfizer is referred to individually as a "**Party**" and collectively as the "**Parties**."

Recital

WHEREAS, Myovant has under development pharmaceutical formulations and dosage forms containing the Compound (as defined below) that are intended to be used in the Oncology Field and the WH Field (as defined below);

WHEREAS, Myovant and Pfizer, either directly or with or through its Affiliates, each has significant experience in developing, manufacturing, marketing and promoting pharmaceutical products and believes it can contribute to the potential development and commercialization of the Products (as defined below); and

WHEREAS, both Myovant and Pfizer desire to enter into an agreement for the co-exclusive co-development, co-commercialization and co-promotion of the WH Product(s) and the Oncology Product(s) in Field in the Co-Promotion Territory (each as defined below), and for Pfizer to have an exclusive option to obtain exclusive commercialization and promotion rights and related development rights for the Oncology Product(s) in the Oncology Field in the Pfizer Territory, in each case, subject to the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE I.
DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

Section 1.1 "**2021 Cap**" shall have the meaning set forth in Section 8.5.4(a).

Section 1.2 "**2022 Cap**" shall have the meaning set forth in Section 8.5.4(a).

Section 1.3 "**AAA**" shall have the meaning set forth in Section 17.2.2(b).

Section 1.4 "**AAA Rules**" shall have the meaning set forth in Section 17.2.2(b).

Section 1.5 "**Accountant**" shall have the meaning set forth in Section 8.11.

Section 1.6 "**Accounting Standards**" shall mean U.S. GAAP.

Section 1.7 "**Act**" shall have the meaning set forth in Section 9.1.1(a).

Section 1.8 "**Adverse Event**" shall mean (a) any finding from tests of the applicable Product in laboratory animals or in vitro that suggests a risk for human subjects including reports of mutagenicity, teratogenicity or carcinogenicity or (b) any undesirable, untoward or noxious event or experience associated with the clinical, commercial or other use or occurring following administration of the applicable Product in humans, occurring at any dose, whether expected or not, and whether considered related to or caused by the applicable Product or not, including such an event or experience as occurs in the course of the use of the applicable Product in professional practice, in a Clinical Trial, from overdose, whether accidental or intentional, from abuse, from withdrawal, or from a failure of expected pharmacological or biological therapeutic action of the applicable Product, and including those events or experiences that are required to be reported to the FDA under 21 C.F.R. Sections 312.32 or 314.80 or to foreign Regulatory Authorities under corresponding Applicable Law outside the United States.

Section 1.9 "**Advertising**" shall mean the planning, purchasing and placement of paid advertising for a Product in the Field in the Co-Promotion Territory through any means, including television, print, radio/audio, in-office/placed-based, digital, web, search (SEM/SEO), social media, mobile and any and all new and emerging media channels for consumers, healthcare institutions and healthcare providers.

Section 1.10 "**Advertising Plan**" shall have the meaning set forth in Section 6.5.1.

Section 1.11 "**Affiliate**" shall mean, 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), but only for so long as such Person continues to control, to be controlled by, or to be under common control with such person or entity. 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.

Section 1.12 "**Agreement**" shall have the meaning set forth in the preamble hereto.

Section 1.13 "**Alliance Manager**" shall have the meaning set forth in Section 2.11.

Section 1.14 "**Allowable Expenses**" shall mean Development Costs, Manufacturing Costs, Distribution Costs, Sales and Marketing Costs, Allowable IP Costs, Filing Fees and Third Party Payments allocable to the Co-Promotion Territory, that are incurred by a Party or its Affiliates during the Term (except Built-up Inventory Costs as provided under Section 1.149.1 to the extent incurred prior to the Effective Date), and any other Costs that are incurred by a Party or its Affiliates during the Term and are expressly set out in this Agreement or approved by the JSC to be Allowable Expenses and to the extent not already treated as a deduction in determining Net Sales for the Co-Promotion Territory. All such Development Costs, Manufacturing Costs, Distribution Costs, Sales and Marketing Costs, Allowable IP Costs, Filing Fees, Third Party Payments and other approved Costs of a Party will be included within Allowable Expenses but: (a) in the case of Costs within the Development Costs, only to the extent they are in aggregate less than or equal to [***] of the Costs set forth within the Oncology Joint Medical Affairs and Development Plan and Budget (in the case of Development Costs related to the Oncology Product) or the WH Joint Medical Affairs and Development Plan and Budget (in the case of Development Costs related to the WH Product or Pediatric Product), as applicable, for the applicable Budget Period (any Development Costs in excess of such amount, the "**Excess Development Costs**"); (b) in the case of Costs relating to activities set forth within the Advertising Plan for the Oncology Product or the WH Product, only to the extent they are less than or equal to [***] of the Costs set forth within the budget set out in the Advertising Plan (any Costs for Advertising in excess of such amount, the "**Excess Advertising Costs**"); and (c) in the case of Costs within the Sales and Marketing Costs (other than the Costs set out in subclause (b)), only to the extent they are less than or equal to [***] of the Costs set forth in the Oncology Co-Promotion Commercialization Plan and Budget (in the case of the Oncology Product) or the Costs set forth in the WH Co-Promotion Commercialization Plan and Budget (in the case of the WH Product and the Pediatric Product) for the applicable Budget Period in the applicable Budget (any Sales and Marketing Costs in excess of such amount, the "**Excess Commercialization Costs**"), in each case, unless such excess costs are approved by the applicable JSC for inclusion in the applicable budget(s). The components of Allowable Expenses shall be calculated in accordance with the applicable definition thereof and the applicable terms of this Agreement. No item or deduction used to determine Net Sales may also be an Allowable Expense item, and vice-versa. If any cost or expense is directly attributable or reasonably allocable to more than one activity, such cost or expense shall only be counted as an Allowable Expense with respect to one of such activities. Allowable Expenses will exclude: (i) [***], (ii) [***], or (iii) [***]. The overall budget in relation to Allowable Expenses as of the Effective Date is set out in [***].

Section 1.15 "**Allowable FTE Costs**" shall mean FTE Costs budgeted in any Joint Medical Affairs and Development Plan and Budget or Co-Promotion Commercialization Plan and Budget with respect to the following activities:

1.15.1 [***]; and

1.15.2 [***];

1.15.3 or otherwise agreed between the Parties in writing.

Section 1.16 "**Allowable IP Costs**" shall mean all Costs incurred during the Term in connection with preparation, filing, prosecution and maintenance of Myovant Background Patents, Product Collaboration Patents and Product Trademarks, in each case, in the Co-Promotion Territory, in accordance with Section 11.2 and Section 11.6, as applicable (but, in each case, not including (a) [***], (b) [***], or (c) [***]).

Section 1.17 "**Allowable Regulatory Costs**" shall mean with respect to the Co-Promotion Territory, all Costs and Allowable FTE Costs incurred by a Party or its Affiliates during the Term in the performance of Regulatory Activities with respect to any Product in the Field, in the Co-Promotion Territory, including [***], including [***], excluding [***].

Section 1.18 "**ANDA Act**" shall have the meaning set forth in Section 11.3.1.

Section 1.19 "**Annual Detail Commitment**" shall have the meaning set forth in Section 6.1.2(a).

Section 1.20 "**Annual Net Sales**" shall mean the aggregate Net Sales for any Calendar Year.

Section 1.21 "**Anti-Corruption Laws**" shall mean all applicable anti-bribery and anti-corruption laws and regulations, including the United States Foreign Corrupt Practices Act, the United Kingdom Bribery Act 2010, and the local laws and regulations of any countries in which Products or payments will be provided under this Agreement

Section 1.22 "**API**" shall mean the Compound in active pharmaceutical ingredient form.

Section 1.23 "**Applicable Law**" shall mean, individually and collectively, all statutes, ordinances, regulations, rules or orders of any kind whatsoever of any Governmental Authority, courts, tribunals, legislative bodies and commissions that may be in effect from time to time and applicable to the activities contemplated by this Agreement.

Section 1.24 "**Approval Milestone**" shall mean the UF Approval Milestone or the Endometriosis Approval Milestone.

Section 1.25 "**Arbitration Matter**" shall mean any dispute concerning the validity, interpretation or construction of, or compliance with, or breach of, this Agreement.

Section 1.26 "**Arbitration Notice**" shall have the meaning set forth in Section 17.2.2(a).

Section 1.27 "**Arbitrators**" shall have the meaning set forth in Section 17.2.2(b).

Section 1.28 "**At-Fault Claim**" shall have the meaning set forth in Section 14.3.5.

Section 1.29 "**At-Fault Party**" shall have the meaning set forth in Section 14.3.5.

Section 1.30 "**Audited Party**" shall have the meaning set forth in Section 8.10.

Section 1.31 "**Auditing Party**" shall have the meaning set forth in Section 8.10.

Section 1.32 "**Background IP**" shall mean, with respect to Myovant, Myovant Background IP, and, with respect to Pfizer, Pfizer Background IP.

Section 1.33 "**Binding Obligation**" shall mean, with respect to a Party (a) any oral or written agreement or arrangement that binds or affects such Party's operations or property, including any assignment, license agreement, loan agreement, guaranty, or financing agreement, (b) the provisions of such Party's charter, bylaws or other organizational documents or (c) any order, writ, injunction, decree or judgment of any court or Governmental Authority entered against such Party or by which any of such Party's operations or property are bound.

Section 1.34 "**Breaching Party**" shall have the meaning set forth in Section 15.3.1(a).

Section 1.35 "**Budget Period**" shall mean (a) the period from the Effective Date through [***] and (b) the [***] period thereafter.

Section 1.36 "**Built-up Inventory Costs**" has the meaning set out in Section 1.149.1.

Section 1.37 "**Business Day**" shall mean a day other than (a) a Saturday or Sunday, or (b) a bank or other public or federal holiday in Basel, Switzerland, or in San Francisco, California, United States or State of New York, United States.

Section 1.38 "**Calendar Quarter**" shall mean each of the successive three (3)-month periods ending on March 31, June 30, September 30 and December 31 of any given Calendar Year, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the first to occur of March 31, June 30, September 30 and December 31 after the Effective Date and the last Calendar Quarter of the Term shall end on the last day of the Term.

Section 1.39 "**Calendar Year**" shall mean any period beginning on January 1 and ending on the immediately following December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on the December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on the January 1 of the year in which the Term ends and the end on the last day of the Term.

Section 1.40 "**cGCP**" shall mean the then current Good Clinical Practice requirements promulgated or endorsed for the United States by the FDA and its equivalent in other countries or regulatory jurisdictions.

Section 1.41 "**cGLP**" shall mean the then current Good Laboratory Practice requirements promulgated or endorsed for the United States by the FDA and its equivalent in other countries or regulatory jurisdictions.

Section 1.42 "**cGMP**" shall mean the then current Good Manufacturing Practice requirements promulgated or endorsed for the United States by the FDA and its equivalent in other countries or regulatory jurisdictions.

Section 1.43 "**CIA**" has the meaning set forth in Section 13.3.11.

Section 1.44 "**Clinical Trials**" shall mean any tests and studies of pharmaceutical products in human subjects.

Section 1.45 "**CMC**" shall mean Chemistry and Manufacturing Controls.

Section 1.46 "**Co-Administration Study**" shall mean a Clinical Trial for purposes of testing the safety or efficacy of, and generating data to support, a regulatory filing for the Regulatory Approval of the administration to patients of a Product in the Field together with another product other than a Product for the treatment of one or more diseases or conditions in such patients in the Field.

Section 1.47 "**Code**" shall mean the Internal Revenue Code of 1986, as amended.

Section 1.48 "**Collaboration IP**" shall mean Collaboration Know-How and Collaboration Patents.

Section 1.49 "**Collaboration Know-How**" shall mean any and all Know-How, whether or not patentable, that is invented, conceived, discovered, developed or otherwise made, solely or jointly, by or on behalf of either Party (or its Affiliates or its or their Sublicensees) directly in the conduct of activities under this Agreement and any Related Agreements. For clarity, Collaboration Know-How includes Product Collaboration Know-How and Other Collaboration Know-How.

Section 1.50 "**Collaboration Patents**" shall mean any and all Patents filed based on Collaboration Know-How.

Section 1.51 "**Combination Product**" shall mean any Product in the Field comprising: (a) a Compound and (b) at least one other active compound or ingredient, whether such components or ingredients are co-formulated in the same pharmaceutical formulation, or are separate components in a co-packaged form.

Section 1.52 "**Commercialization**" shall mean any and all activities directed to the preparation for sale of, the offering for sale of, or sale of the Products in the Field in the Territory, including activities related to marketing, promoting, distributing, importing and establishing pricing and reimbursement with respect to such Products, and REMS programs for such Products, as well as interacting with Regulatory Authorities regarding any of the foregoing, but excluding Development and Manufacturing. When used as a verb, "**to Commercialize**" and "**Commercializing**" shall mean to engage in Commercialization, and "**Commercialized**" shall have a corresponding meaning.

Section 1.53 "**Commercialization Component**" shall have the meaning set forth in Section 10.5.5(a).

Section 1.54 "[***]" shall mean, (i) with respect to the efforts of [***], or considerations to be undertaken, [***] with respect to any objective, activity or decision to be undertaken under this Agreement with respect to a Product, [***], and (ii) with respect to the efforts of [***], or considerations to be undertaken, [***] with respect to any objective, activity or decision to be undertaken under this Agreement with respect to a Product, [***].

Section 1.55 "**Committees**" shall have the meaning set forth in Section 2.2.

Section 1.56 "**Competition Clearance**" shall mean: (a) the making of any notification(s), submission(s) or filing(s); (b) the expiry, lapse or termination of any applicable waiting periods (including extensions of such periods); (c) the clearance, approval, authorization or other permission of any Governmental Authority, in each case ((a) to (c)), arising under any applicable Competition Law and which is necessary to permit Pfizer to acquire the rights contemplated under the Pfizer Territory Option under this Agreement; or (d) the absence of any condition imposed on either Party or their Affiliates by any Governmental Authority under any applicable Competition Law in connection with Pfizer's acquisition of such rights.

Section 1.57 "**Competition Law**" shall mean the national and directly effective legislation of any jurisdiction which governs the conduct of companies or individuals in relation to the control of acquisitions or mergers, including licensed rights, as applicable (including, if applicable, the Hart-Scott Rodino Antitrust Improvements Act 1976 (as amended) and the regulations made under such Act and Council Regulation (EC) No 139/2004 (EC Merger Regulation)).

Section 1.58 "**Compound**" shall mean the gonadotropin-releasing hormone receptor antagonist, N-(4-(1-(2,6-difluorobenzyl)-5-((dimethylamino)methyl)-3-(6-methoxy-3-pyridazinyl)-2,4-dioxo-1,2,3,4-tetrahydrothieno[2,3-d]pyrimidin-6-yl)phenyl)-N'-methoxyurea, having the chemical structure set forth in Exhibit 1.58, and any [***] thereof.

Section 1.59 "**Confidential Information**" shall mean, all non-public or proprietary information disclosed by a Party ("**Disclosing Party**") to the other Party ("**Receiving 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; provided, however, "Confidential Information" shall not include any information that (1) can be demonstrated by documentation or other competent proof to have been

in the Receiving Party's or its Affiliates' possession prior to disclosure by the Disclosing Party without any obligation of confidentiality with respect to such information; (2) is or becomes part of the public domain through no fault, wrongful act or negligence of the Receiving Party or its Affiliates; (3) can be demonstrated by documentation or other competent proof to have been independently developed by or for the Receiving Party or its Affiliates without use of, reliance on or reference to the Disclosing Party's Confidential Information; or (4) the Receiving Party or its Affiliate subsequently obtains from a Third Party that is not bound by any confidentiality obligation with respect to such information. Confidential Information will include derivative information prepared by or on behalf of Receiving Party (such as notes, drawings, plans, projections, analyses, records and materials) that incorporates or reflects and also include the terms and conditions of this Agreement. Subclause (1) and (3) shall not apply to any Joint Other Collaboration IP and, in the case of Pfizer, Product Collaboration IP.

Section 1.60 "**Continuing Party**" shall have the meaning set forth in Section 11.2.2.

Section 1.61 "**Control**" or "**Controlled**" shall mean, with respect to any item of Know-How, Regulatory Materials, material, Patent or other intellectual property right, possession of the right of a Party or its Affiliates, directly or indirectly, and whether by sole, joint or other ownership interest, license, covenant or otherwise (other than by operation of the licenses and other rights granted in Section 3.8.1, Section 4.6, Section 10.1 and Section 10.2), to grant a license, sublicense, covenant or other right to or under such item of Know-How, Regulatory Materials, material, Patent or other intellectual property right as provided for herein without misappropriating the Know-How, proprietary rights or the materials of any Third Party or otherwise violating any terms of any agreement or other arrangement with a Third Party.

Section 1.62 "**Co-Promotion**" shall mean the Commercialization of the Products in the Field jointly by the Parties as contemplated by this Agreement in the Co-Promotion Territory, including promotion of the Products in the Field by Sales Representatives from each Party, and the verb "**Co-Promote**" shall have a corresponding meaning.

Section 1.63 "**Co-Promotion Branding Strategy**" shall have the meaning set forth in Section 5.2.2.

Section 1.64 "**Co-Promotion Commercialization Plan and Budget**" shall have the meaning set forth in Section 5.2.1.

Section 1.65 "**Co-Promotion Territory**" shall mean the United States and Canada, excluding any Terminated Territory with respect to the applicable Product.

Section 1.66 "**Core Data Sheet**" shall mean a document that specifies the essential information that is required to be provided to persons prescribing or advising on the use of a Product in the Field and that contains the relevant and most up-to-date medically and scientifically documented information relating to such Product.

Section 1.67 "**Corporate Names**" shall mean, with respect to a Party, its entity-identifying Trademarks identified on Exhibit 1.67 hereto and its other corporate Trademarks as such Party may designate in writing to the other Party from time to time.

Section 1.68 "**Costs**" shall mean, with respect to an activity under this Agreement, any out-of-pocket costs incurred by a Party or its Affiliates during the Term (except as provided in Sections 1.149.1 or Section 15.8 or otherwise as expressly provided in this Agreement) that are specifically identifiable or reasonably allocable to such activity (including any sales, use, excise, turnover, inventory, or value added taxes (but excluding income taxes and similar taxes) incurred by such Party or its Affiliates applicable to such costs).

Section 1.69 "**Cover**" or "**Covered**" or "**Covering**" shall mean, with respect to a relevant Patent or Product, but for the rights granted to a Person under such Patent the act of making, using or selling such Product by such Person would infringe a Valid Claim included in such Patent, or in the case of a Patent that is a patent application, would infringe a Valid Claim in such patent application if it were to issue as a patent.

Section 1.70 "**Data Protection Laws**" shall mean any law, statute, declaration, decree, directive, legislative enactment, order, ordinance, regulation, rule or other binding restriction (as amended, consolidated or re-enacted from time to time) that relates to the protection of individuals with regards to the Processing of Personal Data.

Section 1.71 "**Declining Party**" shall have the meaning set forth in Section 11.2.2.

Section 1.72 "**Detail**" or "**Detailing**" shall mean with respect to a Product in the Field in the Co-Promotion Territory, the communication by a Sales Representative to a Targeted Professional during a customer interaction (a) involving face-to-face, telephonic, video, teledetailing or e-detail contact, (b) describing in a fair and balanced manner the FDA-approved indicated uses, safety, effectiveness, contraindications, side effects, warnings and other relevant characteristics of such Product, and (c) using the Promotional and Educational Materials in an effort to educate and inform Targeted Professionals regarding such Product for its FDA-approved indicated uses. Details or Detailing shall not include (i) activities conducted by medical affairs (such as Medical Science Liaisons), (ii) activities conducted at conventions or similar gatherings and activities performed by market development specialists, managed care account directors and other personnel not performing calls set forth in Section 1.72(a) above or not specifically trained with respect to a pharmaceutical product; (iii) self-directed e-details or (iv) literature drops.

Section 1.73 "**Detailing Shortfall**" shall have the meaning set forth in Section 6.1.2(c).

Section 1.74 "**Detailing Shortfall Rate**" shall mean, with respect to the Oncology Product in the Oncology Field, [***] for each Detail, and with respect to the WH Product in the WH Field, [***] for each Detail, in each case, or such other rate as mutually agreed by the Parties from time to time.

Section 1.75 "**Development**" shall mean, with respect to the Compound or the Products in the Field, any and all activities, whether before, on or after First Commercial Sale of the Products in the Field, directed to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, Manufacturing process development, Manufacturing scale-up, qualification and validation, quality assurance/quality control development, Clinical Trials, Other Studies, pre-approval REMS preparation, statistical analysis and report writing, the preparation and submission of Drug Approval Applications, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful for, or otherwise requested, required or recommended by a Regulatory Authority, Governmental Authority or other payor as a condition or in support of obtaining, maintaining or expanding Regulatory Approval. When used as a verb, "**Develop**" shall mean to engage in Development.

Section 1.76 "**Development Component**" shall have the meaning set forth in Section 10.5.5(b).

Section 1.77 "**Development Costs**" shall mean [***], and the [***], that are specifically identifiable or reasonably allocable to: (a) the activities with respect to the [***] following the Effective Date in accordance with and as set forth in or required to be budgeted (subject to any permitted overages) in the applicable Joint Medical Affairs and Development Plan and Budget (and, if such activities are allocated for performance by a Party under such Joint Medical Affairs and Development Plan and Budget, solely to the extent such activities are performed by the designated Party); or (b) the [***] performed under this Agreement, including:

1.77.1 [***];

1.77.2 [***];

1.77.3 [***];

1.77.4 [***]; and

1.77.5 [***].

Section 1.78 "**Disclosing Party**" shall have the meaning set forth in Section 1.59.

Section 1.79 "**Dispute**" shall have the meaning set forth in Section 17.2.1.

Section 1.80 "**Distribution Cost**" shall mean all Costs actually incurred by or on behalf of Myovant during the Term under the [***], including [***]. In the event that the [***] is terminated, the Parties shall agree on an alternate definition of "Distribution Costs" that reflects the alternative distribution channel. [***].

Section 1.81 "**Dollars**" or "**$**" shall mean U.S. Dollars.

Section 1.82 "**Domain Names**" shall have the meaning set forth in Section 11.6.2.

Section 1.83 "**Drug Approval Application**" shall mean an NDA, or any corresponding foreign application in the Territory, including with respect to the European Union, a Marketing Authorization Application filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in the European Union with respect to the mutual recognition or any other national approval procedure.

Section 1.84 "**Effective Date**" shall have the meaning set forth in the preamble hereto.

Section 1.85 "**EMA**" shall mean the European Medicines Agency or any successor agency thereto.

Section 1.86 "**Endometriosis**" shall mean a condition resulting from the presence of endometrial tissue outside the uterus.

Section 1.87 "**Endometriosis Approval Milestone**" shall have the meaning set out in Section 8.2.

Section 1.88 "**Environmental Manufacturing Responsibilities**" shall have the meaning set forth in Section 9.2.4.

Section 1.89 "**European Union**" shall mean the countries that are the member states of the European Union as constituted from time to time. For clarity, as of the Effective Date, the European Union excludes the United Kingdom, however, in the event the centralized Regulatory Approval of the EMA covers the United Kingdom, then the United Kingdom shall be considered as a part of the European Union accordingly.

Section 1.90 "**Excess Advertising Costs**" shall have the meaning set out in Section 1.14.

Section 1.91 "**Excess Commercialization Costs**" shall have the meaning set out in Section 1.14.

Section 1.92 "**Excess Development Costs**" shall have the meaning set out in Section 1.14.

Section 1.93 "**Excluded Affiliate**" shall mean (a) any Myovant Parent Affiliate; (b) any direct or indirect subsidiary of a Myovant Parent Affiliate that (i) is controlled (as defined in Section 1.11 (Affiliate)) by such Myovant Parent Affiliate but is not controlled by Myovant and (ii) is established for the development and commercialization of compounds and products other than the Compound and any products containing the Compound; or (c) any Person who controls (as defined in Section 1.11 (Affiliate)) any direct or indirect subsidiary of a Myovant Parent Affiliate.

Section 1.94 "**Excluded Claim**" shall have the meaning set forth in Section 17.2.2(a).

Section 1.95 "**Executive Officer**" shall mean, for Myovant, [***] and for Pfizer, [***], as applicable, or such other officer reporting directly to the applicable individual of such Party as may be designated by such Party.

Section 1.96 "**Existing CMO**" shall mean the Third Parties set out in Exhibit 1.96, being the Third Party subcontractors engaged by Myovant or its Affiliates to Manufacture the Oncology Product in the Oncology Field as of the Effective Date.

Section 1.97 "**Existing Myovant Third Party**" shall mean any of [***].

Section 1.98 "**Existing Myovant Third Party Agreements**" shall mean:

1.98.1 [***];

1.98.2 [***]

1.98.3 [***].

Section 1.99 "**Exploit**" shall mean to make, have made, import, use, sell or offer for sale, including to Develop, Commercialize, Manufacture, register, hold or keep (whether for disposal or otherwise), have used, export, transport, distribute, have distributed, promote, market or have sold or otherwise dispose of a product or a process, and "**Exploitation**" shall mean the act of Exploiting a product or process.

Section 1.100 "**FDA**" shall mean the United States Food and Drug Administration, or any successor agency thereto.

Section 1.101 "**FFDCA**" shall mean the United States Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

Section 1.102 "**Field**" shall mean (a) in the Co-Promotion Territory, the WH Field and the Oncology Field; (b) following Option Closing (if any), in the Pfizer Territory, the Oncology Field; and (c) in the case of the Pediatric Product, the Pediatric Field.

Section 1.103 "**Filling Fees**" shall mean filing fees in connection with the filing of an NDA for the WH Product in the WH Field in the Co-Promotion Territory, any other filing fees in connection with filing of Regulatory Materials (including for label expansions or supplemental NDAs) for the Products in the Field in the Co-Promotion Territory and annual program fees under the PDUFA with respect to any Product in the Field in the Co-Promotion Territory.

Section 1.104 "**Financial Records**" shall have the meaning set forth in Section 8.9.

Section 1.105 "**First Commercial Sale**" shall mean, (i) with respect to a country in the Co-Promotion Territory and any Product, the first sale of such Product by a Party or its Affiliate, Excluded Affiliate or Sublicensee to a Third Party in such country for use or consumption by the general public (and excluding research or educational use, charitable or compassionate use, and indigent care) after all Regulatory Approvals (other than pricing and reimbursement approvals) have been obtained in such country; and (ii) with respect to a country in the Pfizer Territory and any Oncology Product, the first sale of such Oncology Product by Pfizer or its Affiliate or Sublicensee to a Third Party in such country for use or consumption by the general public (and excluding research or educational use, charitable or compassionate use, and indigent care) after all Regulatory Approvals (other than pricing and reimbursement approvals) have been obtained in such country.

Section 1.106 "**Force Majeure**" shall have the meaning set forth in Section 18.1.

Section 1.107 "**FTE**" shall mean the equivalent of the work of one (1) employee full time for one (1) Calendar Year (consisting of at least a total of [***] hours per Calendar Year (or such other number as may be agreed by the applicable JSC) of work directly related to Development activities (including Regulatory Activities, safety and quality activities) or Commercialization activities performed in accordance with a Joint Medical Affairs and Development Plan and Budget, a Co-Promotion Commercialization Plan and Budget, or any other activities for which FTE costs are applicable as expressly set out in this Agreement or as agreed by the applicable JSC. No additional payment shall be made with respect to any person who works more than [***] hours per Calendar Year (or such other number as may be agreed by the applicable JSC) and any person who devotes less than [***] hours per Calendar Year (or such other number as may be agreed by the applicable JSC) shall be treated as an FTE on a pro rata basis based upon the actual number of hours worked divided by [***] (or such other number as may be agreed by the applicable JSC). The applicable JSC may modify the number [***] as used in this definition to an alternate number for some or all activities charged on an FTE basis.

Section 1.108 "**FTE Costs**" shall mean, with respect to any period for the applicable activity, the product of (a) the actual total FTEs during such period engaged in the applicable activity (pro rated if applicable), and (b) [***] (or such other rate as agreed by the Parties from time to times).

Section 1.109 "**Generic Competition Percentage**" shall mean, on a Oncology Product-by-Oncology Product and country-by-country basis, total aggregate sales of the applicable Generic Products in the applicable Calendar Quarter in such country divided by the sum of: (a) total aggregate sales of the Oncology Product sold in such Calendar Quarter in such country and (b) total aggregate sales of the Generic Product in such Calendar Quarter in such country, where, in each case ((a) and (b)), the total aggregate sales of the Oncology Product and each Generic Product will be based on the average of the monthly data provided by [***].

Section 1.110 "**Generic Product**" shall mean, with respect to an Oncology Product in the Oncology Field, any pharmaceutical product in the Oncology Field that (a) is sold in the Pfizer Territory by a Third Party that is not an Affiliate or Sublicensee of Pfizer under a marketing authorization granted by a Regulatory Authority to a Third Party, (b) contains the same Compound as such Oncology Product and (c) is approved in reliance on a prior Regulatory Approval of such Oncology Product granted to Pfizer, any of Pfizer's Affiliate, Myovant, any of Myovant's Affiliates or a Sublicensee by the applicable Regulatory Authority; provided, however, that any Oncology Product in the Oncology Field manufactured, sold or authorized by Pfizer, its Affiliates or Sublicensees shall not constitute a Generic Product.

Section 1.111 "**Good Practices**" shall mean cGCP, cGLP and cGMP.

Section 1.112 "**Government**" or "**Governmental Authority**" shall mean: (a) any national, federal, state, local, regional, or foreign government, or level, branch, or subdivision thereof; (b) any multinational or public international organization or authority; (c) any ministry, department, bureau, division, authority, agency, commission, or body entitled to exercise any administrative, executive, judicial, legislative, police, regulatory, or taxing authority or power; (d) any court, tribunal, or governmental arbitrator or arbitral body; (e) any government-owned or -controlled institution or entity; (f) any enterprise or instrumentality performing a governmental function; and (g) any political party.

Section 1.113 "**Government Official**" shall mean: (a) any elected or appointed Government official (*e.g.*, a legislator or a member of a ministry of health); (b) any employee or person acting for or on behalf of a Government, a Government department or agency, an institution or entity owned or controlled by a Government (*e.g.*, a HCP employed by a Government-owned or -controlled hospital, or a person serving on a healthcare committee that advises a Government), or an enterprise or instrumentality performing a governmental function; (c) any candidate for public office, or officer, employee, or person acting for or on behalf of a political party or candidate for public office; (d) an employee or person acting for or on behalf of a public international organization (*e.g.*, the United Nations, the Red Cross, or the World Bank); (e) any member of a military or a royal or ruling family; and (f) any person otherwise categorized as a Government official under law.

Section 1.114 "**HCP**" or "**Healthcare Professional**" shall mean any healthcare professional, including any physician, nurse, pharmacist, or other person who may administer, prescribe, purchase, or recommend pharmaceutical products or other healthcare products.

Section 1.115 "**Incentive Compensation**" shall mean the product based incentive compensation for which a Sales Representative is eligible through his/her Detailing activities (for the purposes of this definition, the reference to "Product" in the definition of "Detailing" shall be construed as "product"), and which is calculated based on the sales or prescriptions of products generated by such sales representative, including [***], but, for clarity, is not based on [***].

Section 1.116 "**IND**" shall mean an investigational new drug application filed with the FDA for authorization to commence Clinical Trials in the United States (including all additions, supplements, extensions and modifications thereto) and its equivalent in other countries or regulatory jurisdictions.

Section 1.117 "**Indemnification Claim Notice**" shall have the meaning set forth in Section 14.4.1.

Section 1.118 "**Indemnified Party**" shall have the meaning set forth in Section 14.4.1.

Section 1.119 "**Indemnitees**" shall mean Myovant Indemnitees or Pfizer Indemnitees.

Section 1.120 "**Independent Charity PAPs**" shall have the meaning set forth in Section 13.3.12.

Section 1.121 "**Infringement**" shall have the meaning set forth in Section 11.3.1.

Section 1.122 "**Infringement Notice**" shall have the meaning set forth in Section 11.3.1.

Section 1.123 "**Initial Commercialization Operation Period**" shall have the meaning set forth in Section 5.2.1.

Section 1.124 "**Insolvency Event**" shall mean, with respect to a Party, any one of the following: (a) a case is commenced by or against either Party under Title 11, United States Code, as amended, or analogous provisions of Applicable Law outside the United States (the "**Bankruptcy Code**") and, in the event of an involuntary case under the Bankruptcy Code, such case is not dismissed within [***] after the commencement thereof, (b) either Party files for or is subject to the institution of bankruptcy, liquidation or receivership proceedings (other than a case under the Bankruptcy Code or any voluntary solvent restructuring), (c) either Party assigns all or a substantial portion of its assets for the benefit of creditors (for clarity, excluding the grant of any security interest under such assets under a loan agreement or similar agreement), (d) a receiver or custodian is appointed for either Party's business, or (e) a substantial portion of either Party's business is subject to attachment or similar process.

Section 1.125 "**Intellectual Property Operating Committee**" or "**IPOC**" shall mean the intellectual property operating committee established pursuant to Section 2.8.

Section 1.126 "**Joint Commercialization Committee**" or "**JCC**" shall mean the Oncology JCC or WH JCC, as applicable.

Section 1.127 **"Joint Finance Committee"** or **"JFC"** shall mean the joint finance committee with the responsibilities set forth in Section 2.7.

Section 1.128 **"Joint Manufacturing Committee"** or **"JMC"** shall mean the joint supply and manufacturing committee with the responsibilities set forth in Section 2.6.

Section 1.129 "**Joint Medical Affairs and Development Plan and Budget**" shall have the meaning set forth in Section 3.1.1.

Section 1.130 "**Joint Medical Affairs Plan**" shall have the meaning set forth in Section 7.2.

Section 1.131 "**Joint Medical, Development and Regulatory Committee**" or "**JMDRC**" shall mean the WH JMDRC or Oncology JMDRC, as applicable.

Section 1.132 "**Joint Oncology Review Committee**" shall have the meaning set forth in Section 2.10.6(a).

Section 1.133 "**Joint Other Collaboration IP**" shall mean the Joint Other Collaboration Know-How and the Joint Other Collaboration Patents.

Section 1.134 "**Joint Other Collaboration Know-How**" shall mean any Other Collaboration Know-How that is invented, conceived, discovered, developed or otherwise made jointly by (a) Myovant (or its Affiliates or its or their Sublicensees), on one hand and (b) Pfizer (or its Affiliates or its or their Sublicensees), on the other hand.

Section 1.135 "**Joint Other Collaboration Patents**" shall mean all Patents filed based on the Joint Other Collaboration Know-How.

Section 1.136 "**Joint Promotional and Educational Materials**" shall have the meaning set forth in Section 6.3.1.

Section 1.137 "**Joint Review Committee**" shall have the meaning set forth in Section 2.10.6(a).

Section 1.138 "**Joint Steering Committee**" or "**JSC**" shall mean the WH JSC or Oncology JSC, as applicable.

Section 1.139 "**Joint WH Review Committee**" shall have the meaning set forth in Section 2.10.6(a).

Section 1.140 "**Know-How**" shall mean any proprietary know-how and information, including trade secrets, technology, methods, processes, formulae, techniques, procedures, designs, specifications, data, results and other material (including any chemical or biological material) including study designs and protocols, assays and biological methodology, and any inventions, improvements, discoveries, and developments included therein, in each case (whether or not patentable) in written, electronic or any other form now known or hereafter developed, but excluding in any event any published Patents.

Section 1.141 "**Knowledge**" with respect to a Party, shall mean the actual knowledge of such Party at the relevant time, without any requirement to make any additional inquiries or investigation.

Section 1.142 "**Long-Term Study Plan**" shall have the meaning set forth in Section 3.1.1(b).

Section 1.143 "**Losses**" shall have the meaning set forth in Section 14.1.

Section 1.144 "**Major [***] Provinces**" shall mean each of [***].

Section 1.145 "**Major Country**" shall mean, with respect to each Region, the country or countries designated as the major country for such Region in Exhibit 1.145.

Section 1.146 "**Major Market Country**" shall mean [***].

Section 1.147 "**Major Regulatory Filing**" shall mean Drug Approval Applications, NDAs, INDs, and material Product Labeling supplements.

Section 1.148 "**Manufacture**" and "**Manufacturing**" shall mean any and all activities directed to the formulation development, production, manufacture, processing, filling, finishing, packaging, labeling, shipping, holding and disposing of the Compound or the Products in the Field, or any intermediate thereof, including stability testing, quality assurance, and quality control and interacting with Regulatory Authorities regarding any of the foregoing.

Section 1.149 "**Manufacturing Cost**" shall mean any and all of: (a) for clinical trial supplies, a Party's standard cost of goods therefor, pursuant to the applicable Joint Medical Affairs and Development Plan and Budget, (b) for process development, scale up or technology transfer, Costs plus reasonable overhead each as agreed to by the Parties in writing and, subject to any budget developed by the JMC and agreed to by the Parties in writing, and (c) for commercial supplies, including for launch supplies and Samples, the standard cost of goods therefor, including quality assurance (i.e., testing, documentation and release of drug product), that are specifically identifiable or reasonably allocable to the Manufacture (or acquiring from a Third Party) of a Product for the Co-Promotion Territory following the Effective Date, and, to the extent not already included in Distribution Costs, any Costs of shipment, storage and handling of such Products (or such API, drug product or other component), in each case after the Effective Date (other than as provided under Section 1.149.1) and in accordance with the Accounting Standards, consistently applied. Manufacturing Costs shall include:

1.149.1 the cost of the inventory of Products, and API, drug products and other components of the Products, in each case, built up in advance of the Effective Date that will be used in the Development or Commercialization activities under this Agreement as set forth in [***] (the "**Built-up Inventory Costs**"). All such costs shall be deemed to be incurred by Myovant during the Term for the purposes of this Agreement;

1.149.2 with respect to Manufacturing activities conducted by such Party (or its Affiliates) during the Term: (a) [***], (b) [***], and (c) [***];

1.149.3 with respect to Manufacturing activities conducted by Third Parties for such Party or its Affiliates, the invoiced Costs, [***], of suppliers of goods and services directly related to such Manufacturing activities for the Product for the Co-Promotion Territory; and

1.149.4 Costs incurred in the performance of any capacity expansion plan to the extent approved by the JSC pursuant to Section 9.2.2.

Section 1.150 "**Medical Affairs Costs**" shall mean, with respect to the Products in the Field in the Co-Promotion Territory Costs incurred in connection with medical affairs activities for the Products in accordance with the applicable Joint Medical Affairs and Development Plan and Budget, including (a) [***], (b) [***], (c) [***], (d) [***], (e) [***], (f) [***], (g) [***], (h) [***] and (i) [***].

Section 1.151 "**Medical Science Liaison**" or "**MSL**" shall mean a field-based colleague that is part of a Party's medical organization. Such professionals at Myovant are referred to as "[***]", and at Pfizer are referred to as "[***]".

Section 1.152 "**Myovant**" shall have the meaning set forth in the preamble hereto.

Section 1.153 "**Myovant Background IP**" shall mean any and all Know-How or Patents that are (a) Controlled by Myovant or its Affiliates (i) as of the Effective Date or (ii) independent of this Agreement during the Term, and (b) necessary or reasonably useful to Exploit any Product in the Field in the Territory.

Section 1.154 "**Myovant Background Patents**" shall mean Patents within the Myovant Background IP. Myovant Background Patents existing as of the Effective Date are listed in [***].

Section 1.155 "**Myovant Controlled Matter**" shall have the meaning set forth in Section 2.10.3(c)(i).

Section 1.156 "**Myovant Other Collaboration IP**" shall mean Other Collaboration IP that is invented, conceived, discovered, developed or otherwise made, independently or solely, by or on behalf of Myovant (or its Affiliates or its or their Sublicensees).

Section 1.157 "**Myovant Other Collaboration Patents**" shall mean Patents within Myovant Other Collaboration IP.

Section 1.158 "**Myovant Parent Affiliate**" shall mean any Person that controls (as defined in Section 1.11) Myovant, including [***].

Section 1.159 "**Myovant Patents**" shall mean Myovant Background Patents and Product Collaboration Patents.

Section 1.160 [***] shall mean [***].

Section 1.161 "**Myovant Product Trademarks**" shall have the meaning set forth in Section 11.6.1.

Section 1.162 "**Myovant Regulatory Documentation**" shall have the meaning set forth in Section 4.6.

Section 1.163 "**NDA**" shall mean a New Drug Application submitted to the FDA in the United States in accordance with the FFDCA with respect to a pharmaceutical product or any analogous application or submission with any Regulatory Authority outside of the United States.

Section 1.164 "**Net Profits**" and, with correlative meaning, "**Net Losses**," shall mean, with respect to the Co-Promotion Territory for a period, Net Sales (with respect to both Oncology Product(s) and WH Product(s)) in the Co-Promotion Territory for such period less Allowable Expenses for such period.

Section 1.165 "**Net Sales**" shall mean, with respect to a Product, the gross amount invoiced or received (whichever first occurs) by Myovant in the Co-Promotion Territory or, following Option Closing (if it

occurs), Pfizer in the Pfizer Territory, their respective Affiliates or Excluded Affiliates, and Sublicensees (other than Third Party Distributors) for sales of such Product, as applicable, to Third Parties (including Third Party Distributors), less the following deductions, to the extent such deductions are paid, incurred, or otherwise taken, reasonable and customary, provided to Third Parties, and actually allowed with respect to such sales:

1.165.1 [***];

1.165.2 [***];

1.165.3 [***];

1.165.4 [***];

1.165.5 [***];

1.165.6 [***]; or

1.165.7 [***].

All such discounts, allowances, credits, rebates, and other deductions will be fairly and equitably allocated between such Product and other products of the applicable Party, its Affiliates, Excluded Affiliates and Sublicensees such that such Product does not bear a disproportionate portion of such deductions. Notwithstanding the foregoing, amounts received or invoiced by the applicable Party, its Affiliates, Excluded Affiliates or Sublicensees (other than Third Party Distributors) for the sale of such Product among the Parties or their respective Affiliates, Excluded Affiliates or Sublicensees (other than Third Party Distributors) for resale will not be included in the computation of Net Sales hereunder. In any event, any amounts received or invoiced by the applicable Party, its Affiliates, Excluded Affiliates or Sublicensees will be accounted for only once. For purposes of determining Net Sales, a Product will be deemed to be sold when invoiced. Net Sales will be accounted for in accordance with Accounting Standards. A particular deduction may only be accounted for once in the calculation of Net Sales. Net Sales will exclude [***].

Section 1.166 "**New Product**" means any Product other than (a) the Oncology Product as approved by the FDA in the United States as of the Effective Date or (b) the WH Product that has been filed for approval by Myovant with the FDA in the United States as of the Effective Date.

Section 1.167 "**Non-Breaching Party**" shall have the meaning set forth in Section 15.3.1(a).

Section 1.168 "**Non-Fault Party**" shall have the meaning set forth in Section 14.3.5.

Section 1.169 "**Non-Regulatory Party**" shall mean the Party that is not the Regulatory Party for the applicable country or jurisdiction.

Section 1.170 "**Non-Selling Party**" shall mean: (a) with respect to the Products in the Field the Co-Promotion Territory, Pfizer and (b) with respect to the Oncology Product in the Oncology Field in the Pfizer Territory (following Option Closing (if it occurs)), Myovant.

Section 1.171 "**Occurrence**" shall have the meaning set forth in Section 13.3.10.

Section 1.172 "**OIG Guidance**" shall have the meaning set forth in Section 13.1.5.

Section 1.173 "**Oncology Competing Product**" shall mean [***].

Section 1.174 "**Oncology Co-Promotion Commercialization Plan and Budget**" shall have the meaning set forth in Section 5.2.1.

Section 1.175 "**Oncology Field**" shall mean [***].

Section 1.176 "**Oncology JCC**" shall mean the joint commercialization committee with respect to the Oncology Products in the Oncology Field, with the responsibilities set forth in Section 2.5.

Section 1.177 "**Oncology JMDRC**" shall mean the joint medical, development and regulatory committee with respect to the Oncology Products in the Oncology Field, with the responsibilities set forth in Section 2.2.

Section 1.178 "**Oncology Joint Medical Affairs and Development Plan and Budget**" shall have the meaning set forth in Section 3.1.1.

Section 1.179 "**Oncology JSC**" shall mean the joint steering committee with respect to the Oncology Products in the Oncology Field, with the responsibilities set forth in Section 2.3.

Section 1.180 **"Oncology Product**" shall mean any product in the Oncology Field Developed or Commercialized pursuant to this Agreement that contains the Compound.

Section 1.181 "**OPDP Strategy**" shall have the meaning set forth in Section 2.10.7(c).

Section 1.182 "**Option Closing**" shall have the meaning set forth in Section 10.5.2.

Section 1.183 "**Option Exercise Notice**" shall have the meaning set forth in Section 10.5.2.

Section 1.184 "**Option Exercise Payment**" shall have the meaning set forth in Section 8.4.

Section 1.185 "**Option Period**" shall mean the [***] period beginning on the date when a Drug Approval Application is filed with the EMA with respect to the Oncology Product for prostate cancer.

Section 1.186 "**Other Collaboration IP**" shall mean Other Collaboration Know-How and Other Collaboration Patents.

Section 1.187 "**Other Collaboration Know-How**" shall mean any and all Collaboration Know-How, excluding any Product Collaboration Know-How.

Section 1.188 "**Other Collaboration Patents**" shall mean any and all Patents filed based on Other Collaboration Know-How.

Section 1.189 "**Other Product**" shall mean a product that that does not contain the Compound and is being researched, developed or commercialized by either Party or any of their respective Affiliates.

Section 1.190 "**Other Studies**" shall mean real world evidence, observational clinical and similar studies that are not Clinical Trials.

Section 1.191 "**Party(ies)**" shall have the meaning set forth in the preamble hereto.

Section 1.192 "**Patents**" shall mean any and all: (a) issued patents, including any utility or design patent, utility models or petty patents; (b) patent applications, including provisionals, non-provisionals, substitutions, divisionals, continuations, continuations in-part or renewals, and all patents granted thereon; (c) patents of addition, restorations or extensions (by existing or future extension or restoration mechanisms), including patent term adjustments, patent term extensions, supplementary protection certificates (or the equivalent thereof), registration or confirmation patents, patents resulting from post-grant proceedings, re-issues, and re-examinations; (d) other patents or patent applications claiming priority directly or indirectly to: (i) any such specified patent or patent application specified in (a) through (c), or (ii) any patent or patent application from which a patent or patent application specified in (a) through (c) claim direct or indirect priority; (e) inventor's certificates; (f) other rights issued from a Governmental Authority similar to any of the foregoing specified in (a) through (e); and (g) in each of (a) through (f), whether such patent, patent application or other right arises in the U.S. or any other jurisdiction in the world.

Section 1.193 "**Patent Office**" shall mean a Governmental Authority that administers and regulates patents, such as the United States Patent and Trademark Office, or other similar Governmental Authority.

Section 1.194 "**Patent Term Extension**" shall have the meaning set forth in Section 11.2.6.

Section 1.195 "**PDUFA**" shall mean the Prescription Drug User Fee Act (as may be amended from time to time).

Section 1.196 "**PDUFA Date**" shall mean the initial date, as may be adjusted for reason other than due to [***], which is the deadline for the FDA to complete review of an NDA for a particular Product.

Section 1.197 "**Pediatric Field**" shall mean any pediatric indication for which a Pediatric Product is developed hereunder as set out in the WH Joint Medical Affairs and Development Plan and Budget.

Section 1.198 "**Pediatric Product**" shall mean any product containing the Compound for any pediatric indication, that is developed pursuant to this Agreement, and is not the WH Product in the WH Field or Oncology Product in the Oncology Field existing as of the Effective Date.

Section 1.199 "**Pfizer**" shall have the meaning set forth in the preamble hereto.

Section 1.200 "**Pfizer Background IP**" shall mean any and all Know-How or Patents that are Controlled by Pfizer or its Affiliates as of the Effective Date or independent of this Agreement during the Term.

Section 1.201 "**Pfizer Background Patents**" shall mean Patents within the Pfizer Background IP.

Section 1.202 "**Pfizer Controlled Matter**" shall have the meaning set forth in Section 2.10.3(c).

Section 1.203 "**Pfizer Operation Plan**" shall have the meaning set forth in Section 10.5.5.

Section 1.204 "**Pfizer Other Collaboration IP**" shall mean Other Collaboration IP invented, conceived, discovered, developed or otherwise made, independently or solely, by or on behalf of Pfizer (or its Affiliates or its or their Sublicensees).

Section 1.205 "**Pfizer Other Collaboration Patents**" shall mean Patents within Pfizer Other Collaboration IP.

Section 1.206 "**Pfizer Regulatory Documentation**" shall have the meaning set forth in Section 4.6.

Section 1.207 "**Pfizer Territory**" shall mean worldwide, excluding: (a) the Co-Promotion Territory; (b) the Takeda Territory; and (c) any Terminated Territory with respect to the applicable Product.

Section 1.208 "**Pfizer Territory Option**" shall have the meaning set forth in Section 10.5.1.

Section 1.209 "**Person**" shall mean any natural person, corporation, partnership, trust, joint venture, limited liability company, Governmental Authority or any other entity or organization.

Section 1.210 "**Personal Data**" shall mean any data that identifies or could identify a living person.

Section 1.211 "**Pharmacovigilance Agreement**" shall have the meaning set forth in Section 4.5.

Section 1.212 "**Presentation and Publication Plans**" shall have the meaning set forth in Section 12.6.1(a).

Section 1.213 "**Pricing Matters**" shall mean matters relating to pricing strategies, including price, price terms and other contract terms respecting sales of Products in the Field in the Territory to Third Parties in the applicable jurisdiction, including [***]. "**Pricing Matters**" includes [***].

Section 1.214 "**Processing**" shall have the meaning given to such term in the Data Protection Laws, and "**Process**" and "**Processed**" shall be construed accordingly.

Section 1.215 "**Product**" shall mean any of (a) a WH Product; (b) an Oncology Product; or (c) a Pediatric Product(s), and "**Products**" shall mean all of them.

Section 1.216 "**Product Collaboration IP**" shall mean Product Collaboration Know-How and Product Collaboration Patents.

Section 1.217 "**Product Collaboration Know-How**" shall mean Collaboration Know-How, whether or not patentable, that is necessary or used by either Party to Exploit the Compound or Products.

Section 1.218 "**Product Collaboration Patents**" shall mean all Patents filed based on Product Collaboration Know-How.

Section 1.219 "**Product Labeling**" shall mean, with respect to the applicable Product in the Field in a country in the Territory, (a) the Regulatory Authority approved full prescribing information for such Product for such country, including any required patient information, and (b) all labels and other written, printed, or graphic matter upon a container, wrapper, or any package insert utilized with or for such Product in such country.

Section 1.220 "**Product Liability Claim**" shall have the meaning set forth in Section 14.3.5.

Section 1.221 "**Product Trademark Guidelines**" shall have the meaning set forth in Section 11.6.3(c).

Section 1.222 "**Product Trademarks**" shall mean the Trademark(s) to be used by either Party, its Affiliates or its or their respective Sublicensees in accordance with this Agreement for the Commercialization of a Product in the Field anywhere in the Territory and any registrations thereof or any pending applications relating thereto in the Territory, including any unregistered Trademark rights specific to such Product as may exist through use before, on or after the Effective Date (excluding, in any event, any trademarks, service marks, names, trade dress, or logos that include any Corporate Names of the Parties or their Affiliates).

Section 1.223 "**Promotional and Educational Materials**" shall mean any printed, written, graphic, audio, video, electronic, digital or other materials, branded or unbranded, used or intended specifically for use to promote a Product in the Field in the Territory, including all promotional brochures, value propositions, patient education materials, economic models, copay offers, journal ads, selling aids, posters, reprints of published articles, video or audio tapes, press releases, service or reminder items, price lists, monographs, formulary binders, direct mail, website content, materials or advertising (in print media, electronic media such as television, radio, telephone communication systems or on the internet).

Section 1.224 "**Proposed Co-Administration Studies**" shall have the meaning set forth in Section 3.8.1.

Section 1.225 "**Prosecute and Maintain**" shall have the meaning set forth in Section 11.2.1(a).

Section 1.226 "**Publications**" shall have the meaning set forth in Section 12.6.1(a).

Section 1.227 "**Quality Agreement**" shall have the meaning set forth in Section 9.1.3.

Section 1.228 "**Recall Costs**" shall mean actual Costs incurred by a Party or its Affiliates as the direct result of a recall or withdrawal of a Product in the Field in a country in the Territory, such as [***], but shall not include [***].

Section 1.229 "**Receiving Party**" shall have the meaning set forth in Section 1.59.

Section 1.230 "**Records**" shall have the meaning set forth in Section 3.4.1.

Section 1.231 "**Region**" shall mean any of the regions as specified in Exhibit 1.144.

Section 1.232 "**Regulatory Activities**" shall have the meaning set forth in Section 4.1.2(a).

Section 1.233 "**Regulatory Approval**" shall mean, with respect to a country in the Territory, the grant of any and all approvals (including approval of Drug Approval Applications), licenses, registrations or authorizations of any Regulatory Authority necessary for the commercial distribution, marketing or sale of any Product in the Field for one or more indications in such country, including, where applicable, (a) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto), (b) labeling approval, (c) with respect to the United States, scheduling by the Drug Enforcement Administration, (d) means the approval of any application for pricing or reimbursement for such pharmaceutical product in a given country or other regulatory jurisdiction by the Regulatory Authority for such country or other regulatory jurisdiction and (e) the satisfaction of all applicable regulatory and notification requirements.

Section 1.234 "**Regulatory Authority**" shall mean any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to any Product or the Exploitation thereof in the Territory, including the FDA in the United States and the EMA in the European Union, but excluding any government entities responsible for pricing and reimbursement.

Section 1.235 "**Regulatory Exclusivity Period**" shall mean, with respect to a country in the Territory, a period of exclusivity granted or afforded by Applicable Law or by a Regulatory Authority in such country that confers data, marketing, or other exclusivity with respect to the applicable Product in such country.

Section 1.236 "**Regulatory Materials**" shall mean all (a) regulatory submissions, notifications, registrations, licenses, authorizations, applications (including all INDs, Drug Approval Applications and associated common technical documents) and approvals (including any Regulatory Approval) and all amendments and supplements to any of the foregoing and (b) correspondence and reports submitted to or received from Regulatory Authorities and all supporting documents with respect thereto, including drug lists, advertising and promotion documents, Adverse Event files, and complaint files, in each case ((a) and (b)) relating to the Compound or a Product in the Field.

Section 1.237 "**Regulatory Party**" shall mean Myovant, except: (a) in the case of [***]; and (b) following the Option Closing (if it occurs), in relation to any country or jurisdiction in the Pfizer Territory, [***].

Section 1.238 "**Related Agreements**" shall mean the Pharmacovigilance Agreement, the Quality Agreement, the Supply Agreement, the [***] and any other written agreements between the Parties with respect to the Development, Manufacturing, supply or Commercialization of the Compound or the Product in the Field, as such agreements may be amended by the Parties from time to time.

Section 1.239 "**REMS**" shall mean risk evaluation and mitigation strategy meeting the requirements and standards of the applicable Regulatory Authority.

Section 1.240 "**Required Study**" shall mean any studies, including any Clinical Trials and Other Studies, that are required to be conducted (including as a condition to maintain the applicable Regulatory Approval) pursuant to requirements imposed by a Regulatory Authority in the Territory with respect to the applicable indication for any Product in the Field.

Section 1.241 "[***]" shall have the meaning set forth in Section 1.98.2.

Section 1.242 "[***]" shall have the meaning set forth in Section 1.98.2.

Section 1.243 "**Royalty Term**" shall mean, following Option Closing (if it occurs), on a country-by-country basis in the Pfizer Territory and Oncology Product-by-Oncology Product basis, the period commencing on the First Commercial Sale of an Oncology Product in such country and continuing until the latest of:

1.243.1 [***];

1.243.2 [***]; and

1.243.3 [***] after the First Commercial Sale of such Oncology Product in such country.

Section 1.244 "**Sales and Marketing Costs**" shall mean Costs incurred following the Effective Date that are specifically identifiable or reasonably allocable to the performance of Commercialization activities of a Product in the Field in the Co-Promotion Territory as set forth in, or required to be budgeted in, subject to permitted overages, and in accordance with the applicable Co-Promotion Commercialization Plan and Budget (and, if such activities are allocated for performance by a Party under such Co-Promotion Commercialization Plan and Budget, solely to the extent such activities are performed by the designated Party), including Costs incurred with respect to:

1.244.1 [***];

1.244.2 [***]

1.244.3 [***];

1.244.4 [***];

1.244.5 [***];

1.244.6 [***];

1.244.7 [***];

1.244.8 [***];

1.244.9 [***];

1.244.10 [***];

1.244.11 [***];

1.244.12 [***];

1.244.13 [***];

1.244.14 [***];

1.244.15 [***]; and

1.244.16 [***].

Section 1.245 "**Sales Force**" shall mean a Party's (or its Affiliate's) personnel that are assigned the responsibility to Detail the applicable Product and includes Sales Representatives, managers and trainers.

Section 1.246 "**Sales Representative**" shall mean, with respect to a Party, an individual who engages in Detailing on behalf of such Party; *provided, however*, that a Sales Representative of one Party or its Affiliates shall not be considered a Sales Representative of the other Party's Sales Force or its Affiliates.

Section 1.247 "**Sample**" shall mean a packaged and labeled Product in the Field that is intended for use to trial the Product and not for sale and that is marked "Sample – Not for Resale" or with words of similar effect, including in any language other than English.

Section 1.248 "**Selling Party**" shall mean (a) with respect to the Products in the Co-Promotion Territory, Myovant, its Affiliates, or its or their Sublicensees and (b) with respect to the Oncology Product(s) in the Pfizer Territory, Pfizer, its Affiliates or its or their Sublicensees.

Section 1.249 "**Shared Losses**" shall have the meaning set forth in Section 14.3.1.

Section 1.250 "**Significant Violation**" shall mean conduct that a reasonable person would consider a probable violation of applicable policies or procedures designed to ensure compliance with Applicable Laws, which will or is reasonably expected to result in significant or substantial liability if a Governmental Authority determined such conduct to be a violation of Applicable Law.

Section 1.251 "[***]" shall have the meaning set forth in Section 2.10.3(c)(iii).

Section 1.252 "**Sublicensee**" shall mean, with respect to a Party, any Person, other than an Affiliate or Excluded Affiliate, that is granted a sublicense by such Party under the grants in Section 4.6, Section 10.1.1 or Section 10.2, as applicable.

Section 1.253 "[***]" shall have the meaning set forth in [***].

Section 1.254 "[***]" shall have the meaning set forth in [***].

Section 1.255 "**Sunshine Act**" shall have the meaning set forth in Section 18.6.

Section 1.256 "**Supply Agreement**" shall have the meaning set forth in Section 9.1.2.

Section 1.257 "**Supply Plan**" shall have the meaning set forth in Section 9.2.1.

Section 1.258 "**Surviving Provisions**" shall have the meaning set forth in Section 15.9.1.

Section 1.259 "[***]" shall have the meaning set forth in Section 1.98.1.

Section 1.260 "[***]" shall have the meaning set forth in [***].

Section 1.261 "[***] **Patents**" shall have the meaning set forth in Section 15.7.3.

Section 1.262 "**Takeda Territory**" shall mean Japan, China, Hong Kong, Indonesia, Korea, Malaysia, Philippines, Singapore, Taiwan, Thailand, and Vietnam, including, in each case, the territories and possession of each of the foregoing.

Section 1.263 "**Targeted Professional**" shall mean (a) those health care professionals with prescribing authority for the applicable Product in the Field in the Co-Promotion Territory and (b) any other health care professionals, quality directors, health system executives and office staff without prescribing authority but who (i) is reasonably believed to assist with patient care and reimbursement for healthcare service in the office of a health care provider who has authority to prescribe the Product under Applicable Law, and (ii) is allowed to receive information or educational materials to whom Details are to be performed as set forth in the applicable Co-Promotion Commercialization Plan and Budget or, if not so set forth, as designated by the applicable JCC.

Section 1.264 "**[***]**" shall mean, with respect to a Party and the WH Product in the WH Field or the Oncology Product in the Oncology Field, as the case may be, a performance measurement for compensating its Sales Representatives with respect to such Product other than Incentive Compensation. Such performance at Pfizer are referred to as [***] and [***].

Section 1.265 "**Term**" shall have the meaning set forth in Section 15.1.1.

Section 1.266 "**Terminated Territory**" shall have the meaning set forth in Section 15.3.1.

Section 1.267 "**Termination Effective Date**" shall have the meaning set forth in Section 15.3.1(c).

Section 1.268 "**Termination Notice**" shall have the meaning set forth in Section 15.3.1.

Section 1.269 "**Termination Notice Period**" shall have the meaning set forth in Section 15.3.1.

Section 1.270 "**Termination Product**" shall have the meaning set forth in Section 15.3.1(b).

Section 1.271 "**Territory**" shall mean: (a) with respect to the WH Product(s), the Co-Promotion Territory, and (b) with respect to the Oncology Product(s) and the Pediatric Product, the Co-Promotion Territory and, following the Option Closing (if it occurs) and payment of the Option Exercise Payment in full, the Pfizer Territory.

Section 1.272 "**Third Party**" shall mean any Person other than Myovant, Pfizer and their respective Affiliates and Excluded Affiliates.

Section 1.273 "**Third Party Claims**" shall have the meaning set forth in Section 14.1.

Section 1.274 "**Third Party Distributor**" shall mean the Third Party distributor to which the Selling Party for such country delegates primary responsibility for Commercializing the applicable Product in such country and which purchases such Product from such Selling Party (or its Affiliate) for resale in such country.

Section 1.275 "**Third Party Infringement Claim**" shall have the meaning set forth in Section 11.4.

Section 1.276 "**Third Party License**" shall mean a license with a Third Party entered into by a Party or any of its Affiliates on or after the Effective Date in accordance with the terms of this Agreement in consideration of any rights necessary (as reasonably determined by a Party) for the Exploitation of any Compound or Product in the Field in the Territory.

Section 1.277 "**Third Party Payment**" shall mean: (a) [***] and (b) with respect to any Third Party License entered into by a Party in accordance with Section 10.3.6 following the Effective Date, any consideration, whether monetary or otherwise, including (i) [***], (ii) [***] and (iii) [***]. If such consideration is not monetary, the Parties shall agree on an equivalent monetary amount to be attributed to such non-monetary consideration.

Section 1.278 "**Trademark**" shall mean any word, name, symbol, color, shape, designation, or any combination thereof, including any trademark, service mark, trade name, brand name, sub-brand name, trade dress, product configuration, program name, delivery form name, certification mark, collective mark, logo, tagline, slogan, design or business symbol, that functions as an identifier of source, quality or origin, whether or not registered and all statutory and common law rights therein and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.

Section 1.279 "**United States**" shall mean the United States of America and its territories and possessions, including the District of Columbia and Puerto Rico.

Section 1.280 "**Unresolved Committee Matter**" shall have the meaning set forth in Section 2.10.3(b).

Section 1.281 "**U.S. GAAP**" shall mean generally accepted accounting principles current in the United States, as consistently applied.

Section 1.282 "**Uterine Fibroids**" shall mean the condition in which a non-cancerous tumor originates from the muscular layer of the uterus wall.

Section 1.283 "**Valid Claim**" shall mean, with respect to a particular country and Product in the Territory, (a) [***]; or (b) [***].

Section 1.284 "**WAC**" shall mean, with respect to a Product, the manufacturer's list price for the pharmaceutical drug or biological product to wholesalers or direct purchasers for such Product.

Section 1.285 "[***]" shall have the meaning set out in the [***].

Section 1.286 "**WAC Matter**" shall mean any Pricing Matter: (a) relating to: (i) the establishment of the initial WAC of the WH Product in the WH Field in any country in the Co-Promotion Territory, *provided that* , with respect to the WH Product in the WH Field, [***] or (ii) the establishment of the initial WAC of the Oncology Product in the Oncology Field in Canada upon its launch; or (b) relating to the modification of the initial WAC of the WH Product in the WH Field in any country in the Co-Promotion Territory or the Oncology Product in the Oncology Field in any country in the Co-Promotion Territory, in each case, *provided that* [***].

Section 1.287 "**WH Competing Product**" shall mean [***].

Section 1.288 "**WH Co-Promotion Commercialization Plan and Budget**" shall have the meaning set forth in Section 5.2.1.

Section 1.289 "**WH Field**" shall mean the [***] that is added to the WH Joint Medical Affairs and Development Plan and Budget.

Section 1.290 "**WH JCC**" shall mean the joint commercialization committee with respect to the WH Products, with the responsibilities set forth in Section 2.5.

Section 1.291 "**WH Joint Medical Affairs and Development Plan and Budget**" shall have the meaning set forth in Section 3.1.1.

Section 1.292 "**WH JMDRC**" shall mean the joint medical, development and regulatory committee with respect to the WH Products, with the responsibilities set forth in Section 2.4.

Section 1.293 "**WH JSC**" shall mean the joint steering committee with respect to the WH Products, with the responsibilities set forth in Section 2.2.

Section 1.294 "**WH Product**" shall mean: (a) the single tablet, coformulation of the Compound with estradiol and norethindrone acetate for use in the WH Field and (b) any other product in the WH Field Developed or Commercialized pursuant to this Agreement that contains the Compound.

Section 1.295 "[***]" shall have the meaning set out in the [***].

Section 1.296 "**Working Group**" shall have the meaning set forth in Section 2.10.5.

ARTICLE II.
GOVERNANCE

Section 2.1 Executive Officers. The Executive Officers shall resolve matters presented to them and disputes raised to them by each JSC in accordance with Section 2.10.3 or Section 17.2.1.

Section 2.2 Committee Formation. On the Effective Date, the Parties shall establish the WH JSC, Oncology JSC, WH JMDRC, Oncology JMDRC, WH JCC, Oncology JCC, JMC, JFC, IPOC and Compliance Committee (the "**Committees**"). Each Committee (other than the IPOC and the Compliance Committee) shall consist of [***] representatives from each of the Parties, and the IPOC shall consist of [***] representatives from each of the Parties, and the Compliance Committee shall consist [***] representative from each of the Parties, each with the requisite experience and seniority to enable such person to make decisions on behalf of the Party appointing him or her with respect to the issues falling within the jurisdiction of such Committee. As of the Effective Date, each Party's representatives of each Committee are as set out in Exhibit 2.2. From time to time, each Party may substitute one or more of its representatives to each Committee on written notice to the other Party. Myovant shall select from its representatives the initial chairperson for the Oncology JSC, the WH JMDRC, the WH JCC, the JMC, the IPOC and the Compliance Committee. Pfizer shall select from its representatives the initial chairperson for the WH JSC, Oncology JMDRC, Oncology JCC and

the JFC. At the beginning of each Calendar Year the Party for which the then-current chairperson of a Committee, other than the JMC, is not a representative shall select from its representatives the new chairperson for such Committee. For clarity, the second chairperson of a Committee (*i.e.*, first change of chairpersons) shall become effective on January 1, 2022. Myovant shall select from one of its representatives the chairperson for the JMC, unless the Parties agreed that Pfizer will perform any Manufacturing activities for the Products in the Territory under Section 9.1.4, then, during the period when Pfizer performs such Manufacture, Pfizer shall select from its representatives the new chairperson for the JMC during the first [***] after the commencement of such performance, and every [***] thereafter the Party for which the then-current chairperson is not a representative shall selects from its representatives the new chairperson for the JMC. From time to time, the Party with the right to appoint the chairperson may change the representative who will serve as chairperson on written notice to the other Party.

Section 2.3 Joint Steering Committees. Subject to the dispute resolution authority of the Executive Officers as set forth in Section 2.1, the WH JSC and the Oncology JSC shall have overall responsibility for monitoring and providing general operational oversight with respect to the Parties' activities under this Agreement with respect to, respectively, the WH Product(s) and any Pediatric Product(s), if Developed, in the case of the WH JSC and the Oncology Product(s) in the case of the Oncology JSC. In particular, the WH JSC (with respect to the WH Product(s) and Pediatric Product(s)) or the Oncology JSC (with respect to the Oncology Product(s)) shall be responsible for:

2.3.1 overseeing the strategic operational aspects of the Development and Commercialization of the WH Product(s), or Oncology Product(s) (as applicable) in the Field and Territory pursuant to the applicable Joint Medical Affairs and Development Plan and Budget and Co-Promotion Commercialization Plan and Budget;

2.3.2 reviewing and discussing reports from the various Committees and other future Committees, and providing guidance thereto;

2.3.3 directing and overseeing the various Committees on all significant strategic issues that fall within the purview of the various Committees;

2.3.4 resolving matters presented to it by, and disputes raised to it by each JMDRC; each JCC, the JMC, the JFC, the IPOC, the Compliance Committee or any Working Group established by the applicable JSC;

2.3.5 reviewing and approving each update or change to the applicable Joint Medical Affairs and Development Plan and Budget proposed by the applicable JMDRC other than an amendment to the budget (which shall be governed by Section 2.3.10), including any such update or change to include any Product in the WH Field or Oncology Field other than the Products as they exist as of the Effective Date or a new women's health or oncology indication for any Product;

2.3.6 reviewing the Pfizer Operation Plan and amendments thereto provided by Pfizer under Section 10.5.5;

2.3.7 reviewing and approving any Co-Administration Study for inclusion in the Joint Medical Affairs and Development Plan and Budget;

2.3.8 reviewing and approving the budget and resources in support of each protocol for each Clinical Trial or Other Study with respect to the Products in the Field in the Co-Promotion Territory and if needed amend the applicable Joint Medical Affairs and Development Plan and Budget to provide for such budget and resources;

2.3.9 reviewing and approving each update or change with respect to any Co-Promotion Commercialization Plan and Budget proposed by the applicable JCC other than an amendment to the budget (which shall be governed by Section 2.3.10);

2.3.10 reviewing and approving any amendment of the budget, in any Joint Medical Affairs and Development Plan and Budget (subject to Section 2.4.21) or Co-Promotion Commercialization Plan and Budget;

2.3.11 reviewing and approving any additional costs to constitute Allowable Costs;

2.3.12 reviewing and approving any Excess Development Costs, Excess Advertising Costs and Excess Commercialization Costs;

2.3.13 to the extent permitted under Applicable Law, discussing and approving Pricing Matters in the Co-Promotion Territory;

2.3.14 discussing and agreeing whether to recall or withdraw the applicable Product in the Field or distribute a "Dear Doctor" letter pursuant to Section 4.4;

2.3.15 reviewing and approving the Co-Promotion Branding Strategy for the WH Product(s) or the Oncology Product(s) in the Field in the Co-Promotion Territory (as applicable) prepared by the applicable JCC;

2.3.16 approving the pricing and rebating strategies for any Product in the Field in the Co-Promotion Territory;

2.3.17 overseeing the activities of the applicable Joint Review Committee, and seek to resolve disputes referred by any Joint Review Committee;

2.3.18 reviewing recommendations of the IPOC;

2.3.19 approving the entry into any Third Party License with respect to the Co-Promotion Territory pursuant to Section 10.3.6;

2.3.20 establishing any reasonable policies to effectuate exchange of data and Know-How in accordance with Section 3.6,

2.3.21 reviewing and agreeing on any capacity expansion plan set out in Section 9.2.2;

2.3.22 providing operational direction for and coordinating the Parties' activities under this Agreement, including operational oversight of any JMDRC, any JCC, the JMC, the JFC, the IPOC, the Compliance Committee or other Committee;

2.3.23 establishing Working Groups in accordance with Section 2.10.5; and

2.3.24 performing such other functions as are assigned to the applicable JSC as set forth herein or as the Parties may mutually agree in writing.

Section 2.4 Joint Development, Medical and Regulatory Committees. Subject to the authority of the applicable JSC as set forth in Section 2.3, the WH JMDRC and the Oncology JMDRC shall develop the strategies for and oversee the Development of, and shall serve as a forum for the coordination of medical affairs and Development activities for the WH Product(s) and any Pediatric Product(s), if Developed (in the case of the WH JMDRC), or the Oncology Product(s) (in the case of the Oncology JMDRC) in the Territory. In particular, the WH JMDRC (with respect to the WH Product(s) and any Pediatric Product(s), if Developed) and the Oncology JMDRC (with respect to the Oncology Product(s)) shall have responsibility to:

2.4.1 prepare, review and recommend for approval by the applicable JSC, each Joint Medical Affairs and Development Plan and Budget for the Products in the Field in the Co-Promotion Territory, it being understood that the initial Joint Medical Affairs and Development Plan and Budget for the Products in the Field in the Co-Promotion Territory that are attached to this Agreement have been agreed to by the Parties;

2.4.2 review and approve any pre-clinical activities to be performed by Pfizer (which activities shall be limited to using the Compound in the Field, WH Product in the WH Field or Oncology Product in the Oncology Field) outside of the Joint Medical Affairs and Development Plan and Budget (and, as part of any such approval, establishing how data and results arising from such pre-clinical activities will be reported or otherwise made available to Myovant, and the amount of API to be supplied by Myovant to Pfizer for the performance of such pre-clinical activities);

2.4.3 following Option Closing (if it occurs), review and approve any Clinical Trials or Other Studies proposed to be performed by Pfizer for the Oncology Product in the Oncology Field in the Pfizer Territory;

2.4.4 in coordination with the JFC, review and update quarterly financial forecasts for medical affairs and Development in the Co-Promotion Territory, including regulatory activities, to ensure actual and anticipated expenditure is within the approved Joint Medical Affairs and Development Plan and Budget for the relevant Calendar Year and make recommendations to the JSC for approval to any variances before such additional expenditure is incurred;

2.4.5 oversee the conduct of medical affairs and Development activities under the applicable Joint Medical Affairs and Development Plan and Budget and reporting in connection therewith pursuant to Section 3.4, and track the performance of the medical affairs and Development activities against the applicable Joint Medical Affairs and Development Plan and Budget, provided that, the CMC activities with respect thereto shall be overseen by the JMC;

2.4.6 review and approve any Product in the WH Field or Oncology Field other than the Products as they exist as of the Effective Date for inclusion in the Joint Medical Affairs and Development Plan and Budget;

2.4.7 in coordination with the JFC, review and propose to the JSC for approval any Excess Development Costs for inclusion in the budget of the applicable Joint Medical Affairs and Development Plan and Budget;

2.4.8 serve as a forum for discussing proposed medical affairs and Development activities with respect to the Products in the Field in the Co-Promotion Territory and the possible inclusion thereof in the applicable Joint Medical Affairs and Development Plan and Budget;

2.4.9 review and serve as a forum for discussing proposed amendments to the applicable Joint Medical Affairs and Development Plan and Budget and propose to the applicable JSC for its approval appropriate amendments thereto;

2.4.10 review and approve the protocol and any amendments thereto for each Clinical Trial included in the applicable Joint Medical Affairs and Development Plan and Budget, provided that each such protocol shall be consistent with the requirements for such Clinical Trial set forth in such Joint Medical Affairs and Development Plan and Budget, and review and serve as a forum for discussing the budget and resources in support of such protocol and propose to the applicable JSC for its approval each such budget and resources as an amendment to the applicable Joint Medical Affairs and Development Plan and Budget;

2.4.11 assign to a Party the responsibilities in respect of operationalizing any new protocols approved for inclusion in the Oncology Joint Medical Affairs and Development Plan and Budget;

2.4.12 review and approve all Major Regulatory Filings with respect to the Products in the Field the Co-Promotion Territory (provided that, the CMC portions of such Major Regulatory Filings shall be subject to approval by the JMC under Section 2.6.3);

2.4.13 serve as a forum for discussing strategies for obtaining and maintaining Regulatory Approval for the Products in the Field in the Co-Promotion Territory and oversee regulatory matters in the Co-Promotion Territory with respect to the Products in the Field;

2.4.14 oversee and review Development Costs with respect to the applicable Product in the Field in the Co-Promotion Territory and any invoices or other appropriate supporting documentation for any payments made by a Party or its Affiliates to Third Parties reported under Section 3.5.2, and track the actual Development Costs incurred against the budget therefor included in the applicable Joint Medical Affairs and Development Plan and Budget;

2.4.15 decide whether and when to initiate or discontinue any Clinical Trials or Other Studies conducted under the Joint Medical Affairs and Development Plan and Budget (except to the extent that the applicable JSC assigns all or part of this responsibility to the applicable JMDRC);

2.4.16 establish and oversee a joint medical review committee for review of medical materials with respect to the Products in the Field in the Co-Promotion Territory;

2.4.17 oversee the quality and safety matters with respect to the Products in the Field in the Co-Promotion Territory;

2.4.18 review, discuss and coordinate the Presentation and Publication Plans;

2.4.19 review and facilitate discussion of proposed Publications and resolve disputes with respect thereto;

2.4.20 oversee and review medical-to-medical activities, including the nature of the medical affairs activities for the Products in the Field to be conducted in each country in the Co-Promotion Territory (including procedures for responding to information requests from healthcare providers) and the Joint Medical Affairs Plan;

2.4.21 approve the Joint Medical Affairs Plan in accordance with Section 7.2;

2.4.22 coordinate with the applicable JCC as appropriate;

2.4.23 provide updates on the applicable JMDRC's activities and achievements to the applicable JSC as requested by the applicable JSC; and

2.4.24 perform such other functions as are assigned to the JMDRC as set forth herein or as the Parties may mutually agree in writing.

Section 2.5 Joint Commercialization Committees. Subject to the authority of each JSC as set forth in Section 2.3, the WH JCC and the Oncology JCC shall develop the strategies for and oversee the Commercialization of, respectively, the WH Product(s) or the Oncology Product(s) in the Territory. In particular, the WH JCC and the Oncology JCC shall (with respect to the WH Product(s) or the Oncology Product(s), respectively):

2.5.1 establish a commercial strategy for the Commercialization of the Products in the Co-Promotion Territory;

2.5.2 oversee the implementation of each Co-Promotion Commercialization Plan and Budget;

2.5.3 oversee the implementation of any Sample plan under Section 6.4.1;

2.5.4 discuss, prepare, and submit to the applicable JSC for review and approval each Co-Promotion Commercialization Plan and Budget in accordance with Section 5.2;

2.5.5 review and serve as a forum for amendments or updates to the Co-Promotion Commercialization Plan and Budgets, and propose to the applicable JSC for its approval of any such amendments or update, including any such amendment or update with respect to the inclusion of appropriate Commercialization activities with respect to the applicable Product in the Field in the Co-Promotion Territory after grant of Regulatory Approval;

2.5.6 oversee Detailing efforts of each Party, including reviewing each Party's performance with respect to Incentive Compensation Allocation or [***] (if applicable) of its Sales Force, for the Products in the Field in the Co-Promotion Territory in the applicable Calendar Quarter;

2.5.7 in coordination with the JFC, review and propose to the JSC for approval any Excess Advertising Costs or Excess Commercialization Costs for inclusion in the budget of the applicable Co-Promotion Commercialization Plan and Budget;

2.5.8 oversee Commercialization activities in the Field in the Co-Promotion Territory with respect to any Product in the Field and reporting in connection therewith pursuant to Section 6.1.4 and Section 8.5.3;

2.5.9 develop any Joint Promotional and Educational Materials in accordance with Section 6.3.1;

2.5.10 review and approve the OPDP Strategy;

2.5.11 discuss and agree which Party shall be responsible for developing [***] marketing campaigns, in each case, with respect to the Products in the Field in the Co-Promotion Territory;

2.5.12 approve and oversee [***] patient support marketing material for the Products in the Field the Co-Promotion Territory;

2.5.13 approve rebates, contracting strategy and contracting rates, approve and oversee contracting and government reporting for the Products in the Field in the Co-Promotion Territory;

2.5.14 review the sales forecast of the Products under the Co-Promotion Commercialization Plan and Budget, and based on such sales forecast, discuss and agree on the demand forecast in respect of the supply of the Products in the Field in the Co-Promotion Territory;

2.5.15 following Option Closing (if it occurs), if Myovant is responsible for the Manufacture of the Oncology Product in the Pfizer Territory, discuss the demand forecast in respect of the supply of the Oncology Product(s) in the Pfizer Territory;

2.5.16 serve as a forum for discussing Allowable Expenses against the budget therefor included in the Co-Promotion Commercialization Plan and Budget;

2.5.17 review and approve any joint Sales Representative training program(s) for each Product in the Field in the Co-Promotion Territory;

2.5.18 discuss Pricing Matters in the Co-Promotion Territory, for approval by the applicable JSC;

2.5.19 coordinate with the applicable JMDRC as appropriate, including to consult with such JMDRC with respect to Product Labeling in the Co-Promotion Territory;

2.5.20 provide updates on the JCC's activities and performance to the Co-Promotion Commercialization Plans and Budgets;

2.5.21 discuss and approve the use of any Product Trademark with any Product in the Field in the Co-Promotion Territory (to the extent not already used with such Product in the Co-Promotion Territory);

2.5.22 discuss the pricing and rebating strategies for any Product in the Field in the Co-Promotion Territory; and

2.5.23 perform such other functions as are assigned to the applicable JCC as set forth herein or in the Related Agreements or as the Parties may mutually agree in writing.

Section 2.6 Joint Supply and Manufacturing Committee. Subject to the authority of each JSC as set forth in Section 2.3, the JMC shall develop the strategies for and oversee operational efficiency in the supply chain with respect to the Compounds, WH Product(s) and Oncology Product(s) for Commercialization in the Field in the Co-Promotion Territory and in the Pfizer Territory, to the extent Myovant is supplying Oncology Product(s) to Pfizer in the Pfizer Territory or to the extent the Parties are jointly engaging the same Existing CMO with respect to the Manufacture of Products. In particular, solely with respect to the Compounds and Products in the Field in the Pfizer Territory, if applicable, and Co-Promotion Territory, the JMC shall:

2.6.1 oversee and coordinate the Manufacturing and supply of the Compound for use in the Products in the Field in the Territory hereunder as well as all aspects of Manufacturing and supplying Products for use hereunder and reporting in connection therewith pursuant to Section 9.4, including activities under any Supply Agreement(s) and Quality Agreement(s);

2.6.2 oversee quality and compliance in Manufacturing and supply;

2.6.3 review and approve the CMC portions of any Major Regulatory Filing with respect to the Products in the Co-Promotion Territory, which may be prepared by a Working Group to be established by the JMC;

2.6.4 oversee the CMC activities with respect to the Products in the Field in the Territory;

2.6.5 review Manufacturing capacity and evaluate Pfizer's capability as a secondary supplier of the Products in the Field in the Territory for use hereunder and oversee any technology transfer that the JMC authorizes hereunder;

2.6.6 review and serve as a forum for discussing proposed amendments to any Joint Medical Affairs and Development Plan and Budget related to Manufacturing process, development scale-up, Manufacturing process validation (including validation batches), Manufacturing improvements and qualification and validation with respect to the Products in the Field in the Territory, and propose to the applicable JSC for its approval appropriate amendments thereto;

2.6.7 review and serve as a forum to discuss matters in relation to supply forecasts, all significant work necessary to establish capacity for and to support ongoing or anticipated Commercialization of the Products in the Field in the Territory, including the timelines thereof; any process development or other activities with a view to improving cost of goods for such Products;

2.6.8 developing any budget for inclusion in the Joint Medical Affairs and Development Plan and Budget in respect of any process development, scale up or, technology transfer as agreed to by the Parties with respect to the Products in the Field in the Territory;

2.6.9 unless otherwise agreed between the Parties in the applicable Supply Agreement or the Quality Agreement, review and revise, as appropriate, the Manufacturing specifications of Products in the Field in the Territory;

2.6.10 review and discuss inventory holding strategies and stock levels of raw materials and intermediates for Products and finished Product in the Field in the Territory;

2.6.11 unless otherwise agreed between the Parties in the applicable Quality Agreement, review results of regulatory and environmental, health, and safety inspections and audits related to the Manufacture of Products in the Field in the Territory and review steps taken by either Party to address any deficiencies noted;

2.6.12 promptly report to the applicable JSC, JMDRC and JCC all quality and manufacturing issues that substantially adversely affect or are reasonably expected to substantially adversely affect the clinical or commercial manufacture or supply of the Products in the Field in the Territory, and review and discuss any comments from the applicable JSC, JMDRC and JCC with respect to such quality and manufacturing issues; and

2.6.13 perform such other functions as are assigned to the JMC as set forth herein or as the Parties may mutually agree in writing.

Section 2.7 Joint Finance Committee. Subject to the authority of each JSC as set forth in Section 2.3, the Joint Finance Committee shall have the following responsibilities with respect to Products hereunder:

2.7.1. working with the other Committees to assist in financial, forecasting, budgeting and planning matters as required, including (a) assisting in the preparation, for approval by the JSC, of such reports on financial matters as are requested by the JSC for the implementation of the financial aspects of the Development and Commercialization activities with respect to the Products in the Co-Promotion Territory, (b) overseeing the preparation by the Parties of the budgets of the Joint Medical Affairs and Development Plan and Budgets and the Co-Promotion Commercialization Plan and Budgets by each JMDRC and JCC, as applicable, for such Development and Commercialization activities as a whole for submission to the JSC for review and approval, (c) assisting in the preparation and review of requests for approval by the JSC of inclusion of Excess Development Costs, Excess Advertising Costs or Excess Commercialization Costs in the applicable Budget, as applicable (d) assisting in the preparation of other budgets and annual and long-term plans for JSC approval, (e)

as requested by a Party, coordinating the preparation of quarterly updates to annual budgets, (f) assisting the JCC and JCC in developing the long-range forecast for commercial supply of the Products, (g) supporting the development of the revenue forecast model or methodology; (h) supporting development and review of Product revenue forecasts at each official submission and update; and (i) review of the any question regarding reports set out in Section 8.3.4 with respect to Net Sales and calculation of resulting royalties;

2.7.2. recommending and approving procedures, formats and timelines consistent with this Agreement for reporting financial data and assist in resolving differences that relate to the financial terms of this Agreement; provided, that no Party shall be required to make any material changes to its internal accounting and reporting systems and standards;

2.7.3. recommending to the JSC any changes to, or additional items to be included within the Allowable Expenses;

2.7.4. on a quarterly basis, reviewing the costs and expenses to be included in the Allowable Expense calculation in accordance with the terms of this Agreement;

2.7.5. reviewing calculations of the amount of any payments to be made by the Parties (or their Affiliates) hereunder, reviewing the reconciliation of payments and discussing and recommending to the Parties the most appropriate and tax effective methods of cost sharing and determination and distribution of the Net Profits or Net Losses to a Party or its Affiliates consistent with this Agreement;

2.7.6. coordinating audits of data where appropriate and required or allowed by this Agreement;

2.7.7. coordinating with the other Committees, as appropriate and applicable;

2.7.8. establishing the inter-party procedures, contracts (if necessary), and financial structure necessary to effect that economic result contemplated by this Agreement and monitoring and maintaining such structure;

2.7.9. recommending and approving adjustments to the timing of true-up payments pursuant to Section 8.4; and

2.7.10. perform such other functions as are assigned to the JFC as set forth herein or as the Parties may mutually agree in writing.

Section 2.8 Intellectual Property Operating Committee. Subject to the authority of each JSC as set forth in Section 2.3, the IPOC shall be responsible for overseeing all intellectual property matters related to the Compound and Products (including the Parties' publication of material regarding the Compound or Products), including with respect to the matters set forth below, and recommending strategies with respect thereto, but the IPOC shall not have any decision-making authority. The IPOC's responsibilities shall include (i) providing guidance with respect to procedural matters regarding the prosecution and maintenance of intellectual property related to the Compounds and Products; (ii) making recommendations, including to applicable Committees, regarding strategies for Product exclusivity and market protection and for obtaining, maintaining, defending and enforcing patent or trademark protection for the Compounds and Products, including claiming strategy, country scope for patent filings, trademark filing strategy, country scope for trademark filings, Patent extensions, enforcement actions, freedom to operate clearances, challenges to Third Party blocking intellectual property and licensing strategies for intellectual property necessary or useful for Exploiting the Compounds and Products in the Field in the Territory; (iii) performing review and clearance of disclosures and publications of intellectual property related to the Compounds or Products as set forth in Section 12.2.1 and Section 12.6; (iv) serving as a forum for the prompt disclosure of all material issues relating to the intellectual property that is the subject of this Agreement; (v) facilitating cooperation between the Parties (including their respective internal and external counsels) on the intellectual property provisions set forth under this Agreement and local Applicable Law in the Territory; and (vi) updating or reconfirming the anticipated market exclusivity period for each Product for the United States, the European Union and other markets as needed by applicable Committees.

Section 2.9 Compliance Committee. The Parties agree to establish a Compliance Committee (the "**Compliance Committee**") within [***] days after the Effective Date of this Agreement. The Compliance

Committee shall be comprised of [***] representative from each Party or such other number as may be mutually agreed by the Parties, provided that each Party at all times shall have an equal number of representatives on the Compliance Committee. Subject to the terms and conditions of this Agreement, the Compliance Committee shall have overall responsibility for seeking to resolve discrepancies between the Parties' respective compliance policies; managing compliance with corporate integrity agreements and deferred prosecution agreements (or similar agreements/settlement documents) to which either of the Parties, which are engaged in Development or Commercialization, are subject; and ensuring a process to monitor the Parties' activities under this Agreement for compliance with all Applicable Law. The Compliance Committee shall not have any decision-making authority.

Section 2.10 General Provisions Applicable to Committees. The following general provisions shall govern the conduct of each of the Committees, except as otherwise agreed by the Parties:

2.10.1 Meetings and Minutes. Each JSC shall meet at least [***] per year and each JMDRC, each JCC, the JMC and JFC shall each meet quarterly or, in each case, at such higher frequency as otherwise agreed by the Parties, with the location of such meetings, if not virtual, alternating between locations designated by Myovant and locations designated by Pfizer. Representatives of the Parties on a Committee may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by, and be heard by, the other participants. The chairperson of the applicable Committee shall be responsible for calling meetings on no less than [***] Business Days' notice (unless the Parties consent in writing to a shorter notice period). Each Party shall make all proposals for agenda items and shall provide all appropriate information with respect to such proposed items at least [***] Business Days in advance of the applicable meeting; *provided* that under exigent circumstances requiring input by a Committee, a Party may provide its agenda items to the other Party within a shorter period of time in advance of the meeting or may propose that there not be a specific agenda for a particular meeting, so long as the other Party consents to such later addition of such agenda items or the absence of a specific agenda for such meeting, such consent not to be unreasonably withheld, conditioned or delayed. The chairperson of a Committee shall prepare and circulate for review and approval of the Parties minutes of each meeting within [***] days after the meeting. The Parties shall agree on the minutes of each meeting promptly, but in no event later than the next meeting of the applicable Committee.

2.10.2 Procedural Rules. Each Committee shall have the right to adopt such standing rules as shall be necessary for its work, to the extent that such rules are not inconsistent with this Agreement. A quorum of the Committee shall exist whenever there is present at a meeting at least one (1) representative appointed by each Party. Employees of each Party (or its Affiliates) that are not representatives of such Party on a Committee may attend meetings of such Committee with prior written notice to the other Party; *provided*, *however*, that such attendees (a) shall not vote or otherwise participate in the decision-making process of the Committee, and (b) are bound by obligations of confidentiality and non-disclosure equivalent to those set forth in Article XII.

2.10.3 Decision-Making.

(a) Within the Committees. Except as expressly provided in this Section 2.10.3, actions to be taken by each Committee shall be taken only following a unanimous vote, with the representatives of each Party on such Committee collectively having one (1) vote. Each Party shall use, and shall ensure that its representatives on a Committee use, reasonable good faith efforts to reach consensus on all matters submitted to any such Committee or Working Group.

(b) Disagreements on a Committee. Without limiting the other rights and obligations of the Parties under this Agreement, any disagreement between the designees of the Parties on any JMDRC, the JMC, the JFC, any JCC, IPOC or Compliance Committee as to matters within such Committee's jurisdiction shall upon notice by a Party to the other, be submitted to either JSC for resolution (provided that: (i) if the matter relates solely or mainly to the WH Product(s) or Pediatric Product(s), if Developed, such matter shall be submitted to the WH JSC, (ii) if the matter relates solely or mainly to the Oncology Product(s), such matter shall be submitted to the Oncology JSC; and (iii) with respect to any matter that does not fall within the foregoing subclause (i) or (ii), such matter shall be submitted to both JSCs). If (x) such JSC does not resolve any such matter submitted to it for resolution within [***] Business Days after such submission (or, in the case of any matter described in Section 2.10.3(b)(iii), if both JSCs do not unanimously agree on such matter submitted to them for resolution within [***] Business Days after such submission), or (y) any JSC fails to resolve any

disagreement between the designees of the Parties on such JSC with respect to any other matter within its jurisdiction within [***] Business Days after initially considering such matter, the matter shall be submitted for attempted resolution by the Executive Officers. If such matter is not resolved by the Executive Officers within [***] Business Days of such matter having referred to them, such unresolved matter shall constitute an "**Unresolved Committee Matter**."

(c) Final Decision-Making; Deadlock. With respect to any Unresolved Committee Matter:

(i) Myovant shall have final decision-making authority with respect to the following Unresolved Committee Matters (each, a "**Myovant Controlled Matter**"): (A) [***]; (B) [***]; (C) [***]; (D) [***]; (E) [***]; (F) [***]; and (G) [***].

(ii) Subject to subclause (i) above, Pfizer shall have final decision-making authority with respect to the following Unresolved Committee Matters (each, a "**Pfizer Controlled Matter**"): (A) [***]; (B) [***]; (C) [***]; (D) [***]; (E) [***]; (F) [***]; and (G) [***].

(iii) Any Unresolved Committee Matter that is not a Myovant Controlled Matter or Pfizer Controlled Matter [***], except that, if such Unresolved Committee Matter is an Arbitration Matter, either Party may refer any such Arbitration Matter for resolution under Section 17.2. [***].

2.10.4. Limitations on Authority. Each Party shall retain the rights, powers, and discretion granted to it under this Agreement and no such rights, powers, or discretion shall be delegated to or vested in a Committee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. No Committee shall have the power to amend, modify, or waive compliance with any provision of this Agreement, which may only be amended or modified as provided in Section 18.7 or compliance with which may only be waived as provided in Section 18.12.

2.10.5. Working Groups. From time to time, any Committee may establish and delegate duties to other committees or directed teams (each, a "**Working Group**") on an "as-needed" basis to oversee particular projects or activities. Each such Working Group shall be constituted and shall operate as such Committee determines; *provided* that each Working Group shall have equal representation from each Party unless otherwise agreed to by the applicable Committee; *provided*, *further*, unless otherwise expressly set forth herein, that any dispute between the representatives of each Party shall be referred to such Committee for resolution in accordance with Section 2.10.3 and the other terms and conditions of this Agreement. Working Groups may be established on an ad hoc basis for purposes of a specific project, for the Term or on such other basis as such Committee may determine. Each Working Group and its activities shall be subject to the oversight, review and approval of, and shall report to, such Committee. In no event shall the authority of the Working Group exceed that specified for the relevant Committee in this Article II.

2.10.6. Joint Review Committees.

(a) On the Effective Date in the case of the Oncology Product(s), and in the case of the WH Product(s) reasonably in advance of launch of the WH Product(s) in the Co-Promotion Territory, the Parties shall establish a joint review committee to govern the implementation and use of Promotional and Educational Materials with respect to the WH Product(s) in the Co-Promotion Territory (the "**Joint WH Review Committee**"), and a joint review committee to govern the implementation and use of Promotional and Educational Materials with respect to the Oncology Product(s) in the Co-Promotion Territory (the "**Joint Oncology Review Committee**") (each such committee, a "**Joint Review Committee**"), as a Working Group under the overall supervision of the WH JSC or the Oncology JSC, respectively. Each Joint Review Committee shall consist of at least [***] representatives from each of the Parties, with [***] representative from each of such Party's medical, legal and regulatory teams, each with the requisite experience and seniority to enable such person to make decisions on behalf of the Party appointing him or her with respect to the issues falling within the jurisdiction of such Joint Review Committee. As of the Effective Date, each Party's representatives of each Joint Review Committee are as set out in Exhibit 2.2.

2.10.7. The Joint WH Review Committee and the Joint Oncology Review Committee shall (with respect to the WH Product(s) and the Oncology Product(s) in the Co-Promotion Territory, respectively):

(a) review and, where appropriate, approve the proposed Promotional and Educational Materials for the applicable Product in the Field for use in the Co-Promotion Territory;

(b) periodically evaluate the suitability of any Promotional and Educational Materials with respect to the applicable Product in the Field in the Co-Promotion Territory; and

(c) discuss and propose the strategy to the applicable JCC in relation to submissions and interactions with the Office of Prescription Drug Promotion (OPDP) in the US (the "**OPDP Strategy**").

2.10.8. [***].

Section 2.11 Alliance or Project Manager.

2.11.1. Appointment. Within [***] days following the Effective Date, each Party shall appoint (and notify the other Party of the identity of) a representative of such Party to act as its alliance or project manager under this Agreement (each an "**Alliance Manager**"). Each Party may replace its Alliance Manager at any time by written notice to the other Party. Each Party's Alliance Manager shall be an additional representative on each Committee.

2.11.2. Specific Responsibilities. The Alliance Managers will serve as the primary contact point between the Parties for the activities under this Agreement for the purpose of providing each Party with information on the progress of Development and Commercialization of the Products and shall have the following responsibilities:

(a) facilitate the flow of information and otherwise promote communication, coordination and collaboration between the Parties;

(b) coordinate the various functional representatives of each Party, as appropriate, in developing and executing strategies and plans for the Products;

(c) provide a single point of communication for seeking consensus both internally within each Party's organization and between the Parties regarding key strategy and planning issues, including updates to the Committees;

(d) assist the integration of teams across functional areas;

(e) assist Committees in identifying and raising cross-Party or cross-functional disputes in a timely manner; and

(f) perform such other functions as agreed by the Parties.

Section 2.12. Expenses. Each Party shall bear its own costs, including travel costs and taxes (whether imposed on the personnel or the Party), for personnel serving on the Committees or Working Groups, except as otherwise explicitly agreed herein. Expenses so borne by either Party shall not be deemed to constitute Allowable Expenses.

Section 2.13. Disbandment. Notwithstanding anything to the contrary herein, any Committee or Working Group under this Agreement may be dissolved upon the mutual written agreement of the Parties. In the event of disbandment of any Working Group, all responsibilities and decisions allocated to such Working Group shall revert to the Committee that created such Working Group. In the event of disbandment of any Committee other than a JSC, all responsibilities and decisions allocated to such Committee shall be deemed allocated to the applicable JSC. In the event of disbandment of a JSC, all responsibilities and decisions allocated to such JSC shall be deemed allocated to the Executive Officers, *provided* that the final decision-making authority of each Party shall remain in accordance with Section 2.10.3(c).

ARTICLE III.
DEVELOPMENT

Section 3.1 Joint Development.

3.1.1 Joint Medical Affairs and Development Plans and Budgets.

(a) The Development and medical affairs related activities with respect to the WH Product(s) in the WH Field and, if Developed, the Pediatric Product in the Pediatric Field in the Co-Promotion Territory shall be conducted pursuant to a plan and budget (the "**WH Joint Medical Affairs and Development Plan and Budget**"), and the Development and medical affairs related activities with respect to Oncology Product(s) in the Oncology Field in the Co-Promotion Territory shall be conducted pursuant to a plan and budget (the "**Oncology Joint Medical Affairs and Development Plan and Budget**") (each such plan and budget, a "**Joint Medical Affairs and Development Plan and Budget**"), which, with respect to the WH Product(s) or the Oncology Product(s), respectively, shall:

(i) set forth the budget for the anticipated Development Costs and Manufacturing Costs in relation to such Development, including those with respect to such medical affairs and Development activities, with separate budget allocation for: (a) [***]; (b) [***] and (c) [***]; and

(ii) assign responsibility for performing all such medical affairs and Development activities as between the Parties; *provided* that, unless otherwise agreed by the Parties: (1) [***]; and (2) [***]; and (3) [***].

(b) The initial WH Joint Medical Affairs and Development Plan and Budget is attached to the [***], and the initial Oncology Joint Medical Affairs and Development Plan and Budget is attached to the [***]. Each such initial Joint Medical Affairs and Development Plan and Budget includes: (i) an initial budget covering anticipated Development Costs from the Effective Date through [***]; and (ii) a plan setting out a list of Clinical Trials and Other Studies to be performed covering the period from the Effective Date through [***] and the general budget of estimated costs and timelines with respect thereto (such list, the "**Long-Term Study Plan**"). Prior to each [***] after the Effective Date, each JMDRC shall review the applicable Joint Medical Affairs and Development Plan and Budget, for the purpose of considering appropriate amendments thereto, and review and update such plans to reflect the Development Costs reasonably expected to be incurred for the subsequent Budget Period for the then ongoing medical affairs activities and Development of the applicable Product(s) in the Field in the Co-Promotion Territory. Any updated Joint Medical Affairs and Development Plan and Budget for a Calendar Year will be agreed to by the applicable JSC by [***] of the preceding Calendar Year, and must set out the budget for Development Costs in relation to the Clinical Trials and the Other Studies set out in the Long-Term Study Plan.

(c) The applicable JSC shall agree if and when the Parties shall commence Development of the Products in the Field in Canada. Following such time, the applicable JSC shall amend the applicable Joint Medical Affairs and Development Plan and Budget to reflect the additional medical affairs and Development activities and budget with respect to Canada, such amendment shall include any Required Studies with respect to such Product in Canada and any additional regulatory costs associated therewith shall be included in the amended budget.

3.1.2 Additional Amendments to the Joint Medical Affairs and Development Plan and Budget.

(a) In addition to the annual review of each Joint Medical Affairs and Development Plan and Budget by the applicable JMDRC under Section 3.1.1(b), either Party, directly or through its representatives on the relevant JMDRC, may propose updates or amendments to the applicable Joint Medical Affairs and Development Plan and Budget from time to time as appropriate. Any and all such updates or amendments to any Joint Medical Affairs and Development Plan and Budget shall be considered by the applicable JMDRC and approved by the applicable JSC as set forth in Section 2.3.5 and Section 2.3.10.

(b) No amendments to any Joint Medical Affairs and Development Plan and Budget shall take effect, unless and until such amendments are approved by the applicable JSC.

3.1.3 Diligence; Cost Overruns.

(a) Co-Promotion Territory.

(i) [***] shall use [***] to perform the medical affairs and Development activities assigned to it under each Joint Medical Affairs and Development Plan and Budget for the Co-Promotion Territory in accordance with the timeline and budget set forth therein, including [***].

(ii) [***] shall use [***] to Develop and obtain Regulatory Approval of the WH Product for Uterine Fibroids and the WH Product for Endometriosis, in each case, in the United States.

Following the date agreed by the Parties for the commencement of the Regulatory Activities with respect to Canada pursuant to Section 4.1.2(a), the Party responsible for seeking Regulatory Approval for the WH Product in the Field and the Oncology Product in the Field in Canada, as determined by the Parties, which may be the same or different Parties, shall use [***] Commercially Reasonable Efforts to obtain Regulatory Approval of the Oncology Product for prostate cancer, or the WH Product for Uterine Fibroids and the WH Product for Endometriosis, as applicable, in Canada.

(iii) [***] shall use [***] to [***] set forth in (i) the WH Joint Medical Affairs and Development Plan and Budget related to seeking Regulatory Approval of the WH Product for Uterine Fibroids and the WH Product for Endometriosis, in each case, in the United States and (ii) following the date agreed by the JSC for the commencement of Development of the Products in the Field in Canada pursuant to Section 3.1.1(c), the applicable Joint Medical Affairs and Development Plan and Budget related to seeking Regulatory Approval of the Oncology Product for prostate cancer, the WH Product for Uterine Fibroids and the WH Product for Endometriosis, in Canada.

(iv) Operational or tactical level decisions necessary to execute the medical affairs and Development activities assigned to a Party pursuant to each Joint Medical Affairs and Development Plan and Budget, shall be within the decision-making authority of such Party; *provided* that: (i) all such decisions shall be consistent with the terms of this Agreement, the scope of such assignment, Applicable Law, the applicable Joint Medical Affairs and Development Plan and Budget and the decisions of the applicable Committees hereunder; and (ii) such Party shall periodically consult the applicable JMDRC with respect to operationalizing such operational or tactical level decisions and shall reasonably take into account such JMDRC's comments with respect thereto.

(b) Pfizer Territory. Following Option Closing (if it occurs):

(i) if Pfizer wishes to perform any Clinical Trials or Other Studies for the Oncology Product in the Oncology Field in the Pfizer Territory which are not already set out in the then-current Development Component of the Pfizer Operation Plan, Pfizer shall submit detailed particulars of such proposed Clinical Trials or Other Studies for the Oncology JMDRC's approval. Upon any approval by the Oncology JMDRC of such proposal, such proposal shall be deemed to be included as part of the Development Component of the Pfizer Operation Plan.

(ii) Following Option Closing (if it occurs), operational or tactical level decisions necessary to execute any medical affairs and Development activities in the Pfizer Territory shall be within the decision-making authority of Pfizer; *provided* that: (i) all such decisions shall be consistent with the terms of this Agreement and Applicable Law; and (ii) Pfizer shall periodically consult the Oncology JMDRC with respect to operationalizing such operational or tactical level decisions and shall reasonably take into account the Oncology JMDRC's comments with respect thereto.

Section 3.2 Performance Obligations.

3.2.1 Each Party shall perform, or cause to be performed, any and all of its Development activities in a good scientific manner and in compliance with all Applicable Law, including applicable Good Practices.

3.2.2 Clinical Trial Transparency. Without limiting the foregoing, each Party will maintain compliance with all Applicable Laws related to clinical trial transparency for the Products in the Field in the Territory, as well as any industry guidelines or codes of conduct, or other internal transparency policies that may apply to either the sponsor of any Clinical Trial for the Products in the Field in the Territory or the owner of any Regulatory Approval for the Products in the Field in the Territory. Without limiting the foregoing: (a) for clinical trial transparency activities associated with clinical trial sponsorship, each Party: (i) will perform registration (e.g., posting and maintaining protocol information) and summary results posting and maintenance activities on public registries or websites as required by Applicable law for all Clinical Trials or Other Studies of Products in the Field in the Territory, whether before or after the Effective Date, (ii) may register and post summary results for any Clinical Trials or Other Studies of Products in the Field in the Territory commenced after the Effective Date in accordance with such Party's individual registration transparency policies for clinical trials that such Party sponsors, and (iii) will follow its patient-level data and document sharing policies, will comply with any applicable data sharing requirements relating to Clinical Trials or Other Studies sponsored by

such Party, and will provide appropriate notification to the other Party of any such data sharing; and (b) each Party will retain responsibility for clinical trial transparency activities and requirements applicable to such Party as the owner of an NDA. The Parties will cooperate with each other as reasonably requested so that each Party may satisfy its Clinical Trial transparency and data sharing requirements consistent with this Section 3.2.2.

Section 3.3 No Development Outside of Development Plan in Co-Promotion Territory.

3.3.1 Except as set forth in Section 3.7 below, Pfizer shall not, and shall ensure that its Affiliates and Sublicensees shall not, directly or indirectly, conduct, initiate, sponsor, fund (other than via any investigator-initiated research outside of the Field), or supply any Product for any Development activities anywhere in the world with respect to the Products unless such activities are set forth in a Joint Medical Affairs and Development Plan and Budget, or, following Option Closing, if it occurs, the Development Component of the Pfizer Operation Plan (provided that, in relation to any Clinical Studies and Other Studies set out in the Development Component, solely as approved by the applicable JMDRC under Section 2.4.3) or otherwise by written agreement between the Parties.

3.3.2 Myovant shall not, and shall ensure that its Affiliates and Sublicensees shall not, directly or indirectly, conduct, initiate, sponsor, fund, or supply any Product in the Field for any Development activities with respect to the Products in the Field in the Territory unless such activities are assigned to Myovant in a Joint Medical Affairs and Development Plan and Budget or otherwise by agreement between the Parties (including pursuant to any Supply Agreement, if any); provided, however, that nothing in this Section 3.3.2 shall prevent Myovant, any Existing Myovant Third Party, or its Affiliates or Excluded Affiliates, from performing any such activities solely with respect to the (i) WH Product(s) in the WH Field for the Pfizer Territory or (ii) Products for the Takeda Territory.

Section 3.4 Records and Reports; Inspections.

3.4.1 Each Party shall, and shall cause its Affiliates and Third Party subcontractors to, maintain, in good scientific manner, complete and accurate written records, accounts, notes, reports, and data pertaining to its Development activities hereunder (all the foregoing, the "**Records**"), including [***] in sufficient detail to verify compliance with its obligations under this Agreement, in conformity with standard pharmaceutical practices and the terms of this Agreement. Without limiting the foregoing, such Records shall (a) be appropriate for patent and regulatory purposes, (b) be in compliance with Applicable Law, (c) properly reflect all work done and results achieved in the performance of the Development activities, and (d) be retained by such Party for at least [***] years after the expiration or termination of this Agreement in its entirety or for such longer period as may be required by Applicable Law. Each Party shall have the right, no more than once per Calendar Year, during normal business hours and upon reasonable prior written notice, at its own cost (such cost will not be an Allowable Expense) to inspect and review all such Records maintained by the other Party or its Third Party subcontractors pursuant to this Section 3.4.1 to ensure compliance with the terms of this Agreement; *provided* that the inspecting Party shall maintain such books and records and information disclosed therein in confidence in accordance with Article XII. Solely to the extent (i) [***] and (ii) required for Myovant to meet its obligations under the [***], Pfizer shall send to Myovant legible copies of such Records relating to activities under any Joint Medical Affairs and Development and Budget or, if following Option Closing (if it occurs), the Development Component of the Pfizer Operation Plan. In addition, Pfizer shall, upon Myovant's request, participate in good faith discussions with Myovant and Takeda at least annually to facilitate information sharing and the global coordination of the Exploitation of the Compound and Product.

3.4.2 Without limiting Section 3.4.1, each Party shall keep the applicable Committee informed of progress and results of activities for which it is responsible or that it is permitted to conduct hereunder through its members on such Committee at each regularly scheduled meeting thereof and as otherwise provided herein. Without limiting the foregoing, within [***] days following [***], or such other timeframe agreed by the JDC, during which a Party is conducting any Development activities hereunder, such Party shall provide the applicable JDC with a reasonably detailed report of such Development activities it has performed, or caused to be performed, since the preceding report (or with respect to the first such report, since the Effective Date) and its Development activities in process, and the future activities it expects to initiate, and such other information as determined by the JDC, which shall include such information as required for Myovant to provide [***].

Section 3.5 Development Costs.

3.5.1 Allocation of Development Costs.

(a) Joint Medical Affairs and Development Costs. Each Party (or any of its Affiliates) shall initially bear the costs and expenses incurred by such Party (or any of its Affiliates) in connection with performing medical affairs and Development activities under the Joint Medical Affairs and Development Plan and Budget, and any Development Costs to the extent constituting Allowable Expenses shall be shared between the Parties in accordance with Section 8.5.1 subject to Section 8.5.4.

(b) Other Allocation of Development Costs. Following Option Closing (if it occurs), Pfizer shall bear [***] of all FTE costs and Costs incurred by or on behalf of Pfizer or its Affiliates for Development of the Oncology Product in the Oncology Field in the Pfizer Territory.

3.5.2. Development Cost Reports. Each Party shall report to the other Party and each JMDRC, within [***] days after the end of each month, the Development Costs incurred by or on behalf of such Party or its Affiliates during such month under the applicable Joint Medical Affairs and Development Plan and Budget. Such report shall specify in reasonable detail, in a form as the Parties may mutually agree from time-to-time, all amounts included in such Development Costs during such month. Each such report shall enable the receiving Party to compare the reported Development Costs against the applicable Joint Medical Affairs and Development Plan and Budget, on both a monthly basis and a cumulative basis for each activity. The Parties shall seek to resolve any questions related to such cost reports within [***] days following receipt by each Party of the other Party's report hereunder.

3.5.3. Payments. As part of the reconciliation of Net Profits and Net Losses set forth in Section 8.5, Development Costs shall also be reconciled so that each Party bears [***] of the Development Costs provided in Section 3.5.1 for the applicable Calendar Quarter. There will be a single reconciliation of Net Profit/Net Losses under Section 8.5 and Development Costs such that there is one net payment made by one of the Parties to achieve the necessary reconciliation.

Section 3.6. Sharing of Data and Know-How. Each Party shall (and shall cause its Affiliates to) reasonably cooperate with the other Party to promptly share and provide access to the following (to the extent not already shared under Section 10.4): (a) all Clinical Trial data and results generated pursuant to the applicable Joint Medical Affairs and Development Plan and Budget and (b) such Other Collaboration Know-How, Product Collaboration Know-How and Know-How in Myovant Background IP (in the case of Myovant) and Know-How in Pfizer Background IP (in the case of Pfizer), including the Core Data Sheet, as is reasonably necessary for the other Party to exercise its rights or fulfill its obligations under this Agreement. Without limiting the foregoing, each Party shall promptly inform and disclose to the other Party through the IPOC all Joint Other Collaboration Know-How and Product Collaboration Know-How no later than [***] days after it first learns of the creation, discovery or development thereof if such Joint Other Collaboration Know-How or Product Collaboration Know-How contains patentable information based on the reasonable judgement of such Party. The JSC may establish, to the extent mutually agreed to by the Parties, reasonable policies to effectuate such exchange of data and Know-How between the Parties.

Section 3.7. Pre-Clinical Activities. Should [***] wish to conduct pre-clinical activities involving any Compound or Product outside the Joint Medical Affairs and Development Plan and Budget ([***]), [***] will submit a proposal in writing to the applicable JMDRC for approval. [***] shall ensure that such proposal shall include the [***] reasonably necessary for the performance of such activities. If the applicable JMDRC approves such pre-clinical activities: (a) [***] may perform such pre-clinical activities at its cost, and [***] will use [***] to provide [***] Pfizer with [***] approved by JMDRC, subject to availability and as promptly as practicable; and (b) [***] shall report or otherwise share the data and results from such pre-clinical activities in the manner agreed by the JMDRC. The cost of [***] by [***] (including the [***]) shall be deemed to be [***].

Section 3.8. Co-Administration Studies, New Products and Pediatric Products.

3.8.1. In the event that either Party desires to conduct one or more Co-Administration Studies involving an Other Product and the Compound or Product, such Party, on or before initiating such Co-Administration Study or Studies (the "**Proposed Co-Administration Studies**") shall provide the applicable

JMDRC with a study plan(s), proposed protocol(s) and budget(s) for such Proposed Co-Administration Studies as well as additional information that the applicable JMDRC may reasonably request related to such Co-Administration Studies. If such JMDRC approves the inclusion of such Proposed Co-Administration Studies in the applicable Joint Medical Affairs and Development Plan and Budget, such JMDRC shall amend the applicable Joint Medical Affairs and Development Plan and Budget for conducting such Proposed Co-Administration Studies and the applicable Party may perform such Co-Administration Study in accordance with the terms of this Agreement. Without limiting the licenses granted hereunder, each Party, with respect to the Other Product to the extent developed or commercialized by such Party and used in any Co-Administration Studies conducted under this Section 3.8.1 and, with respect to the Product in the Field used in any Co-Administration Studies conducted under this Section 3.8.1, shall have the perpetual, irrevocable right and license to utilize the data obtained from such Co-Administration Studies in connection with submission of Regulatory Materials, seeking Regulatory Approvals for and commercializing such Other Product. No other right, title, interest or license, express or implied, in or to the Other Product, including the right to receive any payments in connection with the commercialization of such Other Product, is granted by either Party or any of its Affiliates to the other Party or any of its Affiliates hereunder, notwithstanding any participation in or sharing of any costs by such Party.

3.8.2. New Products. Neither Party may perform any Development activities with respect to any New Product in the Field in the Territory, unless the Parties have agreed in writing to Develop a New Product as part of the Joint Medical Affairs and Development Plan and Budget, provided that, the Parties shall also agree to any relevant adjustments to this Agreement to account for such New Product, [***], any [***] used or incorporated in such New Product, as applicable. Nothing in this Section 3.8.2 shall prevent Myovant (whether by itself or with any Existing Myovant Third Party) from performing [***].

3.8.3. Pediatric Products. The Development activities with respect to the Pediatric Product in the Pediatric Field in the Co-Promotion Territory are set out in the initial WH Joint Medical Affairs and Development Plan and Budget. In addition, either Party may propose to include any additional Product for Development in a pediatric indication or any additional pediatric indication in the WH Joint Medical Affairs and Development Plan and Budget.

ARTICLE IV.
REGULATORY MATTERS AND DATA PRIVACY

Section 4.1 Regulatory Activities.

4.1.1 Regulatory Strategy in the Co-Promotion Territory. Each Joint Medical Affairs and Development Plan and Budget shall include the regulatory strategy for obtaining and maintaining Regulatory Approvals for the applicable Product in the Field in the Co-Promotion Territory.

4.1.2 Regulatory Activities Generally.

(a) Co-Promotion Territory. The Parties agree that Myovant shall be responsible for and shall have the sole right with respect to (i) the preparation, submission, and maintenance of all Regulatory Materials (including Drug Approval Applications), and (ii) conducting communications with the applicable Regulatory Authorities (together the "**Regulatory Activities**"), in each case, with respect to the Products in the United States. The Parties shall reasonably agree as to when Regulatory Activities with respect to Canada shall commence and which Party shall be responsible for Regulatory Activities for the Products in the Field in Canada and accordingly the Regulatory Party with respect to Canada.

(b) Pfizer Territory.

(i) Following Option Closing (if any), the marketing authorization with respect to the Oncology Product(s) in the Oncology Field in any country or jurisdiction in the Pfizer Territory shall be transferred to or otherwise held by Pfizer, unless otherwise agreed between the Parties in writing. Upon the approval of such transfer to Pfizer by the relevant Regulatory Authority or any other date agreed by the Parties in writing, Myovant shall use [***] to transfer all Regulatory Materials (including Drug Approval Applications) and communications with the applicable Regulatory Authorities for the Pfizer Territory to Pfizer and Pfizer shall, following such transfer, be responsible for and shall have the sole right with respect to the Regulatory Activities with respect to such Oncology Product(s) in such country or jurisdiction in the Pfizer Territory.

Pfizer shall fully co-operate with Myovant in order to facilitate such transfer of Regulatory Materials from Pfizer to Myovant, including executing any documents required for such transfer. Myovant shall be responsible for its costs of providing any reasonable assistance to Pfizer with respect to such transfer of marketing authorization to Pfizer, provided that, if Myovant is required to perform any regulatory activities or assistance beyond what is considered reasonable in connection with such transfer, the Parties shall agree in writing the cost to be reimbursed to Myovant for such activities or assistance prior to such costs being incurred by Myovant.

(ii) Following Option Closing (if it occurs), Pfizer shall use [***] to seek Regulatory Approvals for the Oncology Product in the Oncology Field in the applicable [***] as determined in accordance with Exhibit 1.144 in the Pfizer Territory.

4.1.3 Consistency with Joint Medical Affairs and Development Plan and Budget. Each Regulatory Party shall ensure that the Regulatory Materials (including Product Labeling) and communications, for which it is responsible: (a) in the Co-Promotion Territory shall be consistent with the applicable Joint Medical Affairs and Development Plan and Budget and the then-current Core Data Sheet for the applicable Product, and (b) in the Territory, the then-current Core Data Sheet for the applicable Product.

4.1.4 Coordination through JMDRC.

(a) Co-Promotion Territory. In respect of the Regulatory Activities for which the Regulatory Party is responsible in the Co-Promotion Territory, the Regulatory Party shall promptly provide to the applicable JMDRC all proposed material Regulatory Materials to be filed with or submitted to any Regulatory Authority, and copies and details of Regulatory Materials including final Product Labeling and specifications received by such Regulatory Party from the Regulatory Authorities in the Co-Promotion Territory, in each case, relating to any Product in the Field, for the Non-Regulatory Party's review and comments (and, in the case of the Major Regulatory Filings, for JSC approval under Section 2.4.12 or JMC approval under Section 2.6.3 in relation to CMC portions thereof), sufficiently in advance of the Regulatory Party's filing or submission thereof. The Regulatory Party shall reasonably consider all comments provided by such Non-Regulatory Party in connection with the Regulatory Materials with respect to the Co-Promotion Territory and shall respond within a reasonable time frame to all reasonable inquiries by such Non-Regulatory Party with respect thereto.

(b) Pfizer Territory. In respect of the Regulatory Activities for which the Regulatory Party is responsible in the Pfizer Territory, the Regulatory Party shall promptly provide to the other Party copies of all Major Regulatory Filings filed with any Regulatory Authority in the Pfizer Territory, in each case, relating to any Product in the Field. In addition, to the extent requested by [***], if Pfizer is the Regulatory Party with respect to the Pfizer Territory, Pfizer shall provide copies of proposed Regulatory Materials to be filed with any Regulatory Authority relating to any such Product sufficiently in advance of Pfizer's filing or submission thereof, and shall reasonably consider all comments provided by [***] via Myovant to the extent required under the [***] Agreement.

Section 4.2 Regulatory Materials. Except as otherwise agreed by the Parties, all Regulatory Materials (including any Regulatory Approval and Product Labeling) relating to any Product in the Field in a country in its Territory shall be owned by, and shall be the sole property and held in the name of, the Regulatory Party for such country or its designated Affiliate or designee. The Non-Regulatory Party for a country hereby assigns to the Regulatory Party for a country (or its designated Affiliate or designee) all of its right, title, and interest in and to all Regulatory Materials (excluding any Know-How in or other intellectual property with respect to such Regulatory Materials, the ownership of which is governed Article XI) that may be owned by such Non-Regulatory Party or its Affiliates with respect to such country from time to time during the Term (other than such Regulatory Materials that are personal to such Non-Regulatory Party or its Affiliates and not relating primarily to one or both of the Products). If any such written or electronic correspondence received by a Party or its Affiliates from any Regulatory Authority relates to the withdrawal, suspension or revocation of Regulatory Approval for any Product, the prohibition or suspension of the Manufacture or supply of such Product, or the initiation of any investigation, review or inquiry by such Regulatory Authority concerning the safety of such Product, such Party shall notify the other Party and provide the other Party with copies of such written or electronic correspondence, as permitted by Applicable Law, as soon as practicable, but not later than [***] Business Days after receipt thereof.

Section 4.3 Interactions with Regulatory Authorities.

4.3.1 Subject to oversight of the applicable JMDRC, the applicable Regulatory Party for a country and a Product in the Field (or its Affiliate or designee) shall have primary responsibility for interacting with Regulatory Authorities in the applicable country, responding to inquiries of such Regulatory Authorities with regard to the Regulatory Materials for such Product and filing all post-approval updates to Regulatory Materials, such as periodic or ad-hoc safety update reports, supplements and amendments, as well as routine maintenance of the submissions of the Regulatory Materials that must be provided with respect to such Product at periodic intervals to such Regulatory Authorities. The Non-Regulatory Party shall use [***] to cooperate with such Regulatory Party and to provide such assistance as reasonably requested by such Regulatory Party in connection with such activities.

4.3.2 In respect of the Regulatory Activities in the Co-Promotion Territory for which the Regulatory Party is responsible, the Non-Regulatory Party shall be permitted to have up to [***] of its designees attend all in person or other meetings with Regulatory Authorities (or, in the case of Regulatory Activities for the Pfizer Territory, [***] designee from [***] to the extent requested by [***] and required under the [***] Agreement), notice of which shall be given by such Regulatory Party to such Non-Regulatory Party sufficiently in advance thereof to allow such Non-Regulatory Party to prepare for and participate meaningfully in such meeting; *provided, however*, that if prior to such meeting, such Regulatory Party cannot reasonably provide notice to such Non-Regulatory Party because the meeting must take place immediately, such Regulatory Party may act at its own discretion, in a manner consistent with the applicable Joint Medical Affairs and Development Plan and Budget or the Development Component. The Regulatory Party shall promptly furnish the other Party with copies of all substantive contact reports concerning substantive conversations or minutes from any substantive meetings with a Regulatory Authority with respect to any IND related to a Product in the Field in the Co-Promotion Territory. The Non-Regulatory Party for a country shall use [***] to support the Regulatory Party for such country in obtaining Regulatory Approval for such Product in such country and in the activities in support thereof, including providing necessary documents or other materials, including applicable CMC documentation and cGLP, cGCP, cGMP documentation and data, required by Applicable Law to obtain such Regulatory Approval, *provided that*, following Option Closing (if it occurs), in the case of the Pfizer Territory, Myovant shall be responsible for its costs of providing any reasonable assistance to Pfizer with respect to such support to enable Pfizer to obtain Regulatory Approval for the Oncology Product in the Major Countries, provided that, if Myovant is required to perform any activities or assistance beyond what is considered reasonable, the Parties shall agree in writing the cost to be reimbursed to Myovant for such activities or assistance prior to such costs being incurred by Myovant.

Section 4.4 Product Withdrawals and Recalls; Clinical Trial Holds.

4.4.1 If (a) any Regulatory Authority threatens, initiates or advises any action to remove a Product in the Field from the market in any country the Territory or requires or advises a Party or any of their respective Affiliates, Sublicensees or Third Party Distributors to distribute a "Dear Doctor" letter or its equivalent regarding use of such Product, or (b) either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal of such Product or distribution of a "Dear Doctor" letter or its equivalent regarding use of the Product, then in each case ((a) or (b)) Myovant or Pfizer, as applicable, shall notify the other Party of such event or determination immediately, and in any event within [***] hours (or sooner if required by Applicable Law) after such Party becomes aware of the event or makes such determination. The applicable JSC shall discuss and agree upon whether to recall or withdraw such Product or distribute such "Dear Doctor" letter under Section 2.3.14. If the JSC cannot agree on how to proceed in light of such potential recall, market withdrawal or "Dear Doctor" letter, then the applicable Regulatory Party for a country and a Product in the Field (or its Affiliate or designee) will have the casting vote with respect to such matter in accordance with Section 2.10.3(c). Subject to Article XIV, (x) to the extent that a withdrawal or recall results from a Party's breach of its obligations hereunder, or from such Party's or its Affiliates' or Sublicensees' gross negligence or willful misconduct, such Party shall bear the associated Recall Costs, and (y) with respect to any other withdrawal or recall of such Product: (1) in the Co-Promotion Territory, the Recall Costs shall be included in Sales and Marketing Costs hereunder (provided that, in the case of any such withdrawal or recall, the JSC shall increase the budget in the Co-Promotion Commercialization Plan and Budget to reflect the costs of such withdrawal or recall); (2) the Parties will bear [***] of such Recall Costs for the Pfizer Territory, to the extent [***]; and (3) subject to the foregoing subclause (2), Pfizer will bear [***] of such Recall Costs for the Pfizer Territory.

4.4.2 Clinical Trial Holds. Each Party will promptly (but in any event within [***] hours) inform the other Party in the event that any Clinical Trial for a Product in the Field in the Territory is suspended, put on hold, or terminated in the Territory prior to completion as a result of any action by a Regulatory Authority or such Party voluntarily.

Section 4.5 Global Safety Database; Pharmacovigilance Agreement. Myovant shall be solely responsible for, and have the right with respect to, establishing (if applicable), holding and maintaining the global safety database(s) for each Product in the Field and for all matters in relation to the Core Data Sheets for the Products. No later than the date on which Pfizer commences Commercialization of any Product in the Field in the Co-Promotion Territory, the Parties shall enter into a reasonable and customary written pharmacovigilance agreement (the "**Pharmacovigilance Agreement**") governing each Party's obligations with respect to reporting Adverse Events to the other Party and appropriate Regulatory Authorities, and other safety-related matters with respect to the applicable Product. Following Option Closing (if it occurs), the Pharmacovigilance Agreement shall be amended prior to any activities resulting in a regulatory need for the pharmacovigilance agreement to be amended. The Pharmacovigilance Agreement may be amended by the Parties as mutually agreed in writing.

Section 4.6 Rights of Reference.

4.6.1 Myovant's Right of Reference. Pfizer hereby grants to Myovant access to, and a right of reference with respect to, any and all Regulatory Materials and corresponding documentation to the extent Controlled by Pfizer or its Affiliates with respect to any Product in the Field in any country in the Territory and the Terminated Territory ("**Pfizer Regulatory Documentation**"), solely for the purposes of Myovant exercising its rights and performing its obligations under this Agreement in the Co-Promotion Territory and Terminated Territory, as applicable. Pfizer shall transfer to Myovant any internal regulatory documents and any materials documenting any clarifications regarding such Regulatory Materials to the extent requested by [***] and required to be provided by Myovant under the [***] Agreement.

4.6.2 Pfizer's Right of Reference. Following Option Closing (if it occurs), Myovant hereby grants to Pfizer access to, and a right of reference, with a right to grant a further right of reference, with respect to any and all Regulatory Materials, Regulatory Approvals and corresponding documentation to the extent Controlled by Myovant or its Affiliates with respect to any Oncology Product in the Field for use in the Pfizer Territory ("**Myovant Regulatory Documentation**"), in each case solely for the purposes of exercising Pfizer's rights and performing its obligations under this Agreement.

Section 4.7 Data Privacy.

4.7.1 For all Personal Data collected, Processed, hosted, or transmitted in performance of this Agreement, including in connection with the conduct of the Development activities under any Joint Medical Affairs and Development Plan and Budget, each Party shall comply at all times with the Data Protection Laws, and without limiting the foregoing, shall implement and maintain reasonable administrative, technical, and physical safeguards designed to (i) maintain the security and confidentiality of the Personal Data; (ii) protect against reasonably anticipated threats or hazards to the security or integrity of the Personal Data; and (iii) protect against unauthorized access to or use of Personal Data.

4.7.2 Prior to the initiation of any Clinical Trial under the Joint Medical Affairs and Development Plan and Budget (and in any event, prior to the collection or transfer of any Personal Data under this Agreement) and thereafter, the Parties shall cooperate to enter into any necessary agreements with respect to such Personal Data as necessary to comply with Applicable Law, and any Standard Contractual Clauses for transfers from data controllers in the European Union to controllers established outside the European Union or European Economic Area (Decision 2004/915/EC) (as published on the European Commission website), to the extent required.

ARTICLE V.
COMMERCIALIZATION

Section 5.1 Overview.

5.1.1 Co-Promotion Territory. Subject to the terms and conditions of this Agreement, each Party shall be responsible for the performance of the activities in relation to the Commercialization of the Products in the Field in the Co-Promotion Territory allocated to it under each Co-Promotion Commercialization Plan and Budget, in each case, in accordance with such Co-Promotion Commercialization Plan and Budget and subject to the oversight by the applicable JCC pursuant to Section 2.5. The Parties have agreed that [***]. The Parties shall cause their respective representatives on the applicable Committees to divide Detailing activities between the Parties so that Detailing efforts contributed by each Party are [***]. The JCC shall review the Detailing efforts contributed by each Party at least [***] per year and shall, as agreed to by the applicable Committee, make adjustments as necessary in an effort to maintain an equality of efforts contributed by each Party.

5.1.2 Pfizer Territory. Subject to the terms and conditions of this Agreement, following Option Closing (if it occurs), Pfizer shall be solely responsible for Commercialization of the Oncology Product(s) in the Oncology Field and Pediatric Product(s) in the Pediatric Field in the Pfizer Territory in accordance with the Commercialization Component of the Pfizer Operation Plan.

Section 5.2 Co-Promotion Commercialization Plans and Budgets.

5.2.1 Plan and Budget Generally. The Commercialization activities with respect to the WH Product(s) in the Co-Promotion Territory shall be conducted pursuant to a plan and budget (the "**WH Co-Promotion Commercialization Plan and Budget**"), and the Commercialization activities with respect to the Oncology Product(s) in the Co-Promotion Territory shall be conducted pursuant to a plan and budget (the "**Oncology Co-Promotion Commercialization Plan and Budget**") (each, a "**Co-Promotion Commercialization Plan and Budget**"). Each Co-Promotion Commercialization Plan and Budget shall include the Co-Promotion Branding Strategy for the applicable Product in the applicable Field (in accordance with Section 5.2.2) and shall describe in reasonable detail the pre-launch, launch and subsequent Commercialization of the applicable Product in the applicable Field in the Co-Promotion Territory, including the following components (in each case, with respect to such Product): (i) [***]; (ii) [***]; (iii) the nature of the [***] (A) [***]; (B) [***], (C) [***], (D) [***], and (E) [***]; (iv) [***] strategy for such Product in the Co-Promotion Territory; (v) a [***] for such Product in the Co-Promotion Territory; (vi) [***] in the Co-Promotion Territory; (vii) the plan for distributing Samples, and [***], in the Co-Promotion Territory; (viii) [***] pursuant to Section 6.5.1; and (ix) a budget for all such Commercialization activities set forth therein. The applicable Co-Promotion Commercialization Plan and Budget shall assign responsibility for performing all such Commercialization activities between the Parties. The initial WH Co-Promotion Commercialization Plan and Budget for the period commencing on Effective Date and ending on [***] (or for a longer period as agreed by the Parties in writing) is attached to the [***]. The initial Oncology Co-Promotion Commercialization Plan and Budget for the period commencing on the Effective Date and ending on [***] (or for a longer period as agreed by the Parties in writing) is attached to the [***]. For each Co-Promotion Commercialization Plan and Budget, each such period covered by such initial Co-Promotion Commercialization Plan and Budget shall be referred to as the "**Initial Commercialization Operation Period**" for the applicable Product. The Commercialization activities with respect to the Pediatric Product, if Developed and Commercialized in the Co-Promotion Territory, shall be set out in the WH Co-Promotion Commercialization Plan and Budget, subject to approval by the WH JSC. Prior to the launch of the WH Product in the WH Field or the Oncology Product in the Oncology Field in Canada, the applicable JCC shall amend the applicable Co-Promotion Commercialization Plan and Budget to reflect the additional Commercialization activities and budget with respect to Canada.

5.2.2 Co-Promotion Branding Strategy. Each Co-Promotion Commercialization Plan and Budget shall include a branding strategy for the applicable Product for use in the applicable Field in the Co-Promotion Territory, including brand elements, (*e.g.*, brand colors, logos, "look and feel," similar trade dress, typography, and packaging design) (the "**Co-Promotion Branding Strategy**"). The initial Co-Promotion Branding Strategy for the Oncology Product(s) shall be set out in the initial Oncology Co-Promotion Commercialization Plan and Budget. The initial Co-Promotion Branding Strategy for the WH Product(s) shall be set out in the initial WH Co-Promotion Commercialization Plan and Budget. [***].

5.2.3 Plan Updates.

(a) The WH JCC and the Oncology JCC shall review and recommend updates and amendments to, respectively, the initial WH Co-Promotion Commercialization Plan and Budget or the initial Oncology Co-Promotion Commercialization Plan and Budget, in each case, on an as needed basis during the Initial Commercialization Operation Period with respect to the applicable Product and at least annually thereafter to cover the upcoming Budget Period, *provided* that such updates and amendments shall be prepared no later than [***] of each Calendar Year. Any and all updates or amendments to any Co-Promotion Commercialization Plan and Budget shall be subject to approval by the applicable JSC as set forth in Section 2.3.9.

(b) The applicable JCC shall promptly propose any amendment to the Co-Promotion Commercialization Plan and Budget as appropriate to reflect the final Product Labeling approved by the Regulatory Authority for the applicable JSC's review and approval.

Section 5.3 Conduct of Commercialization; Diligence; Reporting; Cost Overruns.

5.3.1 Commercialization Conduct and Diligence.

(a) Co-Promotion Territory. Each Party shall use [***] to perform the Commercialization activities assigned to it in the applicable Co-Promotion Commercialization Plan and Budget. Without limiting the foregoing, each Party shall use [***] to Commercialize the Products in each indication in the Field in Co-Promotion Territory for which Regulatory Approval has been obtained.

(b) Pfizer Territory. Following Option Closing (if it occurs), Pfizer shall: (i) use [***] to Commercialize the Oncology Product(s) in the Oncology Field in each of the Major Countries for which Regulatory Approval has been obtained and (ii) Pfizer shall evaluate whether Commercializing the Oncology Product in each country (other than the Major Countries) in the Pfizer Territory is commercially reasonable, and shall use [***] to Commercialize the Oncology Product(s) in each indication in the Oncology Field in each country in the Pfizer Territory for which Regulatory Approval has been obtained and where Commercialization of such Product has been deemed reasonable, and (ii) without limiting the foregoing, for the first [***] years following the Effective Date, perform the activities under the Pfizer Operation Plan. Pfizer shall bear all costs and expenses incurred in connection with Commercialization of the Oncology Product(s) in the Oncology Field in or for the Pfizer Territory.

5.3.2 Commercialization Information. At least [***] during the period in which a Party is conducting Commercialization activities in the Co-Promotion Territory hereunder, Myovant will provide to Pfizer, for the Products in Co-Promotion Territory, revenues from sales, including [***].

5.3.3 Reports.

(a) Co-Promotion Territory. At least once every [***] during the period in which a Party is conducting Commercialization activities in the Co-Promotion Territory hereunder, such Party shall provide to the applicable JCC reasonably detailed written reports of the Commercialization activities it has performed, or caused to be performed (other than its Detailing activities in the Co-Promotion Territory, which are addressed in Section 6.1.4) in the Co-Promotion Territory, since the preceding report (or with respect to the first such report, since the Effective Date) and the future activities it expects to initiate during the then-current [***]. Each such report shall contain sufficient detail to enable the other Party to assess such Party's compliance with its obligations set forth in Section 5.3.1, including the nature of Commercialization activities conducted.

(b) Pfizer Territory. No later than [***] of each Calendar Year following Option Closing (if it occurs), Pfizer shall provide to the Oncology JCC (and the WH JCC if any Commercialization activities with respect to the Pediatric Product(s) were conducted in such Calendar Year) a detailed written report of the Commercialization activities that Pfizer, its Affiliates and Sublicensees have performed, or caused to be performed, since the preceding report, the future activities it expects to initiate in the Pfizer Territory. Each such report will contain sufficient detail to enable Myovant to assess Pfizer's compliance with its obligations set forth in Section 5.3.1 and will include a rolling [***] year forecast of estimated Net Sales for the Oncology Product in the Pfizer Territory. Without limiting the foregoing, Pfizer shall provide to the Oncology

JCC a revenue report and a revenue projection for the Oncology Product in the Pfizer Territory at the end of each Calendar Quarter after the First Commercial Sale of the Oncology Product in the Pfizer Territory.

5.3.4. Booking of Sales; Title; Distribution. The Selling Party for each country in the Territory shall have the sole right to (a) hold the title of and book sales for the Products; (b) sell, distribute and fill orders with respect to the Products in such country; and (c) invoice sales of the Products in such country. The Selling Party for each country in the applicable Territory shall handle all returns, order processing, invoicing, collection, inventory, distribution and inventory management with respect to Products in such country. The Non-Selling Party in a country shall not take orders for the Products in such country, but if for any reason such Non-Selling Party should receive orders for the Products in such country, such Non-Selling Party shall promptly, and in any event within [***] Business Days, forward such orders to the applicable Selling Party.

Section 5.4. Certain Provisions Relating to the Pfizer Territory. Following the Option Closing if it occurs, this Section 5.4 shall apply. Pfizer shall not, and shall cause its Affiliates not to, and shall use [***] to cause its Sublicensees, subcontractors and Third Party Distributors not to, directly or indirectly, [***] (a) [***], or (b) [***]. Myovant shall not, and shall cause its Affiliates not to, and shall use [***] to cause its Sublicensees, subcontractors and Third Party Distributors not to, directly or indirectly, [***] (a) [***] or (b) [***].

ARTICLE VI.
PROMOTION

Section 6.1 Co-Promotion Generally.

6.1.1 Co-Promotion Principles. In the Co-Promotion Territory, subject to oversight by the applicable JCC, the Parties will collaborate with regard to Co-Promotion of the Products as set forth in the applicable Co-Promotion Commercialization Plan and Budget. For clarity, all decisions under the jurisdiction of the applicable JSC or JCC with respect to Co-Promotion shall be by consensus, subject to Sections 2.10.3 and 2.10.4.

6.1.2 Detailing Efforts.

(a) Except as may otherwise be agreed in writing, each Party shall use [***] to perform the total number of Details for each of the Oncology Product in the Oncology Field and the WH Product in the WH Field in United States assigned to each Party as set forth in the applicable Co-Promotion Commercialization Plan and Budget(the "**Annual Detail Commitment**"). The Parties shall agree, acting reasonably, each Party's Detailing commitment and when any Detailing Shortfall calculations and payments will apply for each of such Products in Canada upon its launch in Canada.

(b) For the purposes of counting Details conducted, a Detail will be counted either as a full Detail or as a partial Detail based on the weightings set forth in Exhibit 6.1.2. For clarity, any Detail with [***] shall not be taken into account when determining whether a Party has fulfilled its obligation to perform Details using [***] under Section 6.1.2(a).

(c) With respect to the Oncology Product in the Oncology Field in the United States, following the date that is [***] months after the launch of such Product in the United States, or, with respect to the WH Product in the WH Field in the United States, following the date that is [***] months after the launch of such Product in the United States, the difference between a Party's Annual Detail Commitment and the Details conducted (as counted per above) shall constitute, if positive, the "**Detailing Shortfall**". If the Detailing efforts contributed by a Party in the prior Calendar Year is [***] or less of the Annual Detail Commitment for such Calendar Year, such Party shall pay to the other Party a payment in an amount equal to the entirety of the Detailing Shortfall for such Calendar Year multiplied by the Detailing Shortfall Rate for such Product. A Detailing Shortfall of less than [***] shall be rectified by the Party incurring such shortfall in the next Calendar Year by increasing its Annual Detail Commitment for the next Calendar Year by a number of Details equaling such Detailing Shortfall. The JCC shall also set, as mutually agreed to by the Parties, appropriate metric tracking and an appropriate trigger or triggers for assessing such disparity prior to any adjustment in Detailing efforts being provided and addressing issues where a Party or Parties are not performing to expectations (e.g., a divergence of [***] in the number of Details performed) including chronic Detail Shortfalls.

(d) If either Party no longer follows an Incentive Compensation-based plan for tracking performance metrics of its Sales Representative with respect to the Oncology Product in the Oncology Field or the WH Product in the WH Field, such Party may use and adopt [***], but in such case the Parties shall agree upon an alternate methodology for weighting of Details that includes the same weightings for Details and creates analogous incentives to Sales Representatives for the applicable Product, consent not to be unreasonably withheld.

6.1.3 Records. Each Party shall keep accurate and complete records, separately, of Details performed on its behalf with respect to the Co-Promotion Territory. Such records shall be maintained for at least [***] years, or longer, if required by Applicable Law. Each Party shall have the right, at its own expense (which expense will not be an Allowable Expense), at reasonable times and upon reasonable prior notice to have access to the other Party's records maintained pursuant to this Section 6.1.3 for the purpose of verifying such other Party's reports described in Section 6.1.4; *provided* that such audit right may not be exercised more than [***] in any [***] period, unless the auditing Party has discovered an overstatement of Details of greater than [***] of the correct amount for the audited period, in which case the auditing Party shall be entitled to conduct such audits every [***] months thereafter until the audited Party has taken reasonable steps designed to cure the problem relating to the inaccurate reporting. Notwithstanding the foregoing, if an audit reveals an overstatement of Details of greater than [***] of the correct amount for the audited period, then the audited Party shall pay the reasonable out-of-pocket cost of such inspection.

6.1.4 Reports. Not later than the [***] day following the end of each Calendar Quarter (commencing with the Calendar Quarter in which such Party begins performing Detailing activities), each Party shall report to the other Party (a) [***] , and (d) such other information as may be specified by the applicable JCC.

Section 6.2 Qualification and Training of Sales Representatives.

6.2.1 Sales Force Responsibility. Each Party shall (i) be solely responsible for recruiting and hiring its own Sales Force and determining the conditions of employment of and compensating, directing and disciplining its Sales Force and (ii) shall ensure that all of the trainers, Sales Representatives and sales managers in its Sales Force are appropriately qualified and experienced in the promotion of pharmaceutical products will be trained how to lawfully and compliantly engage in the promotion of pharmaceutical products and satisfy any other criteria determined by the applicable JCC. Each Party shall treat the Sales Representatives employed by it and its Affiliates as its (or its Affiliate's) own employees for all purposes, including federal, state and local tax and employment laws. Each Party shall comply with all Applicable Law in connection with the hiring, employment and discharge of its Sales Representatives.

6.2.2 Composition of Sales Representatives. Except to the extent otherwise permitted by the applicable Co-Promotion Commercialization Plan and Budget, each Party's (and its Affiliates') Sales Representatives in the Co-Promotion Territory shall [***].

6.2.3 Sales Force Training.

(a) Co-Promotion Territory. Promptly after the Effective Date, Myovant shall provide Pfizer with the training materials it uses for the Oncology Product in the Co-Promotion Territory and Pfizer shall train its own Sales Force for the Oncology Product in the Oncology Field using such training materials, as revised by Pfizer as appropriate at Pfizer's sole discretion (subject to the subsequent sentence) promptly thereafter, at its cost and expense. Either Party may object to the training materials for the WH Product prepared by the other Party through the applicable Joint Review Committee, and Myovant may object to the training materials for the Oncology Product revised by Pfizer, [***]. Each Party shall have the right to train its own Sales Force and develop its own training materials for the WH Product in the WH Field, *provided that* such training materials are subject to review and approval by the applicable Joint Review Committee, and each Party shall schedule its initial training, at its cost and expense, for its Sales Representatives for the WH Product in the WH Field in sufficient time to ensure the applicable women's health Sales Representatives are fully trained prior to the launch of the WH Product in the WH Field in the Co-Promotion Territory. If the Parties agree to jointly train their respective Sales Force, the applicable JCC shall (i) prepare a Product-specific training plan and update such plan as needed, and (ii) develop training materials to be approved through the applicable Joint Review Committee to be used by both Parties and update such training materials from time to time as

appropriate. The Costs for the joint training activities shall be Sales and Marketing Costs but solely to the extent included in the applicable Co-Promotion Commercialization Plan and Budget; otherwise, each Party shall bear its own cost and expense in connection therewith. The applicable JCC-designated Party shall produce (or cause to be produced) sufficient quantities of the approved joint training materials for both Parties' use in the Co-Promotion Territory, and the Costs of such training materials shall be included in Sales and Marketing Costs. The Parties will endeavor to use the joint training materials for consistency and efficiency.

(b) Pfizer Territory. Following the Option Closing if it occurs, Pfizer shall be responsible for training its own Sales Force in the Pfizer Territory at its sole expense.

(c) Additional Training. Except to the extent included in the applicable training materials or training plan (as described above), each Party is responsible for any additional compliance training that is required by Applicable Law or under this Agreement.

6.2.4 Performance of Sales Representatives. Each Party shall be solely responsible for its acts and omissions and for the acts or omissions of its Sales Representatives while performing any Commercialization activities under this Agreement. Without limitation of the foregoing, in the event that information comes to a Party's attention that provides it a reasonable basis for such Party to believe that any Sales Representative of the other Party, while performing any Commercialization activities under this Agreement, may have (a) violated any Applicable Law or (b) failed to comply with this Agreement, such Party shall have an obligation to report to the other Party, and the right to request that the other Party immediately assess the performance of such individuals and to exercise any other rights or remedies available to such Party under this Agreement, at law or in equity. The other Party shall promptly evaluate and use [***] to resolve such issue in accordance with its policies or as it may otherwise deem appropriate, shall keep the reporting Party informed of the progress of, and information learned during, its evaluation, and within [***] Business Days after the reporting Party first brought such information to the other Party's attention, shall provide the reporting Party with a reasonably detailed written report summarizing any steps taken toward resolution of the matter. Each Party shall put in place sufficient measures to regularly monitor its Sales Representatives for their compliance of the following, that its Sales Representatives: (i) do not make any false or misleading statements or comments about any Product; (ii) promote the Products in compliance with Applicable Law; and (iii) without limitation of Section 18.6, do not, directly or indirectly, pay, promise to pay, or authorize the payment of any money, or give, promise to give, or authorize the giving of anything of value to any Government Officials, or of any agency or instrumentality of any government or of any of its agencies or instrumentalities, or to any political party, or official thereof, or to any candidate for political office (including any party, official, or candidate) for the purpose of promoting the sale or use of the Products.

6.2.5 Compensation of Sales Representatives. Each Party shall be solely responsible for determining the compensation structure and, subject to Section 6.1.2, incentives for its Sales Force in a country in the Territory with respect to promoting the Products. All costs and obligations incurred by reason of any persons employed or engaged by a Party shall be for the sole account and expense of such Party, subject only to any reimbursement expressly set forth herein. Without limitation, this Agreement will not be construed so as to grant employees or independent contractors of either Party in any country in the Territory any rights (including any employee benefits or similar rights) against the other Party pursuant to Applicable Law.

Section 6.3 Promotional and Educational Materials.

6.3.1 Co-Promotion Territory. The applicable JCC may from time to time develop Promotional and Educational Materials that each Party may, but is not required to, use in promoting the Products in the Co-Promotion Territory ("**Joint Promotional and Educational Materials**"), which materials shall be reviewed and approved by the applicable Joint Review Committee prior to use. All Promotional and Educational Materials shall comply with Applicable Law and be consistent with the applicable Product Labeling. The applicable Joint Review Committee shall review and determine whether to reapprove the then-most recent Joint Promotional and Educational Materials on at least an annual basis, and either Party may propose amendments thereto during such annual review or at any other time. Myovant shall own all copyrights in and to the Joint Promotional and Educational Materials developed for the Co-Promotion Territory.

6.3.2 Pfizer Territory. Following the Option Closing if it occurs, this Section 6.3.2 shall apply. Pfizer shall be solely responsible for its Promotional and Educational Materials for use by Pfizer in the Pfizer Territory. Pfizer may develop the Promotional and Educational Materials for the Oncology Product(s) in the

Oncology Field for use in the Pfizer Territory that are different than the ones used in the Co-Promotion Territory, *provided* that such Pfizer-developed Promotional and Educational Materials shall not have a substantial adverse effect on the Commercialization activities with respect to the Oncology Product(s) in the Co-Promotion Territory. All Promotional and Educational Materials shall comply with Applicable Law and be consistent with the applicable Product Labeling. Pfizer shall own all copyrights in and to the Promotional and Educational Materials developed for the Oncology Product(s) in the Pfizer Territory under this Agreement.

6.3.3 Use of Promotional and Educational Materials. Each Party may use the Joint Promotional and Educational Materials (and only such Promotional and Educational Materials approved by the Joint Review Committee, together with Product Labeling) in promoting the Products in the Co-Promotion Territory. Neither Party shall, and each Party shall cause its Affiliates not to, change the Joint Promotional and Educational Materials in any way, including by: (a) underlining or otherwise highlighting any text or graphics, (b) adding any notes thereto, or (c) using any electronic materials (*e.g.*, PDFs) on any electronic devices other than the specific electronic devices on which, and in the specific format as, the applicable Joint Review Committee has approved as intended for use with such Promotional and Educational Materials. If Myovant reasonably considers that any Promotional and Educational Materials used or to be used by Pfizer in promoting the Products in the Pfizer Territory has or is reasonably expected to have an substantial adverse effect on the Development or Commercialization of the Products in the Co-Promotion Territory, Myovant may notify Pfizer thereof, upon which the Parties will reasonably discuss the use of such Promotional and Educational Materials by Pfizer in the Pfizer Territory, *provided that* Pfizer will have the final decision with respect to such use.

6.3.4 Regulatory Submission of Promotional and Educational Materials. The Parties shall follow the Pharmaceutical Research and Manufacturers of America's principles and guidelines with respect to the creation, development and use of Promotional and Educational Materials in connection with promotion in the Co-Promotion Territory. To the extent any Promotional and Educational Materials are required by Applicable Law to be submitted to any Regulatory Authority in any country in the Territory, the Regulatory Party for such country shall make such submissions and shall be the liaison with any such Regulatory Authorities for both Parties on such Promotional and Educational Materials, *provided* that such submission shall be subject to the review and approval by the applicable Joint Review Committee pursuant to Section 2.3.

6.3.5 Production and Distribution of Promotional and Educational Materials. The Co-Promotion Commercialization Plan and Budget shall specify which Party shall produce, or cause to be produced, the Joint Promotional and Educational Materials for use by both Parties in the Co-Promotion Territory.

6.3.6 Retrieval of Promotional and Educational Materials. When any individual ceases to be an employee of a Party's Sales Force for any reason, such Party shall use [***] to (a) retrieve any Promotional and Educational Materials held by such person promptly after such membership ends and (b) subsequently destroy such materials subject to Applicable Law or provide such Promotional and Educational Materials to another member of its Sales Force.

6.3.7 Withdrawal of Promotional and Educational Materials. If the applicable Joint Review Committee informs the Parties that a particular Promotional and Educational Material may no longer be used or distributed in a country in the Territory, each Party shall cause its Sales Force to cease using and distributing such Promotional and Educational Material after the no-use date specified by the applicable Joint Review Committee. If, as of such no-use date, either Party has any remaining inventory of the applicable Promotional and Educational Material, such Party shall, within [***] days after such date, destroy in accordance with Applicable Law such Promotional and Educational Materials in its possession, except for a reasonable, limited number of copies to be retained for archival purposes or as required by Applicable Law.

Section 6.4 Samples.

6.4.1 In the Co-Promotion Territory, if Samples are to be distributed, a Sample plan shall be included in the applicable Co-Promotion Commercialization Plan and Budget or shall be separately adopted by the applicable JCC.

6.4.2 In the Pfizer Territory, Pfizer shall determine whether to distribute Samples, at its expense, *provided that* if such Samples are to be Manufactured by Myovant, the ordering thereof shall be subject to the forecast and order procedures in the applicable Supply Agreement.

6.4.3 Each Party shall transport, store, handle and distribute all Samples in compliance with Applicable Law. When any individual ceases to be a member of a Party's Sales Force for any reason, such Party shall retrieve any inventory of Samples held by such person promptly after such membership ends and notify the other Party in the event there is any issue with retrieval or regulatory reporting is required.

6.4.4 Pfizer shall promptly report to Myovant any disparities with respect to any Samples in the Co-Promotion Territory required to be reported under Applicable Law and in the Co-Promotion Territory, Myovant shall be responsible for making any reports or submissions and shall be the liaison with any Regulatory Authorities regarding such disparities.

Section 6.5 Advertising.

6.5.1 Myovant and Pfizer shall develop an annual Advertising Plan for the Products in the Field as part of the Co-Promotion Commercialization Plan and Budget (the "**Advertising Plan**"). The annual Advertising plan shall include the targets and budget for such Advertising and be agreed upon by mutual consent of both Parties, which shall be updated on an annual basis at the same time and in the same manner as the Co-Promotion Commercialization Plan and Budget as part thereof.

6.5.2 Unless otherwise provided in the applicable Co-Promotion Commercialization Plan and Budget, Pfizer shall be responsible for executing the Advertising Plan for the Products in the Field in Co-Promotion Territory, except to the extent Pfizer is unable to execute the Advertising Plan or a portion thereof due to an arrangement entered into by Myovant prior to the Effective Date. The Costs of such media buying shall be included in Sales and Marketing Costs to the extent consistent with the budget in the applicable Co-Promotion Commercialization Plan and Budget and will be equal to the actual cost of such activities billed to Pfizer (including any third party service fees incurred by Pfizer) and [***], administrative fee or service charge.

6.5.3 Myovant agrees (A) not to [***] without the prior written consent of Pfizer, (B) not to [***], without providing Pfizer with a reasonable opportunity for a representative of Pfizer to be present and participate in such meeting and (C) to promptly inform Pfizer if it [***] as set forth in (A) above.

6.5.4 Myovant agrees that any binding commitment made by Pfizer pursuant to this Section 6.5 for media buying for the Products in the Field in the Co-Promotion Territory shall also be binding to Myovant; provided that such commitment is consistent with the applicable Co-Promotion Commercialization Plan and Budget.

6.5.5 After the Effective Date, the Parties will maintain a process via the applicable JCC by which Pfizer will interact with Myovant with respect to the Advertising activities undertaken by Pfizer pursuant to this Section 6.5.

6.5.6 Within [***] days after the end of each Calendar Quarter, Pfizer will deliver to Myovant a report describing in reasonable detail the media buying activities for the just completed Calendar Quarter and any material deviations from the approved Advertising plan that occurred during such Calendar Quarter.

ARTICLE VII.
MEDICAL AFFAIRS

Section 7.1 Medical Affairs. Each Party shall carry out medical affairs activities with respect to the Products in the Field in the Co-Promotion Territory in compliance with its applicable internal policies and procedures, and pursuant to the terms and conditions of this Agreement, and the then-current and approved Joint Medical Affairs and Development Plan and Budget, including the Joint Medical Affairs Plan.

Section 7.2 Joint Medical Affairs Plan. An annual joint medical plan for each Product in the Field for the Co-Promotion Territory (each, "**Joint Medical Affairs Plan**") shall be prepared by and approved by the applicable JMDRC, and shall constitute a part of the applicable Joint Medical Affairs and Development Plan and Budget. The initial version of the Joint Medical Affairs Plan for the WH Product in the WH Field and the initial version of the Joint Medical Affairs Plan for the Oncology Product in the Oncology Field are set out in [***]. In coordination with the branding for the Products in the Field in the Co-Promotion Territory, each Joint Medical Affairs Plan shall include:

(a) Medical affairs-related activities;

(b) Grant plans;

(c) Scientific education;

(d) Plans for medical affairs-led Clinical Trials;

(e) Plans for medical affairs-led Other Studies;

(f) Medical information plans;

(g) Investigator-initiated trial, areas of interest, policies and plans;

(h) an annual joint medical affairs plan budget; and

(i) Publication planning.

ARTICLE VIII.
PAYMENTS

Section 8.1 Upfront Payment. In partial consideration of the rights granted by Myovant to Pfizer hereunder, within [***] Business Days after the Effective Date but in no event later than [***], Pfizer shall pay Myovant a non-refundable, non-creditable upfront amount of six hundred fifty million Dollars ($650,000,000) which amount shall not be refundable or creditable against any other payments due hereunder.

Section 8.2 Milestones.

8.2.1 In partial consideration of the rights granted by Myovant to Pfizer hereunder, Pfizer shall pay to Myovant the following non-refundable, non-creditable milestone amounts set forth below (subject to Section 8.2.2) in connection with achievement of the applicable milestone events set forth below. Myovant shall notify Pfizer promptly of the achievement of each such milestone. Each such milestone payment shall be due within [***] days after the achievement of the applicable milestone (or in the case of a sales milestone, [***] days after the end of the Calendar Quarter in which the sales milestone is achieved). Each such milestone payment shall be payable only once, in each case upon the first achievement of the applicable milestone, and no amounts shall be due for subsequent or repeated achievements of such milestone. For clarity, more than one sales milestone may be due for any given year.

Approval Milestones:

Milestones	Payment
(A) First FDA approval of an NDA for a WH Product for the treatment of Uterine Fibroids in the United States (the "**UF Approval Milestone**")	$100 million
(B) First FDA approval of an NDA for a WH Product for the treatment of Endometriosis in the United States (the "**Endometriosis Approval Milestone**")	$100 million
TOTAL	$200 million

Oncology Sales Milestones:

Milestones (Annual Net Sales of the Oncology Product(s) in the Co-Promotion Territory)	Payment
(A) [***]	$[***]
(B) [***]	$[***]
(C) [***]	$[***]
(D) [***]	$[***]
(E) [***]	$[***]
TOTAL	$[***]

Women's Health Sales Milestones:

Milestones (Annual Net Sales of the WH Product(s) in the Co-Promotion Territory)	Payment
(A) [***]	$[***]
(B) [***]	$[***]
(C) [***]	$[***]
(D) [***]	$[***]
(E) [***]	$[***]
TOTAL	$[***]

Subject to Section 8.2.2, the aggregated amount of all sales milestones is $3.5 billion and the aggregated amount of all milestones (including approval and sales milestones) is $3.7 billion.

8.2.2 WH Product FDA Approval Delay.

(a) Notwithstanding anything set forth in Section 8.2.1 above, if the FDA approval of the WH Product for Uterine Fibroids or Endometriosis in the United States is delayed by the following period for a reason related to [***], the milestone payment with respect to the UF Approval Milestone or the Endometriosis Approval Milestone shall be due within [***] days after the achievement of the applicable milestone, and shall be in the amounts as follows:

(i) if such FDA approval is delayed for a reason related to [***] by [***] to [***] months from: (1) [***] for the WH Product for Uterine Fibroids or (2) the PDUFA Date for the WH Product for Endometriosis, in each case, Pfizer shall pay to Myovant [***] for, respectively, the UF Approval Milestone or the Endometriosis Approval Milestone achieved; or

(ii) if such FDA approval is delayed for a reason related to [***], by more than [***] months from: (1) [***] for the WH Product for Uterine Fibroids or (2) the PDUFA Date for the Product for Endometriosis, in each case, Pfizer shall pay to Myovant [***] for, respectively, the UF Approval Milestone or the Endometriosis Approval Milestone achieved; and

(b) if the launch of the WH Product for Uterine Fibroids or the WH Product for Endometriosis in the Co-Promotion Territory is delayed by at least [***] months from: (1) [***] for such WH Product for Uterine Fibroids or (2) the PDUFA Date for such Product for Endometriosis for a reason related to [***], the Manufacturing Costs with respect to the WH Products for Uterine Fibroids or Endometriosis (as applicable) that are not used due to such delay of launch beyond such [***] month period shall be excluded from Allowable Expenses, provided that, if such WH Products are subsequently used after launch of such Product, the related Manufacturing Costs shall be included in Allowable Expenses.

Section 8.3 Royalties.

8.3.1 Royalty Rate. Following Option Closing (if it occurs) and during each Calendar Quarter of the Royalty Term, Pfizer shall pay to Myovant a non-refundable, non-creditable royalty on the Net Sales of the Oncology Product(s) for such Calendar Quarter in the Pfizer Territory at the royalty rate of [***].

8.3.2 Fully Paid-Up, Royalty Free License. Following expiration of the Royalty Term for an Oncology Product in the Oncology Field in a given country in the Pfizer Territory, no further royalties will be payable in respect of sales of such Product in such country and, thereafter the license granted to Pfizer under Section 10.1.1 with respect to such Oncology Product in such country will automatically become fully paid-up, exclusive, perpetual, irrevocable and royalty-free.

8.3.3 Royalty Adjustments. The following adjustments will be made, on a Product-by-Product and country-by-country basis, to the royalty payable pursuant to Section 8.3.1:

(a) Third Party Patents. If Pfizer cannot Commercialize the Oncology Product(s) in the Pfizer Territory without infringing a Third Party's Patents and if Pfizer pays a royalty to such Third Party for the right to Commercialize such Oncology Product(s) with respect to such Patents, then subject to Section 8.3.3(d), Pfizer may credit [***] of such royalty payments to such Third Party for sales of such Oncology Product(s) in the Pfizer Territory in a given Calendar Quarter against the royalties owned and payable by Pfizer to Myovant on the Net Sales for such Oncology Product(s) hereunder made in the same Calendar Quarter pursuant to Section 8.3.1. Pursuant to Section 10.3.6, Pfizer shall have the first right to negotiate for and obtain rights under any such required Third Party Patents in the Pfizer Territory, *provided, however,* that, where practical, Pfizer shall provide written notice to Myovant at least [***] days prior to commencing negotiations with such Third Party.

(b) No Adjustment for Existing Myovant Third Party Agreements and Inventor Compensation in the Pfizer Territory. Myovant will be solely responsible for all obligations in the Pfizer Territory (including any royalty or other obligations that relate to the Myovant Background IP, Compounds or Products) under the Existing Myovant Third Party Agreements or any agreements that Myovant enters into with a Third Party during the Term. Each Party shall be solely responsible for all payments to its own inventors of its respective Background IP and Collaboration IP, as applicable, including payments under inventorship compensation laws.

(c) Generic Entry. Notwithstanding the foregoing, for any royalty otherwise payable to Myovant under this Agreement with respect to Net Sales based on sales of an Oncology Product in the Oncology Field in a given country in the Pfizer Territory, subject to Section 8.3.3(d), any payments owed with respect to such Oncology Product in such country pursuant to Section 8.3.1 will be (i) reduced by [***] for the remainder of the applicable Royalty Term if the Generic Competition Percentage in such country is greater than [***] but less than [***], or (ii) reduced by [***] for the remainder of the applicable Royalty Term if the Generic Competition Percentage in such country is greater than or equal to [***], such reduction to be prorated for the then-current Calendar Quarter, once one or more Generic Product of such Oncology Product become available and are being sold in such country.

(d) Valid Claim Stepdown. With respect to each Oncology Product in any particular country in the Pfizer Territory, if at any time such Oncology Product is not Covered by a Valid Claim under a Myovant Patent in such country, subject to Section 8.3.3(d), any payments owed with respect to such Oncology Product in such country pursuant to Section 8.3.1 shall be reduced by [***] for the remainder of any applicable Royalty Term.

(e) Cumulative Reduction Floor. In no event will the aggregated royalty amount due to Myovant in any given Calendar Quarter during the Royalty Term for any Oncology Product in the Oncology Field be reduced under this Section 8.3.3 by more than [***] of the amount that otherwise would have been due and payable to Myovant in such Calendar Quarter for such Oncology Product in the Pfizer Territory under Section 8.3.1.

8.3.4. Payment Dates and Reports. Within [***] days after the end of each Calendar Quarter after the First Commercial Sale of the Oncology Product(s) in the Pfizer Territory, Pfizer shall submit to Myovant a written flash reporting setting forth its reasonable good faith estimates of the Net Sales for such Calendar Quarter in sufficient detail for Myovant to comply with its financial reporting obligations and its obligations

under the [***] Agreement. Pfizer shall pay to Myovant the amounts due under Section 8.3.1 with respect to each Calendar Quarter within [***] Business Days after the end of such Calendar Quarter. Each such payment shall be accompanied by a statement including (a) the amount of gross sales the Oncology Product in the Pfizer Territory, (b) an itemized calculation of Net Sales in the Pfizer Territory showing deductions, to the extent practicable, provided for in the definition of "Net Sales", (c) a calculation of the royalty payment due on such Net Sales, and (d) solely to the extent required by Myovant to report to [***] under the [***] Agreement, an accounting of the number of units and prices for the Oncology Product(s) sold and any additional information reasonably required by the other Party for the purpose of calculating royalties payable under Section 8.3. Promptly upon Myovant's reasonable request, Pfizer shall provide a good faith estimate of the Net Sales of the Oncology Product(s) in the Pfizer Territory for the requested reporting period in order for Myovant to estimate the royalty payments for such reporting period.

Section 8.4 Option Exercise Payment. Within [***] Business Days of the Option Closing under Section 10.5.2, Pfizer shall pay to Myovant an amount of fifty million US dollars ($50,000,000) (the "**Option Exercise Payment**"), which amount shall not be refundable or creditable against any other payments due hereunder.

Section 8.5 Net Profit or Net Loss.

8.5.1 Sharing. With respect to the Co-Promotion Territory, each Party shall receive [***] of all Net Profits, and shall bear [***] of all Net Losses, as applicable, during the Term for the Co-Promotion Territory.

8.5.2 Allowable Expenses. Each Party shall record and account for Allowable Expenses in accordance with the Accounting Standards and its customary practices across its products, and in a manner that allocates costs to a specific activity in the applicable Joint Medical Affairs and Development Plan and Budget or Co-Promotion Commercialization Plan and Budget. Each Party shall promptly inform the applicable JMDRC or JCC in writing upon such Party determining that it is likely to have Excess Development Costs, Excess Advertising Costs or Excess Commercialization Costs.

8.5.3 Co-Promotion Territory Reports. Myovant shall report to the applicable JCC, the JFC and Pfizer, within [***] days after the end of each month, the amount of gross sales of each Product and Net Sales made by Myovant and its Affiliates with respect to the Co-Promotion Territory for such month, and each Party shall report to the applicable JCC, JMDRC, the JFC and the other Party the Allowable Expenses incurred by or on behalf of such Party and its Affiliates for such month. [***]. Each such report shall enable the applicable JCC, JMDRC, the JFC and the receiving Party to compare the reported costs against the applicable Joint Medical Affairs and Development Plan and Budget and applicable Co-Promotion Commercialization Plan and Budget, [***]. The Parties shall seek to resolve any questions related to such cost reports within [***] days following receipt by each Party of the other Party's report hereunder. In addition, promptly upon either Party's request, the other Party shall provide a report of the Allowable Expenses incurred by such Party during the prior month, within [***] days of the end of such month.

8.5.4 Payment.

(a) Myovant will bear [***] Pfizer's share of the Allowable Expenses, up to a maximum of one hundred million dollars ($100,000,000) for Calendar Year 2021 (the "**2021 Cap**") and [***] Pfizer's share of the Allowable Expenses, up to a maximum of fifty million dollars ($50,000,000) for Calendar Year 2022 (the "**2022 Cap**"). To the extent Pfizer's share of the Allowable Expenses for Calendar Year 2021 does not meet, or exceed, the 2021 Cap, such Pfizer's share of the Allowable Expenses shall carry over to Calendar Year 2022. To the extent the Pfizer's share of the Allowable Expenses for Calendar Year 2022, plus any carry over costs from Calendar Year 2021, do not meet, or exceed, the 2022 Cap, such Pfizer's share of the Allowable Expenses shall carry over to Calendar Year 2023 and each consecutive Calendar Year until Myovant has assumed in aggregate one hundred fifty million dollars ($150,000,000) of Pfizer's share of the Allowable Expenses incurred by Pfizer. Myovant will include Pfizer's share of the Allowable Expenses, including Pfizer's share of the Built-up Inventory Costs, pursuant to Section 8.5.4(b) in the reconciliation calculation and reconciliation payment per Section 8.5.4(b), such that such amounts will either be paid to Pfizer or if Pfizer would otherwise owe a payment to Myovant, it would reduce such payment by such amount.

(b) Within [***] days after the later of (i) the receipt of each report pursuant to Section 8.5.3 and the corresponding report for Development Costs pursuant to Section 3.5.2 for a Calendar Quarter and (ii) the resolution of any questions with respect to any such report, the applicable Party shall make a reconciling payment to the other Party to achieve the sharing of Net Profits and Net Losses provided in Section 8.5.1, subject to Section 8.5.4(a).

Section 8.6 Mode of Payment. All payments to either Party under this Agreement shall be made by deposit of Dollars in the requisite amount to such bank account as the receiving Party may from time to time designate by notice to the paying Party reasonably in advance. For payments in excess of [***], the paying Party will (i) notify the receiving Party at least [***] business days in advance of such payment the date such payment will be made and the amount (if known) and (ii) on the date of such payment, provide the receiving Party a banking transaction number or other official confirmation of the transfer and the exact amount of such transfer prior to 2 pm ET on the date of such transfer. Notwithstanding anything to the contrary in the Agreement, conversion of sales recorded in local currencies to U.S. dollars will be performed in a manner consistent with Pfizer's normal practices used to prepare its audited financial statements for external reporting purposes, *provided that* such practices use a widely accepted source of published exchange rate.

Section 8.7 Taxes.

8.7.1 VAT. It is understood and agreed between the Parties that any payments made under this Agreement are exclusive of any value added or similar tax (VAT), which shall be added thereon as applicable. Where VAT is properly added to a payment made under this Agreement, the Party making the payment will pay the amount of VAT only on receipt of a valid tax invoice issued in accordance with the laws and regulations of the country in which the VAT tax is chargeable.

8.7.2 Withholding Taxes. In the event any payments made pursuant to this Agreement become subject to withholding taxes under the laws or regulation of any jurisdiction, the Party making such payment shall deduct and withhold the amount of such taxes for the account of the payee to the extent required by applicable laws or regulations and such amounts payable to the payee shall be reduced by the amount of taxes deducted and withheld. Any such withholding taxes required under applicable laws or regulations to be paid or withheld shall be an expense of, and borne solely by, the payee.

8.7.3 Tax Cooperation. To the extent that the Party making a payment is required to deduct and withhold taxes on any payments under this Agreement, the Party making such payment shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to the payee an official tax certificate or other evidence of such withholding sufficient to enable the payee to claim such payments of taxes. The payee shall provide any tax forms to the Party making such payment that may be reasonably necessary in order for such Party not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. The payee shall use reasonable efforts to provide any such tax forms to the Party making the payment at least [***] days prior to the due date for any payments for which the payee desires that the Party making the payment apply a reduced withholding rate. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Law, of withholding taxes, VAT, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or VAT.

8.7.4 Notwithstanding anything in this Agreement to the contrary, (a) if an action (including any assignment or sublicense of its rights or obligations under this Agreement, or any failure to comply with applicable Laws or filing or record retention requirements) by a Party leads to the imposition of withholding tax liability or VAT on the other Party that would not have been imposed in the absence of such action or in an increase in such liability above the liability that would have been imposed in the absence of such action, then the sum payable by that Party (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that the other Party receives a sum equal to the sum which it would have received had no such action occurred; and (b) otherwise, the sum payable by that Party (in respect of which such deduction or withholding is required to be made) shall be made to the other Party after deduction of the amount required to be so deducted or withheld, which deducted or withheld amount shall be remitted in accordance with applicable law.

Section 8.8 Interest on Late Payments. Any amount required to be paid by a Party hereunder which is not paid on the date due shall bear interest compounded daily, to the extent permitted by law, at the Federal Funds Effective Rate (EFFR or any successor to such rate) effective for the date such payment was due, as reported by the Federal Reserve of New York.

Section 8.9 Financial Records. Each Party shall keep or cause to be kept complete and accurate books and records pertaining to Net Sales, Allowable Expenses, Net Profits, Net Losses and in the case of the Pfizer Territory, the applicable royalty calculations, as applicable, in sufficient detail to calculate all amounts payable hereunder ("**Financial Records**"). Such books and records shall be retained until the later of (a) [***] years after the end of the period to which such books and records pertain and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof) or for such longer period as may be required by Applicable Law.

Section 8.10 Audit. A Party (the "**Auditing Party**") shall have the right, at its own expense to have an independent certified public accountant perform a review of the other Party's ("**Audited Party**") Financial Records (including any records kept in the ordinary course of the Audited Party's business) during regular business hours, with not less than [***] Business Days' advance written notice. Such accountant shall advise the Parties simultaneously and promptly upon its completion of its audit whether or not the payments due hereunder (including payments due in connection with the Net Sales, Allowable Expenses, Net Profits, Net Losses and in the case of the Pfizer Territory, the applicable royalty calculations) have been accurately recorded, calculated and reported, and, if not, then the amount of such discrepancy. A Party's Financial Records shall only be subject to one (1) audit per Calendar Year, except in the case of fraud. The Auditing Party's right to perform an audit pertaining to any calendar year shall expire [***] years after the end of such year. Should an inspection pursuant to this Section 8.10 lead to the discovery of a payment discrepancy, then the appropriate Party shall pay to the other Party the amount of the discrepancy. If a payment discrepancy was greater than [***] or [***] of the correct amount for the audited period and the discrepancy was in favor of the Auditing Party, then the Audited Party shall pay the reasonable and documented out-of-pocket cost of such inspection. In no case shall the costs of an audit pursuant to this Section 8.10 be included in Allowable Expenses. This Section 8.10 does not apply to or include Manufacturing operations audits or regulatory inspections, or Detailing audits which matters are addressed elsewhere herein or in applicable ancillary agreements described elsewhere herein.

Section 8.11 Audit Dispute. In the event of a dispute with respect to any audit under Section 8.10, the Parties shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within [***] days, the dispute shall be submitted for resolution to a certified public accounting firm jointly selected in writing by each Party's certified public accountants or to such other Person as the Parties shall mutually agree (the "**Accountant**"). The decision of the Accountant shall be final. The costs of the Accountant shall be borne between the Parties in such manner as the Accountant shall determine. Not later than [***] days after such decision and in accordance with such decision, the Audited Party shall pay the underpayment or overpayment, as the case may be, with interest from the date originally due as provided in Section 8.8, or the Auditing Party shall pay the overpayment or underpayment, as the case may be, in each case, as described in Section 8.10, as applicable.

Section 8.12 Confidentiality. The receiving Party shall treat all information subject to review under this Article VIII in accordance with the confidentiality provisions of Article XII, and the Parties shall cause the Accountant to enter into a reasonably acceptable confidentiality agreement with the audited Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement.

Section 8.13 No Projections. The Parties acknowledge and agree that nothing in this Agreement shall be construed as representing an estimate or projection of anticipated net sales of either Product. NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT EITHER PARTY WILL BE ABLE TO SUCCESSFULLY DEVELOP OR COMMERCIALIZE EITHER PRODUCT OR, IF COMMERCIALIZED, THAT ANY PARTICULAR NET SALES LEVEL OF SUCH PRODUCT WILL BE ACHIEVED.

Section 8.14 No Double Counting. There shall be no double counting of any Development Costs, Distribution Costs, Manufacturing Costs, Sales and Marketing Costs, or deductions from Net Sales, and to the extent a cost or expense has been included in one category or sub-category, it shall not be included in another;

similarly, to the extent any revenue has been taken into account in one category or sub-category it shall not be taken into account in another. If the costs included in a category or sub-category have already been included in one relevant category, they shall not be included in any other category.

ARTICLE IX.
SUPPLY OF PRODUCT

Section 9.1 Supply Obligations.

9.1.1 Manufacturing Party.

(a) Commencing on the Effective Date, and thereafter subject to Section 9.1.4, unless otherwise mutually agreed by the Parties, Myovant shall be the Party responsible for the Manufacture of each Product in the Field and supplying each Product in the Field in the Co-Promotion Territory and, following the Option Closing (if any), in the Pfizer Territory, for all purposes, including preclinical and clinical supplies, commercial supplies and Samples, pursuant to this Agreement and the Supply Agreement, provided that, the foregoing provisions shall not apply with respect to the Manufacture of Products in the Pfizer Territory, if Pfizer contracts directly with the Existing CMOs in accordance with Section 9.1.1(c) or otherwise performs such Manufacture to the extent agreed between the Parties following the Option Closing (if it occurs). Myovant shall use [***] to Manufacture, or ensure the Manufacture by the Existing CMO(s), of the Products in the form as of the Effective Date: (i) in compliance with (1) the Supply Agreements and (2) cGMP and all other Applicable Laws; (ii) in conformance with the specifications therefor in effect at the time of delivery to Pfizer or a Third Party; (iii) such that the Products are not, at the time of delivery, whether for development or commercial use, adulterated or misbranded within the meaning of the U.S. Food and Drug Act ("**Act**") or any analogous Applicable Law outside of the United States; (iv) in conformance, at such time of delivery, in all material respects with the certificates of analysis accompanying the Products when delivered; and (v) in a manner sufficient to meet the requirements for supply of the Products in accordance with the applicable forecast in the Supply Plan and subject to the terms and conditions of the Supply Agreement (subject to Section 9.2.3 and the terms of the Supply Agreement). To the extent Myovant is responsible for such Manufacture, [***], without the prior written consent of Pfizer (not to be unreasonably withheld).

(b) If the applicable JMDRC approves the inclusion of any new form of Product in the Field in the applicable Joint Medical Affairs and Development Plan and Budget, as part of such approval, the applicable JMDRC shall also agree the Manufacture responsibilities of Myovant or Pfizer in relation to such new form of Product. Upon such agreement, the Parties shall record such agreement in writing.

(c) Following the Option Closing, if it occurs, Pfizer may, at its sole discretion and at any time during the Term, contract directly with the Existing CMOs for the supply of the Oncology Product in the Oncology Field to Pfizer for sale in the Pfizer Territory, provided that, if Myovant is engaging such Existing CMO at such time, Pfizer shall [***].

9.1.2 Preclinical, Clinical and Commercial Manufacture and Supply. To the extent that Myovant is responsible for the Manufacture of the preclinical and clinical supply of Compound, the Oncology Product(s) or Pediatric Product, or the commercial supply of Compound, the Oncology Product(s) in the Oncology Field or Pediatric Product in the Pediatric Field in the Pfizer Territory for Pfizer, such supply shall be pursuant to separate supply agreement between Myovant and Pfizer (the "**Supply Agreement**"). Any Supply Agreement, if necessary, will be negotiated in good faith by the Parties following the Option Closing, if it occurs, with a view to entering into such Supply Agreement within [***] months after such Option Closing. Myovant would sell to Pfizer at standard cost of goods therefor, [***], the preclinical, clinical or commercial supply of the Compound, Oncology Product(s) or Pediatric Products, unless and until Pfizer establishes its own source of supply.

9.1.3 The Supply Agreement, if necessary, will set forth the rights and obligations of the Parties in connection with Myovant's supply of the Oncology Product or the Pediatric Product in their respective Fields and will address the qualification of a manufacturing facility or facilities as a second source for Manufacture of the Products (*provided that*, if such second source is a Third Party, subject to Myovant's written approval, not to be unreasonably withheld) and shall contain such terms and conditions as are reasonable and customary for similar supply agreements. Promptly following the Effective Date, the Parties shall enter into a quality agreement on reasonable and customary terms in connection with the Manufacture of the Products in the Field in the Territory hereunder (the "**Quality Agreement**"). If the JSC agrees to add any additional Products to the

applicable Joint Medical Affairs and Development Plan and Budget, the Parties shall discuss as to which Party shall supply the pre-clinical, clinical and commercial supplies of such Products, subject to additional Supply Agreements and Quality Agreements, as necessary, to be entered into between the Parties.

9.1.4 Manufacture by Pfizer. If Pfizer wishes to Manufacture and supply any Product in the Field in the Territory for use hereunder, Pfizer shall notify Myovant thereof through the JMC, upon which the Parties, through the JMC shall discuss the feasibility and desirability of Pfizer's performance of some or all of such manufacture and supply activities, taking into account Myovant's obligations under the Existing Myovant Third Party Agreements:

(a) If such Manufacture and supply relates to any Product in the Field the Co-Promotion Territory, Myovant shall have no obligation to agree to any such Manufacture and supply by Pfizer or any transfer of Manufacture process of such Product in the Field to Pfizer (and any such transfer of Manufacture process if agreed by Myovant shall be subject to Section 9.1.4(c)). If Pfizer establishes its own source of supply for Product, upon the request of Myovant, the Parties shall negotiate in good faith a supply agreement in relation to any future supply of the applicable Product in the Field to Myovant, which supply agreement shall include additional terms and conditions as are reasonable and customary for similar supply agreements and such supply shall be at cost without a mark-up.

(b) If such Manufacture and supply solely relates to the Oncology Product(s) or the Pediatric Product, if Developed, in the Pfizer Territory, Pfizer shall have the right to perform such Manufacture and supply of the Oncology Product or Pediatric Product, if Developed, in their respective portion of the Field, in the Pfizer Territory, including through engaging an Existing CMO in accordance with Section 9.1.1(c). Upon Pfizer's request, Myovant shall provide Pfizer with assistance for the transfer of the Manufacture process of the Oncology Product(s) or Pediatric Product, if Developed, to Pfizer, or its designee, subject to Section 9.1.4(c).

(c) Myovant shall be responsible for its costs of providing Pfizer any assistance for the transfer of the manufacture process of any Product in the Field to Pfizer under this Section 9.1.4, provided that, if Myovant is required to perform any activities or assistance beyond what is considered reasonable, the Parties shall agree in writing the cost to be reimbursed to Myovant for such activities or assistance prior to such costs being incurred by Myovant

9.1.5 Samples. Myovant shall be the Party responsible for supplying all Samples to be used by both Parties in the Territory, unless such responsibilities have been assumed by Pfizer in accordance with Section 9.1.4 and after discussion by the JMC. Pfizer shall be responsible for all costs associated with supply and distribution of Samples of Oncology Product(s) or Pediatric Product, if Developed, for the Pfizer Territory; any Samples of Oncology Product(s) or Pediatric Product, if Developed, manufactured by Myovant for use in the Pfizer Territory shall be purchased by Pfizer at standard cost of goods therefor under the Supply Agreement.

Section 9.2 Capacity and Supply.

9.2.1 Supply Plans. On a Product-by-Product basis, by [***], Myovant shall prepare and submit to the JMC, for its review and discussion, a proposed supply chain management plan for the Products being Manufactured under this Agreement by the Existing CMO to the extent Myovant is responsible for the supply of such Products, such plan to be designed to provide reasonable assurance that Myovant, utilizing the Existing CMO, is able to satisfy the then-current forecast for the Products in the Field in the Co-Promotion Territory (each such plan once determined in accordance with this Section 9.2, a "**Supply Plan**"). Each Supply Plan shall include (a) a plan for producing launch quantities for each such Product, including appropriate capacity and inventory and safety stock levels, (b) a [***] year high-level non-binding forecast for capacity planning purposes and short-term forecasts meeting the requirements established by the JMC, and (c) inventory requirements (for the Products and key raw materials) in order to satisfy supply requirements. After the submission of the initial Supply Plan for the Product, Myovant shall prepare and submit to the JMC for its review and discussion, an updated copy of such Supply Plan periodically as determined by the JMC. The JMC shall submit each updated Supply Plan to the JSC for review and approval on an annual basis. Following Option Closing (if it occurs), the Parties shall update the Supply Plan to include the Products in the Field in the Pfizer Territory, for so long as Myovant is supplying Pfizer such Products.

9.2.2 Capacity Planning. The Parties will work together through the JMC to identify any capacity expansion needs in connection with development of each initial Supply Plan and each update thereto, including

ensuring adequate capacity is available to meet the forecasted demand for the Product. The JMC shall develop and recommend to the JSC options to address necessary capacity expansion, which may include Manufacturing by either or both of the Parties or a Third Party and which will take into account [***], by proposing such activities to the JSC in a capacity expansion plan. If the JSC is unable to agree with respect to a given capacity expansion plan, then such matter will be resolved as set forth in Section 2.10.3(c). Agreement on the capacity expansion plan shall not be a Myovant Controlled Matter or a Pfizer Controlled Matter, and accordingly requires consensus of the relevant representatives of the Parties.

9.2.3 Shortage; Allocation. In the event that Myovant reasonably believes that it will not be able to supply requirements for the Products in the Field in accordance with the Supply Plan provided under Section 9.2.1 and otherwise as necessary to fulfill supply requirements under any applicable Joint Medical Affairs and Development Plan and Budget or Co-Promotion Commercialization Plan and Budget:

(a) it shall provide prompt written notice to Pfizer thereof. If Myovant actually cannot supply a Product in the Field in accordance with such mutually agreed upon supply requirements or otherwise as necessary to fulfill supply requirements under any applicable Joint Medical Affairs and Development Plan and Budget or Co-Promotion Commercialization Plan and Budget, then to the extent required by the [***], Myovant may [***]. The JMC shall develop a revised Supply Plan consistent with the foregoing. If the JMC is unable to reach consensus regarding any such revised Supply Plan, then such issue shall be escalated in accordance with Section 2.10.3(c); and

(b) in relation to the Products in the Field allocated for supply for the Development and Commercialization activities hereunder (after any pro rata allocation to [***] in accordance with Section 9.2.3(a)), it shall reasonably allocate its manufacturing capacity and supply in the following order of prioritization unless the JCC agrees otherwise: (1) to minimize the impact to patients on treatment in ongoing Clinical Trials or treatment after Regulatory Approval; (2) to minimize any disproportionate impact on such Product's development or commercialization hereunder; (3) to meet the requirements for enrolling new patients or new sites for existing Clinical Trials; and (4) to meet the requirements for new Clinical Trials. All of the foregoing provisions shall be subject to and may be set out in further detail in the applicable Supply Agreement and Quality Agreement.

9.2.4 Environmental, Health and Safety. Myovant shall, or shall ensure that the Existing CMO(s), comply (a) in all material respects with Applicable Laws relating to relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants, including obtaining and maintaining permits required under such Applicable Laws; and (b) provide the JMC with verbal notice as promptly as practicable, confirmed in writing, in the event of any major incident, which shall include any event, occurrence, or circumstance, including any governmental or private action, which materially impacts or could reasonably be expected to materially impact the Myovant's ability to fulfill its obligations under this Agreement in relation to Manufacturing the Products in the Territory ("**Environmental Manufacturing Responsibilities**"). Unless otherwise agreed in the applicable Supply Agreement or Quality Agreement, Myovant shall permit Pfizer, or a consultant selected by Pfizer and reasonably acceptable to Myovant, on reasonable advance written notice to conduct periodic reviews or audits (but not more than [***] per year, except for exigent circumstances) during normal business hours of the environmental and health and safety practices and performance of the facility(ies) where the Manufacture of a Product in the Field for the Territory is occurring, provided that any such consultant is bound by confidentiality obligations no less stringent than those set out herein.

Section 9.3 Costs. [***] of the standard cost of goods for any Oncology Product(s) in the Oncology Field for sale in the Pfizer Territory shall constitute Manufacturing Costs and will be reimbursed by Pfizer, [***].

Section 9.4 Reports. Within [***] days following the end of each Calendar Quarter during which a Party is performing any material Manufacturing activities, such Party shall provide each JMC with a reasonable detailed written report of the material Manufacturing activities it has performed, or caused to perform, since the preceding report (or with respect to the first such report, since the Effective Date) and its material Manufacturing activities in process, and the future activities it expects to initiate, and any other information as determined by the JMC to be reported (including any information required under the [***] Agreement), in accordance with a template report reasonably agreed between the Parties.

ARTICLE X.
GRANT OF RIGHTS

Section 10.1 Rights Granted to Pfizer.

10.1.1 License Grant. Subject to the terms and conditions of this Agreement and [***] retained rights under the [***] Agreement, including Section 10.3, Myovant hereby grants to Pfizer the following rights and licenses, with the right to grant sublicenses only in accordance with Section 10.1.2, under the Myovant Background IP, Myovant Other Collaboration IP, Product Collaboration IP and Myovant's interest in the Joint Other Collaboration IP:

(a) a co-exclusive license (with Myovant and its Affiliates) to Develop and have Developed (i) the Oncology Product(s) in the Oncology Field, (ii) the WH Product(s) in the WH Field and (iii) the Pediatric Product(s) in the Pediatric Field, in each case of (i), (ii) and (iii), in the Co-Promotion Territory and solely pursuant to the applicable Joint Medical Affairs and Development Plan and Budget to the extent contemplated by and authorized pursuant to this Agreement;

(b) a co-exclusive license (with Myovant, its Affiliates and its Excluded Affiliates) to Commercialize the Products in the Field in the Co-Promotion Territory solely pursuant to the applicable Co-Promotion Commercialization Plan and Budget to the extent contemplated by and authorized pursuant to this Agreement and expressly excluding the right to sell, offer for sale, have sold, export and import;

(c) effective following the Option Closing if it occurs, a co-exclusive license (with Myovant and its Affiliates) to Develop and have Developed (i) the Oncology Product(s) in the Oncology Field and (ii) the Pediatric Product(s) in the Pediatric Field, in each case of (i) and (ii), in the Pfizer Territory and in accordance with the Joint Medical Affairs and Development Plan and Budget;

(d) a co-exclusive license (with Myovant and its Affiliates) to Manufacture or have Manufactured the Products for use by the Parties in the Co-Promotion Territory, solely to the extent that the Parties have agreed in writing that Pfizer will conduct Manufacturing activities with respect to Products in the Co-Promotion Territory;

(e) a non-exclusive, fully paid, perpetual, irrevocable, royalty-free license, under the Product Collaboration IP invented, conceived, discovered, developed or otherwise made solely by Pfizer, for all purposes other than the Exploitation of the Products;

(f) effective following the Option Closing if it occurs, an exclusive license to Develop and have Developed (i) the Oncology Product(s) in the Oncology Field and (ii) the Pediatric Product(s) in the Pediatric Field, in each case of (i) and (ii), in the Pfizer Territory and in accordance with the Development Component.

(g) effective following the Option Closing if it occurs, an exclusive license to sell, offer for sale, have sold, export, import and Commercialize (i) the Oncology Product(s) in the Oncology Field and (ii) the Pediatric Product(s) in the Pediatric Field, in each case of (i) and (ii), in the Pfizer Territory; and

(h) effective following the Option Closing if it occurs, a co-exclusive license (with Myovant and its Affiliates) to Manufacture or have Manufactured the Oncology Product(s) and Pediatric Product(s) for use by Pfizer in the applicable Field in the Pfizer Territory.

10.1.2 Sublicense Rights. Subject to the terms and conditions of this Agreement, Pfizer shall have the right to sublicense the licenses granted to it by Myovant under Section 4.6 and Section 10.1.1 to Affiliates of Pfizer and to Third Parties; [***]. Pfizer shall cause each of its Affiliates and Sublicensees to comply with the applicable terms and conditions of this Agreement. The grant of any such sublicense shall not relieve Pfizer of its obligations under this Agreement, except to the extent they are satisfactorily performed by such Affiliate or Sublicensee.

Section 10.2 Rights Granted to Myovant. Subject to the terms and conditions of this Agreement, including Section 10.3, Pfizer hereby grants to Myovant a license under the Pfizer Other Collaboration IP solely to enable Myovant to grant a sublicense to [***] as required under the [***] Agreement solely for [***] to (a) Exploit the [***] or [***] in the Takeda Territory to the extent such sublicense is necessary or useful for [***] to Exploit such [***] or [***] in the Takeda Territory (each as defined in the [***] Agreement as it exists as of the Effective Date), (b) Develop the [***] and [***] in the Women's Health Field in the United States (and

Canada to the extent it is included as part of the Co-Promotion Territory under this Agreement) solely for the purpose of Exploiting such [***] or [***] in the Field in the Takeda Territory (each as defined in the [***] Agreement as it exists as of the Effective Date) and (c) Manufacture the [***] or [***] outside the Takeda Territory (each as defined in the [***] Agreement as it exists as of the Effective Date).

Section 10.3 Retention of Rights; No Implied Rights.

10.3.1 Retained Rights of Myovant. Notwithstanding Section 10.1 above, Myovant expressly retains the right on behalf of itself, its Affiliates, Excluded Affiliates and its and their Sublicensees, including the right to license, subject to Section 16.1 and Section 16.2, and grant rights of reference to its Affiliates, Excluded Affiliates and its and their (sub)licensees, solely to:

(a) perform its and their obligations and exercise its and their rights under this Agreement;

(b) Develop, obtain and maintain Regulatory Approvals for and to Manufacture, Commercialize and otherwise Exploit any compound or product other than (i) the Compound, (ii) Products or (iii) any other pharmaceutical product containing any Compound (alone or in combination with one or more other active pharmaceutical ingredients), in any field (including the Field) anywhere in the world;

(c) Develop, obtain and maintain Regulatory Approvals for, and to Manufacture, Commercialize and otherwise Exploit the (i) Products outside the Field or outside the Territory; and (ii) the WH Product(s) outside the Co-Promotion Territory in any field (excluding the Oncology Field);

(d) Manufacture or have Manufactured the Compound or Products, other than a generic form thereof, anywhere in the world; and

(e) Develop and have Developed the Oncology Product(s) and the Pediatric Product(s) in the Pfizer Territory solely for Commercialization in the Co-Promotion Territory in accordance with the Joint Medical Affairs and Development Plan and Budget.

10.3.2 Retained Rights of Pfizer. Notwithstanding anything to the contrary in this Agreement and without limitation of any rights granted or reserved to Pfizer pursuant to any other term or condition of this Agreement, Pfizer hereby expressly retains, on behalf of itself and its Affiliates all right, title and interest in and to the Pfizer Background IP, Pfizer Other Collaboration IP, the Pfizer's interest in the Joint Other Collaboration IP and Pfizer's Corporate Names, in each case (a) to exercise its rights and perform its obligations under this Agreement, including the right to grant licenses thereunder to its Affiliates and Third Parties in connection therewith and (b) subject to Section 16.1, to Exploit any compound or product other than the Compound or the Products in all fields (including the Field) anywhere in the Territory.

10.3.3 No Implied Licenses. Except as expressly set forth in this Agreement, neither Party grants to the other Party any right or license, express or implied, under its Background IP, Collaboration IP, the Product Trademarks or any other intellectual property rights Controlled by such Party.

10.3.4 [***] Agreement. The Parties acknowledge and agree that (a) the licenses under Section 10.1.1 constitute sublicenses under the applicable license rights granted to Myovant by [***] under the [***] Agreement, (b) the licenses under Section 10.1.1 are subject and subordinate to the terms and conditions of the [***] Agreement in all material respects, and (c) that [***] is an intended third party beneficiary under this Agreement with the right to enforce the terms hereof. Pfizer shall participate in discussions with Myovant and [***] at least annually to facilitate information sharing and the global coordination of the Exploitation of the Compounds and Products in the Field in the Territory.

10.3.5 Direct License under [***] License Agreement. To the extent [***] has the right to request and requests a direct license as a result of the termination of the [***] Agreement by Licensee, then Pfizer is not restricted hereunder from taking such a license, subject to the conditions set forth in the [***] Agreement.

10.3.6 Third Party Licenses. If the Development, Commercialization, Manufacture or other Exploitation of any Product by either Party as contemplated herein or any Related Agreement would infringe any Third Party Patent right (other than a Patent to which a Party is already granted a license or sublicense as of the Effective Date), or either Party believes it otherwise necessary or desirable to obtain a license under a Third

Party's Patent rights to avoid any claims or litigation concerning any such infringement against either Party with respect to one or more countries in the Territory, then the Party first having knowledge or opinion of such matter shall promptly bring such matter to the attention of the other Party, and the Parties shall reasonably discuss (via IPOC) the basis for such alleged infringement and whether to take a Third Party License for the Co-Promotion Territory and the taking of such a license in the Co-Promotion Territory shall be subject to approval by the applicable JSC under Section 2.3.18. Pfizer, its Affiliates and Sublicensee shall have the first right to obtain a Third Party License for the Pfizer Territory, and notwithstanding this Section 10.3.6, shall have the final decision-making authority in its determination to obtain such license.

Section 10.4 Initial Disclosure of Know-How. Myovant shall (a) promptly following the Effective Date, without additional consideration, disclose to Pfizer all Myovant Background IP in existence as of the Effective Date that Pfizer reasonably needs, in Myovant's good faith judgement, in order to carry out its obligations or exercise its rights under this Agreement and within the scope of the licenses granted hereunder and (b) upon Pfizer's reasonable written request and at Pfizer's cost and expense, provide any additional Myovant Background IP included within the scope of the licenses granted hereunder, and provide Pfizer with all reasonable assistance necessary or desirable to enable Pfizer to carry out its obligations or exercise its rights under this Agreement and the licenses granted hereunder.

Section 10.5 Pfizer Territory Option.

10.5.1 Option Grant. Myovant hereby grants to Pfizer an exclusive option, to obtain the licenses under Sections 10.1.1(c), 10.1.1(f), 10.1.1(g) and 10.1.1(h) (the "**Pfizer Territory Option**"), exercisable during the Option Period in accordance with this Section 10.5.

10.5.2 Option Exercise. To exercise the Pfizer Territory Option, Pfizer shall provide to Myovant written notice specifying such exercise during the Option Period (such notice, the "**Option Exercise Notice**"). Upon Pfizer's provision of the Option Exercise Notice to Myovant during the Option Period, the Pfizer Territory Option shall be deemed exercised and the licenses set forth in Sections 10.1.1(c), 10.1.1(f), 10.1.1(g) and 10.1.1(h) and any other rights set forth in this Agreement with respect to the Pfizer Territory will automatically be granted without any further action of the Parties, *provided that*, if Pfizer has notified Myovant under Section 10.5.3 that it reasonably determines that Competition Clearance is required, the expansion of the rights of Pfizer hereunder with respect to the Pfizer Territory shall not be effective until any required Competition Clearance has been obtained (such date when all required Competition Clearances are obtained (if there are required Competition Clearances) or the date on which the exercise is made (if there are no required Competition Clearances), the "**Option Closing**"). Upon the Option Closing and provided Pfizer has paid the Option Exercise Payment, the Territory with respect to the Oncology Products shall be deemed to include the Pfizer Territory.

10.5.3 Competition Clearance. If Pfizer determines that Competition Clearance is required for Pfizer to obtain the rights contemplated by the Pfizer Territory Option, then Pfizer shall promptly notify Myovant thereof at least [***] days prior to its delivery of the Option Exercise Notice to Myovant. In the case of any Competition Clearances required, the Parties will coordinate in good faith regarding any required filings and any Costs associated therewith shall be borne by Pfizer. In the event that any required Competition Clearances are not obtained within [***] days after the date of the Option Exercise Notice, then the Pfizer Territory Option shall expire and Pfizer shall have no further rights with respect to the Pfizer Territory.

10.5.4 Expiry of Option Period. If the Option Period has commenced but Pfizer subsequently fails to provide the Option Exercise Notice to Myovant prior to the expiry of the Option Period, then, upon the expiry of the Option Period, the Pfizer Territory Option shall lapse, and Pfizer shall have no further rights with respect to the Pfizer Territory.

10.5.5 Pfizer Operation Plan. Following Myovant's receipt of the Option Exercise Notice from Pfizer (if any), within [***] days from Myovant's receipt of the Option Exercise Notice from Pfizer, Pfizer shall prepare and submit to the JSC for notification, an initial operation plan for its activities with respect to the Oncology Product(s) in the Oncology Field in the Pfizer Territory (such plan, to the extent approved by the JSC and as may be amended form time to time pursuant to this Section 10.5.5, a "**Pfizer Operation Plan**"), which shall include the following components:

(a) reasonable details of: (i) principal strategies with respect to marketing and promoting the Oncology Product(s) in the Oncology Field; (ii) the material activities to be conducted by Pfizer and its Affiliates and Sublicensees in connection with the Commercialization of the Oncology Product(s) in the Oncology Field; and (iii) [***] set forth in this clause (a) ("**Commercialization Component**");

(b) reasonably detailed descriptions of (i) all material Development activities reasonably anticipated to be undertaken by Pfizer to obtain the Regulatory Approval of the Oncology Product in the Oncology Field in the Pfizer Territory; (ii) all activities related to the Development of the Oncology Product in the Oncology Field in the Pfizer Territory; (iii) estimated dates on which Pfizer expects to file a DAA in each country in the Pfizer Territory in which Pfizer is Developing an Oncology Product in the Oncology Field; and (iii) [***] set forth in this clause (b) ("**Development Component**"). The Parties acknowledge that the Development Component must not include any Product in the Field or Co-Administration Study that is not already included in the Joint Medical Affairs and Development Plan and Budget; and

(c) (i) the specific Regulatory Activities to be performed by Pfizer for the Pfizer Territory and the activities to be performed by Myovant to support such Regulatory Activities, including any assistance to be provided by Myovant under Section 4.3.2 with respect to such Regulatory Activities; and (ii) any Regulatory Activities performed by Myovant prior to the transfer of the Regulatory Approvals in the Pfizer Territory to Pfizer, and any other activities performed by Myovant to facilitate such transfer.

Pfizer shall update the Pfizer Operation Plan and submit it to the JSC at least [***] each Calendar Year, *provided that* Pfizer's obligation to update the Pfizer Operation Plan and submit it to the JSC with respect to the Commercialization Component shall end at the [***] anniversary of the First Commercial Sale of the first Oncology Product in the Oncology Field in a Major Market Country. Pfizer may amend the Pfizer Operation Plan as reasonable or necessary at any time during the Term and provide the JSC with a copy of all such amendments.

ARTICLE XI.
INTELLECTUAL PROPERTY

Section 11.1 Ownership of Intellectual Property.

11.1.1 Product Collaboration IP. Subject to the rights and licenses expressly granted under this Agreement, Myovant shall solely own all right, title and interest in and to all Product Collaboration IP. Pfizer, on behalf of itself and its Affiliates and its or their Sublicensees, hereby assigns (and to the extent such assignment can only be made in the future hereby agrees to assign) to Myovant, Pfizer's entire right, title and interest in and to the Product Collaboration IP.

11.1.2 Other Collaboration IP.

(a) Myovant shall own all right, title and interest in any and all Myovant Other Collaboration IP. Pfizer shall own all right, title and interest in any and all Pfizer Other Collaboration IP. Each party shall own an equal, undivided interest in any and all Joint Other Collaboration IP. Subject to the licenses and rights of reference granted under Section 4.6, Section 10.1.1 and Section 10.2, the non-compete obligations set forth in Section 16.2, and each Party's confidentiality obligations under Article XII, each Party shall have the right to Exploit the Joint Other Collaboration IP without a duty of seeking consent or accounting to the other Party. If in a particular country the consent of co-owners is required for one co-owner to grant license rights under or otherwise Exploit Joint Other Collaboration IP as provided in the previous sentence, each Party hereby consents to such license grant to use and otherwise Exploit such Joint Other Collaboration IP in such country without any duty to share profits with (other than such duty under this Agreement), or provide an accounting to, the other Party with respect to such use and Exploitation, and each Party hereby grants to the other Party under such granting Party's interest in such Joint Other Collaboration IP, a perpetual, irrevocable, royalty-free, sublicensable (through multiple tiers), non-exclusive license to Exploit any Joint Other Collaboration IP in such country in any manner and for any purpose whatsoever, subject to the licenses and rights of reference granted under Section 4.6, Section 10.1.1, and Section 10.2, the non-compete obligations set forth in Section 16.2, and each Party's confidentiality obligations under Article XII.

(b) Ownership of Regulatory Materials (including any Regulatory Approval or Product Labeling) relating to either Product shall be governed by Section 4.2.

11.1.3 Background IP. Each Party shall retain all right, title and interest to its Background IP, and, except as expressly set forth in this Agreement, no right or license to such Patents, Know-How and other intellectual property rights included in such Background IP is granted by either Party to the other Party.

11.1.4 United States Law. The determination of whether Know-How is invented, conceived, discovered, developed or otherwise made by a Party for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with Applicable Law in the United States irrespective of where such conception, discovery, development or making occurs. In the event that United States law does not otherwise apply to the invention, conception, discovery, development or making of any Know-How or Patents or other inventions hereunder, each Party shall, and does hereby, assign, and shall cause its Affiliates and its and their Sublicensees to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Patents or Know-How as well as any copyright or other intellectual property rights with respect thereto, as is necessary to fully effect, as applicable, the ownership provided for in this Section 11.1.

11.1.5 Assignment Obligation. Each Party shall cause all Persons who perform Development, Commercialization, Manufacturing or other activities for or on behalf of such Party under this Agreement or who invent, conceive, discover, develop or otherwise make any Know-How or Patents by or on behalf of either Party or its Affiliates or its or their Sublicensees under or in connection with this Agreement to assign (or, if such Party is unable to cause such Person to assign, to provide an exclusive license under) their rights in any such Know-How or Patents resulting therefrom to such Party, except where Applicable Law requires otherwise and except in the case of governmental, not-for-profit, academic and public institutions that have standard policies against such an assignment (in which case a suitable exclusive license with the right to sublicense or right to obtain such a license shall be obtained).

Section 11.2 Prosecution and Maintenance of Patents.

11.2.1 Myovant Patents.

(a) Myovant's Rights. Subject to Section 11.2.1(b), Myovant shall have the sole right outside the Co-Promotion Territory and first right in the Co-Promotion Territory, but not the obligation, through using counsel of its own choice, to prepare, file, prosecute and maintain (including being responsible for any related interference, re-issuance, re-examination and post grant review, including any inter partes review and opposition proceedings) ("**Prosecute and Maintain**") Myovant Patents, the Cost of which activities shall be deemed Allowable IP Costs in the Co-Promotion Territory and be solely borne by Myovant outside the Co-Promotion Territory. Myovant shall consult and reasonably cooperate with Pfizer for all material steps with regard to the Prosecution and Maintenance of the Myovant Patents in the Co-Promotion Territory and shall provide Pfizer with a reasonable opportunity and reasonable time to review and comment on substantive prosecution matters and drafts of any responses or other proposed filings by Myovant before any applicable filings are submitted to any relevant patent office or Governmental Authority and consider in good faith any reasonable comments offered by Pfizer in any final filings submitted by Myovant to any relevant patent office or Governmental Authority in a timely fashion.

(b) Pfizer's Rights. If Myovant elects not to Prosecute and Maintain a Myovant Patent in the Co-Promotion Territory, Myovant shall provide reasonable prior written notice to Pfizer of such intention and Pfizer shall have the second right, but not the obligation, using counsel of its own choice, to Prosecute and Maintain such Myovant Patent in the Co-Promotion Territory, at Pfizer's sole cost and expense, *provided that* Pfizer's step-in rights with respect to Myovant Background Patents in the Co-Promotion Territory are subject to [***] step-in rights under the [***] Agreement. Following the Option Closing if it occurs, the following shall apply. Myovant shall have the first right, but not the obligation, through using counsel of its own choice, to Prosecute and Maintain Myovant Patents that Cover the Oncology Product(s) in the Oncology Field in the Pfizer Territory at Parties' [***] cost and expense. Myovant shall periodically inform Pfizer of all material steps with regard to the Prosecution and Maintenance of such Myovant Patents in the Pfizer Territory and shall provide Pfizer with an opportunity to review and comment on substantive prosecution matters in a timely fashion. If Myovant decides not to Prosecute and Maintain such a Myovant Patent that Cover the Oncology Product(s) in the Oncology Field in the Pfizer Territory, Myovant shall provide reasonable prior written notice to Pfizer of such intention and Pfizer shall thereupon have the option to assume the control and direction of the Prosecution and Maintenance of such Myovant Patent at Pfizer's cost and expense, using counsel of Pfizer's choice,

provided that Pfizer's step-in rights with respect to Myovant Background Patents in the Pfizer Territory are subject to [***] step-in rights under the [***] Agreement. Upon Pfizer's exercise of its second rights to Prosecute and Maintain such Myovant Patent in accordance with this Section 11.2.1(b), Pfizer shall periodically inform Myovant of all material steps with regard to the Prosecution and Maintenance of such Myovant Patents in the Territory and shall provide Myovant with an opportunity to review and comment on substantive prosecution matters in a timely fashion. If Pfizer at any time declines to participate in the Prosecution and Maintenance of any Myovant Patent under this Section 11.2.1(b) or share in the costs of Prosecuting and Maintaining any Myovant Patent under this Section 11.2.1(b), on a country-by-country basis, Pfizer will provide Myovant with [***]-day prior written notice to such effect, in which event, Pfizer will (i) have no responsibility with respect to the Prosecution and Maintenance of the applicable Myovant Patent after the end of such [***] period, (ii) have no responsibility for any expenses incurred in connection with such Myovant Patent after the end of such [***] period and (iii) [***], and Myovant shall have the right to continue or resume the Prosecution and Maintenance of such Myovant Patents, at its own discretion and its sole cost and expense.

11.2.2 Joint Other Collaboration Patents. In the event the Parties make any Joint Other Collaboration Know-How, the Parties will promptly meet to discuss and determine, based on mutual consent, whether to seek patent protection thereon. Neither Party will file any Joint Other Collaboration Patent without mutual consent. If the Parties decide to seek patent protection for any Joint Other Collaboration Know-How, Myovant shall have the first right, but not the obligation, through using counsel mutually acceptable to the Parties, to Prosecute and Maintain such Joint Other Collaboration Patent, the Cost of which activities shall be shared [***] by the Parties [***]. Myovant shall periodically inform Pfizer of all material steps with regard to the Prosecution and Maintenance of the Joint Other Collaboration Patents and shall provide Pfizer with an opportunity to review and comment on substantive prosecution matters in a timely fashion and will reasonably consider Pfizer's comments. Subject to the last sentence of this Section 11.2.2, if Myovant decides not to Prosecute and Maintain a Joint Other Collaboration Patent, Myovant shall provide reasonable prior written notice to Pfizer of such intention and Pfizer shall thereupon have the option to assume the control and direction of the Prosecution and Maintenance of such Joint Other Collaboration Patent at Pfizer's sole cost and expense. If either Party (the "**Declining Party**") at any time declines to participate in the Prosecution and Maintenance of any Joint Other Collaboration Patent or share in the costs thereof, on a country by country basis, the Declining Party will provide the other Party (the "**Continuing Party**") with [***]- days prior written notice to such effect, in which event, the Declining Party will (i) have no responsibility with respect to the Prosecution and Maintenance of the applicable Joint Other Collaboration Patent after the end of such [***] period, (ii) have no responsibility for any expenses incurred in connection with such Joint Other Collaboration Patent after the end of such [***] period, (iii) if the Continuing Party elects to continue the Prosecution and Maintenance of such Joint Other Collaboration Patent, the Declining Party, upon the Continuing Party's request, will execute such documents and perform such acts, at the Continuing Party's expense, as may be reasonably necessary (1) [***] and (2) to permit the Continuing Party to Prosecute and Maintain such Joint Other Collaboration Patent at its sole expense, and (iv) the Declining Party shall retain a non-exclusive, sublicensable, perpetual, irrevocable, royalty-free, fully paid-up worldwide right and license to practice and exploit such Patent for any and all purposes.

11.2.3 Myovant Other Collaboration Patents. Myovant has the sole right, but not the obligation, to file, prosecute and maintain Myovant Other Collaboration Patents in its sole discretion and at its own expense. Notwithstanding the foregoing, following the Option Closing if it occurs, the following shall apply. If Myovant decides not to prepare, file, prosecute or maintain a Myovant Other Collaboration Patent in any country in the Field in the Pfizer Territory, Myovant shall provide reasonable prior written notice to Pfizer of such intention and Pfizer shall thereupon have the option to assume the control and direction of the preparation, filing, prosecution and maintenance of such Myovant Other Collaboration Patent in the Pfizer Territory at Pfizer's sole cost and expense. In the event that Pfizer elects to resume the preparation, filing, prosecution and maintenance of such Myovant Other Collaboration Patent in the Pfizer Territory, such Myovant Other Collaboration Patent shall [***] and Myovant will retain a non-exclusive, sublicensable, perpetual, irrevocable, royalty-free, fully paid-up worldwide right and license to practice and exploit such Patent for any and all purposes.

11.2.4 Pfizer Other Collaboration Patents. Pfizer has the sole right, but not the obligation, to file, prosecute and maintain Pfizer Other Collaboration Patents in its sole discretion and at its own expense. Notwithstanding the foregoing, if Pfizer decides not to prepare, file, prosecute or maintain a Pfizer Other Collaboration Patent in any country in the Field in the Co-Promotion Territory, Pfizer shall provide reasonable prior written notice to Myovant of such intention and Myovant shall thereupon have the option to assume the control and direction of the preparation, filing, prosecution and maintenance of such Pfizer Other Collaboration

Patent in the Co-Promotion Territory at Myovant's sole cost and expense. In the event that Myovant elects to resume the preparation, filing, prosecution and maintenance of such Pfizer Other Collaboration Patent in the Co-Promotion Territory, such Pfizer Other Collaboration Patent shall [***] and Pfizer will retain a non-exclusive, sublicensable, perpetual, irrevocable, royalty-free, fully paid-up worldwide right and license to practice and exploit such Patent for any and all purposes.

11.2.5 Cooperation. The non-prosecuting Party shall, and shall cause its Affiliates to, assist and cooperate with the prosecuting Party, as the prosecuting Party may reasonably request from time to time, in the preparation, filing, prosecution and maintenance of the Collaboration Patents under this Agreement, including that the non-prosecuting Party shall, and shall ensure that its Affiliates, provide access to relevant documents and other evidence and make its employees available at reasonable business hours.

11.2.6 Patent Term Extension and Supplementary Protection Certificate. Myovant shall have the sole right to make decisions regarding, and shall have the right to apply for, patent term extensions worldwide, including in the United States with respect to extensions pursuant to 35 U.S.C. §156 et. seq. and in other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions that are now available or become available in the future ("**Patent Term Extensions**"), wherever applicable, for the Myovant Patents, including whether or not to do so; *provided* that Myovant shall use [***] to consult and reasonably cooperate with Pfizer of all material steps with regard to the preparation, filing and to determine the course of action with respect to such filings and shall provide Pfizer with a reasonable opportunity and reasonable time to review and comment on any proposed Patent Term Extension filings and, specifically prior to the filing of the Patent Term Extension application for the Co-Promotion Territory, and will consider in good faith any reasonable comments offered by Pfizer in any final filing submitted by Myovant. Pfizer shall use [***] to provide reasonable assistance, as requested by Myovant to obtain such extension or supplementary protection certificate.

11.2.7 Common Ownership Under Joint Research Agreements. Notwithstanding anything to the contrary in this Article XI, neither Party shall have the right to make an election under 35 U.S.C. 102(c) when exercising its rights under this Article XI without the prior written consent of the other Party. With respect to any such permitted election, the Parties shall use reasonable efforts to cooperate and coordinate their activities with such Party with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in 35 U.S.C. 100(h).

11.2.8 Patent Listings. Myovant shall have the sole right, but make [***], to make decisions regarding and Myovant shall have the right to make all filings with Regulatory Authorities in the Territory with respect to the Myovant Patents, including as required or allowed (a) in the United States, in the FDA's Orange Book, (b) the European Union, under the national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83, and (c) under other international equivalents; *provided* that prior to such listings (x) Myovant shall consult and reasonably cooperate with Pfizer in all material steps with regard to (1) evaluating and identifying all applicable Patents, wherein each Party will have the right to review, where reasonable, original records relating to any invention for which Patents are being considered by the other Party for any such listing and (2) determining the course of action with respect to such filings in the Co-Promotion Territory and Pfizer Territory and (y) Myovant shall provide Pfizer with a reasonable opportunity and reasonable time to review and comment on any proposed patent listing filings and, specifically prior to the filing of the patent listings for the Co-Promotion Territory, and will consider in good faith any reasonable comments offered by Pfizer in any final patent listing filing submitted by Myovant. Myovant will use [***] in its final decision-making authority as to the listing of all applicable Myovant Patents and any other relevant Patents which it Controls.

Section 11.3 Enforcement of Patents.

11.3.1 Notice. If either Party becomes aware of (a) any suspected infringement of any Myovant Patents in the Territory or (b) any certification filed in the United States under the "Drug Price Competition and Patent Term Restoration Act of 1984" (21 United States Code §355(b)(2)(A)(iv) or (j)(2)(A)(vii)(IV)) ("**ANDA Act**") or similar provisions in other jurisdictions (each of clauses (a) and (b), an "**Infringement**"), such Party shall promptly notify the other Party and provide it with all details of such Infringement of which it is aware (each, an "**Infringement Notice**"); *provided*, that each Party shall give the other Party an Infringement Notice not later than [***] Business Days after it becomes aware of any Infringement described in clause (b) above.

11.3.2 Enforcement of Myovant Background Patents and Product Collaboration Patents.

(a) Myovant's Rights. Myovant shall have the first right, but not the obligation, to prosecute any Infringement with respect to or otherwise enforce the Myovant Patents worldwide, including as a defense or counterclaim in connection with any Third Party Infringement Claim, using counsel of Myovant's choice, the Costs of which shall solely borne by Myovant. Pfizer will have the right to consult with Myovant about such litigation, which Myovant shall reasonably consider Pfizer's comments, and to participate in (including by being joined to such action if so requested and use reasonable efforts to obtain any necessary joinder), and be represented by independent counsel in such litigation at Pfizer's own expense. Myovant shall promptly inform Pfizer if it elects not to exercise its first right under this Section 11.3.2(a) and Pfizer shall, thereafter, have the right, but not the obligation, to initiate and prosecute such suit or other action in the name of both Parties, at Pfizer's cost and expense and its choice of counsel, in the Co-Promotion Territory. Following Pfizer's exercise of its second right to enforce such Myovant Patent in the Co-Promotion Territory, Myovant will have the right to consult with Pfizer about such litigation, which Pfizer shall reasonably consider Myovant's comments, and to participate in and be represented by independent counsel in such litigation at Myovant's own expense.

(b) Pfizer's Right in Pfizer Territory. Following the Option Closing if it occurs, this Section 11.3.2(b) shall apply. With respect to any Infringement with respect to or otherwise enforcement of the Myovant Patents in the Oncology Field in the Pfizer Territory, Myovant shall have the first right to prosecute any such Infringement at its sole cost. Pfizer will have the right to consult with Myovant about such litigation, which Myovant shall reasonably consider Pfizer's comments, and to participate in and be represented by independent counsel in such litigation at Pfizer's own expense. Myovant shall notify Pfizer of Myovant's decision as to whether to take any action at least [***] days before any time limit set forth in an Applicable Law or within [***] days after receiving the Infringement Notice, whichever is shorter. If Myovant decides not to prosecute any such Infringement, unless [***] exercises its right to step-in and take such action at [***] own cost and expense as provided under the [***] Agreement, Pfizer may then elect to prosecute such alleged or threatened infringement at Pfizer's sole cost and expense, using counsel of Pfizer's choice. Following Pfizer's exercise of its second right to enforce such Myovant Patent in the Pfizer Territory, Myovant will have the right to consult with Pfizer about such litigation, which Pfizer shall reasonably consider Myovant's comments, and to participate in and be represented by independent counsel in such litigation at Myovant's own expense.

11.3.3 Enforcement of Other Patents. Pfizer shall have the sole right, but not the obligation, to prosecute Infringement with respect to the Patents within the Pfizer Background IP and Pfizer Other Collaboration IP, including as a defense or counterclaim in connection with any Third Party Infringement Claim, at Pfizer's sole cost and expense, using counsel of its own choice and all recoveries will be retained by Pfizer. Myovant shall have the sole right, but not the obligation, to prosecute Infringement with respect to the Myovant Other Collaboration Patents, including as a defense or counterclaim in connection with any Third Party Infringement Claim, at Myovant's sole cost and expense, using counsel of its own choice and all recoveries will be retained by Myovant. The Parties will promptly meet to discuss and determine, based on mutual consent, whether to prosecute any Infringement with respect to or otherwise enforce any Joint Other Collaboration Patents. Neither Party will enforce any Joint Other Collaboration Patent without mutual consent.

11.3.4 Cooperation. The Parties agree to cooperate fully in any Infringement action pursuant to this Section 11.3, including by making the inventors, applicable records and documents (including laboratory notebooks) of the relevant Patents available to the controlling Party upon such Party's request. Where a Party controls such an action, the other Party shall, and shall cause its Affiliates to, assist and cooperate with the controlling Party, as such controlling Party may reasonably request from time to time, in connection with its activities set forth in this Section 11.3, including where necessary, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours. Unless otherwise set forth herein, the Party entitled to bring any patent infringement litigation in accordance with this Section 11.3 shall have the right to settle such claim; *provided* that neither Party shall have the right to settle any Infringement litigation under this Section 11.3 in a manner that has a material adverse effect on the rights or interest of the other Party or in a manner that imposes any costs or liability on or involves any admission by, the other Party, without the express written consent of such other Party (which consent shall not be unreasonably withheld, conditioned or delayed). In connection with any activities with respect to an Infringement action prosecuted by a Party pursuant to this Section 11.3, the prosecuting Party shall (a) consult with the other Party as to the strategy for the prosecution of such claim, suit or proceeding, (b) consider in good faith any comments

from the other Party with respect thereto and (c) keep the other Party reasonably informed of any material steps taken and provide copies of all material documents filed, in connection with such action.

11.3.5 Recovery. Subject to Section 11.3.3, any other recovery realized as a result of such litigation described above in this Section 11.3 (whether by way of settlement or otherwise) shall be first, allocated to reimburse the Parties for their reasonable out-of-pocket costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses) with any remainder [***].

Section 11.4 Infringement Claims by Third Parties.

11.4.1 Notice. If the Exploitation of any Product in the Field in the Territory pursuant to this Agreement results in, or is reasonably expected to result in, any claim, suit or proceeding by a Third Party alleging infringement by a Party or any of its Affiliates or its or their Sublicensees or customers (a "**Third Party Infringement Claim**"), including any defense or counterclaim in connection with an Infringement action initiated pursuant to Section 11.3, the Party first becoming aware of such alleged infringement shall promptly notify the other Party thereof in writing.

11.4.2 Myovant Rights. Subject to Article XIV, as between the Parties, Myovant shall have the first right, but not the obligation, to defend and control the defense of any such Third Party Infringement Claim in the Co-Promotion Territory, using counsel of Myovant's own choice, the Costs of which shall be solely borne by Myovant. Prior to Option Closing, Myovant shall have the sole right, but not the obligation, to defend and control the defense of any such Third Party Infringement Claim in the Pfizer Territory, the costs of which shall be solely borne by Myovant.

11.4.3 Pfizer Rights. Following the Option Closing if it occurs, Pfizer shall have the first right, but not the obligation, to defend and control the defense of any such Third Party Infringement Claim in the Pfizer Territory, at Pfizer's cost and expense, using counsel of Pfizer's own choice.

11.4.4 Parties' Step-in Rights. If the Party controlling such an action or its designee elects (in a written communication submitted to the other Party within a reasonable amount of time after notice of the alleged patent infringement) not to defend or control the defense of, or otherwise fails to initiate and maintain the defense of, any such claim, suit or proceeding in which the other Party is named as a defendant, within such time periods so that the other Party is not prejudiced by any delays, the other Party may conduct and control the defense of any such claim, suit or proceeding at the other Party's sole cost and expense and with counsel of its choice.

11.4.5 Cooperation. Where a Party controls such an action, the other Party shall, and shall cause its Affiliates to, assist and cooperate with the controlling Party, as such controlling Party may reasonably request from time to time, in connection with its activities set forth in this Section 11.4, including where necessary, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours. Each Party shall keep the other Party reasonably informed of all material developments in connection with any such claim, suit or proceeding. Each Party agrees to provide the other Party with copies of all material pleadings filed in such action and to allow the other Party reasonable opportunity to participate in the defense of the claims.

11.4.6 Recoveries. Any recoveries awarded to a Party in the Territory in connection with any Third Party Infringement Claim defended under this Section 11.4 shall be applied first to reimburse the Parties for reasonable Costs of defending such claim, suit or proceedings, with the balance of any such recoveries [***] in the Co-Promotion Territory and being deemed Net Sales (including any treble, punitive or other multiplier of damages and interest awarded with respect thereto) in the Pfizer Territory. The Party entitled to control the defense of a claim, suit or proceeding under this Section 11.4 shall have the right to settle such claim, suit or proceeding; provided that neither Party shall have the right to settle any claim, suit or proceeding under this Section 11.4 in a manner that has a material adverse effect on the rights or interest of the other Party or in a manner that imposes any costs or liability on or involves any admission by, the other Party, without the express written consent of such other Party (which consent shall not be unreasonably withheld, conditioned or delayed).

Section 11.5 Invalidity or Unenforceability Defenses or Actions. Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability of any of the Myovant Patents by a Third Party and of which such Party becomes aware. As between the Parties, Myovant shall have the first right, but not the obligation, to defend and control the defense of the validity and enforceability of the Myovant Patents in the Co-Promotion Territory, using counsel of Myovant's own choice, including when such invalidity or unenforceability is raised as a defense or counterclaim in connection with an Infringement action initiated pursuant to Section 11.3, the Cost of which shall be solely born by Myovant. Prior to Option Closing, Myovant shall have the sole right, but not the obligation, to defend and control the defense of the validity and enforceability of the Myovant Background Patents and Product Collaboration Patents in the Pfizer Territory, using counsel of Myovant's own choice, including when such invalidity or unenforceability is raised as a defense or counterclaim in connection with an Infringement action initiated pursuant to Section 11.3, the Cost of which shall be solely borne by Myovant. Following the Option Closing if it occurs, Pfizer may participate, at its option, but not the obligation, in any such claim, suit or proceeding in the Pfizer Territory with counsel of its choice at its sole cost and expense; *provided* that Myovant shall retain control of the defense in such claim, suit or proceeding at each Parties' own cost and expense. Following the Option Closing if it occurs and if Myovant or its designee elects not to defend or control the defense of the Myovant Background Patents or Product Collaboration Patents in a suit brought in the Pfizer Territory, then Myovant shall notify Pfizer of its election by written notice and Pfizer may have the option, but not the obligation, to conduct and control the defense of any such claim, suit or proceeding at Pfizer's sole cost and expense, with counsel of its choice. Where a Party controls such an action, the other Party shall, and shall cause its Affiliates to, assist and cooperate with the controlling Party, as such controlling Party may reasonably request from time to time in connection with its activities set forth in this Section 11.5, including, where necessary, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours. In connection with any activities with respect to a defense, claim or counterclaim relating to the Myovant Background Patents or Product Collaboration Patents pursuant to this Section 11.5, the controlling Party shall (x) consult with the other Party as to the strategy for such activities, (y) consider in good faith any comments from the other Party and (z) keep the other Party reasonably informed of any material steps taken and provide copies of all material documents filed, in connection with such defense, claim or counterclaim. The Party entitled to control the defense of a claim, suit or proceeding under this Section 11.5 shall have the right to settle such claim, suit or proceeding; *provided* that neither Party shall have the right to settle any claim, suit or proceeding under this Section 11.5 in a manner that has a material adverse effect on the rights or interest of the other Party or in a manner that imposes any costs or liability on or involves any admission by, the other Party, without the express written consent of such other Party (which consent shall not be unreasonably withheld, conditioned or delayed). Pfizer shall have the sole right, but not the obligation, to defend and control the defense of the validity and enforceability of the Pfizer Background Patents and Pfizer Other Collaboration Patents, at Pfizer's sole cost and expense, using counsel of its own choice. Myovant shall have the sole right, but not the obligation, to defend and control the defense of the validity and enforceability of the Myovant Other Collaboration Patents, at Myovant's sole cost and expense, using counsel of its own choice. The Parties shall discuss in good faith in defending the validity and enforceability of the Joint Other Collaboration Patents.

Section 11.6 Trademarks, Domain Names and Social Media.

11.6.1 Determination of Product Trademarks. Myovant shall determine and own all right, title and interest in and to the Product Trademarks in the Co-Promotion Territory subject to the applicable JCC's approval pursuant to Section 2.5.21, *provided that* if a Product Trademark cannot be legally used (either for regulatory, trademark law or other legal reasons) as determined by the Parties, the Product Trademark will not be used and an alternate trademark will be selected by Myovant. Following the Option Closing if it occurs, Pfizer shall determine and own all right, title and interest in and to the Product Trademarks in the Pfizer Territory subject to the Oncology JCC's approval pursuant to Section 2.5.17. If Pfizer wishes to use any Product Trademark developed or used by Myovant with respect to the Commercialization or the Oncology Product(s) in the Co-Promotion Territory ("**Myovant Product Trademarks**") to Commercialize the Oncology Product(s) in the Pfizer Territory, then the Parties will enter into a separate trademark license agreement containing commercially reasonable and customary terms.

11.6.2 Domain Names and Social Media. Myovant shall own and retain all right, title and interest in and to any and all domain names (including both gTLDs and ccTLDs) and any social media name, tag or handle or similar identifier that incorporate, in whole or in part, any of the Product Trademarks owned by Myovant.

Pfizer shall own and retain all right, title and interest in and to any and all domain names (including both gTLDs and ccTLDs) and any social media name, tag or handle or similar identifier that incorporate, in whole or in part, any of the Product Trademarks owned by Pfizer (collectively, "**Domain Names**").

(a) All the Domain Names shall be registered and renewed in the name of their respective owner and at such owners cost. The Parties may, from time to time, change the registrar with whom the Party has contracted to manage its Domain Name portfolio. The Parties agrees to assist and cooperate with the other Party, the old registrar or the new registrar in any way necessary to effectuate such a change of registrar.

(b) Myovant and Pfizer shall use [***] to maintain the Domain Names, including timely renewing the Domain Names' registration.

11.6.3 Parties' Use of the Product Trademarks.

(a) Each Party shall not (and shall cause each of its Affiliates and its and their respective Sublicensees not to): (i) do any act that endangers, destroys, dilutes or similarly affects, in any material respect, the validity or strength of any Product Trademark or the value of the goodwill pertaining to any Product Trademark; or (ii) attack, dispute or contest the validity of or ownership of any Product Trademark (including an registration or pending registration application relating thereto).

(b) Each Party shall (and shall cause its Affiliates and its and their respective Sublicensees to) comply with any Trademark marking requirements in each jurisdiction in the Territory concerning the Product Trademarks.

(c) In the Co-Promotion Territory (and in the Pfizer Territory following the Option Closing if it occurs and if Pfizer obtains a license to use Myovant Product Trademarks to Commercialize the Oncology Product(s)), Pfizer shall (and shall cause its Affiliates and its and their respective Sublicensees to) (i) subject to the requirements of Applicable Law, ensure that any Product Labeling or Promotional and Educational Materials that bear or display a Product Trademark indicate that such Product Trademark is the registered Trademark of Myovant, if registered in that jurisdiction where such Product Labeling or Promotional and Educational Materials are used (or if not registered in such jurisdiction, that such Product Trademark is the Trademark of Myovant) in a form and content approved by the applicable JCC; (ii) use [***] to comply with the guidelines and procedures provided by Myovant to Pfizer from time to time with respect to the use of the Product Trademarks (the "**Product Trademark Guidelines**"); and (iii) use [***] to ensure that the nature and quality of any Promotional and Educational Materials bearing a Product Trademark produced by or on behalf of Pfizer, are of a high standard and of such style, appearance and quality as to be adequate and suited to the exploitation to the best advantage and to the protection and enhancement of the Product Trademarks, and the goodwill pertaining thereto, and that the same shall not reflect adversely upon the goodwill of Myovant or any Product Trademark.

(d) To maintain and exercise quality control over the use of the Product Trademarks and to protect the goodwill associated therewith in the Co-Promotion Territory (and in the Pfizer Territory following the Option Closing if it occurs and if Pfizer obtains a license to use Myovant Product Trademarks to Commercialize the Oncology Product(s)), and if reasonably requested by Myovant, Pfizer shall provide Myovant with representative samples of uses of, and materials bearing, any Product Trademark for Myovant's review and approval of such uses of such Product Trademark, which approval shall not be unreasonably withheld, conditioned or delayed, and for verification of Pfizer's compliance with this Section 11.6.3 generally.

(e) If Pfizer breaches any of its obligations under this Section 11.6.3, Myovant shall notify Pfizer of such breach in writing, identifying which of the Product Trademarks is affected. The Parties shall discuss in good faith reasonable and appropriate steps to be taken to remedy any alleged breach of this Section 11.6.3 and the period of time in which such action must be taken (which action and time period must be reasonable taking into account all relevant factors). If the Parties cannot agree on such steps and time period, such disagreement shall be resolved pursuant to Section 17.2. Unless Pfizer remedies such breach within such period (as agreed by the Parties or as determined pursuant to Section 17.2), Myovant shall have the right, immediately upon written notice to Pfizer, to terminate the license to use the relevant Product Trademarks.

11.6.4 Registration, Prosecution, Maintenance, Enforcement and Defense of the Product Trademarks.

(a) Myovant shall have the right and obligation, using counsel of its own choice, to conduct clearance activities (including searches), register, prosecute and maintain the Product Trademarks in the Co-Promotion Territory at its own cost and expense. Following the Option Closing if it occurs, Pfizer shall have the right, using counsel of its own choice, to conduct clearance activities (including searches), register, prosecute and maintain the Product Trademarks with respect to the Oncology Product(s) in the Pfizer Territory at its own cost and expense.

(b) Each Party shall reasonably provide to the other Party prompt written notice of any actual or threatened infringement, dilution, misappropriation or other violation of, or unfair trade practices or any other like offense relating to, any Product Trademark in the Territory and of any actual or threatened claim that the use of any Product Trademark in the Territory violates the rights of any Third Party, in each case, of which such Party becomes aware. Myovant shall have the first right, but not the obligation, to enforce and defend the Product Trademarks in the Co-Promotion Territory at its cost and expense, and following the Option Closing if it occurs, Pfizer shall have the right, but not the obligation, to enforce and defend the Product Trademarks in the Pfizer Territory at its cost and expense, *provided that* the controlling Party will consult with the other Party (*e.g.*, via the applicable JCC) in good faith in determining the best way to prevent such infringement, including by institution of legal proceedings against such Third Party. In the Co-Promotion Territory, if Myovant decides not to enforce or defend its Product Trademark, it shall provide reasonable prior written notice to Pfizer of such intention and Pfizer shall thereupon have the option to assume the control and direction of such enforcement or defense. If Pfizer declines to assume the control and direction of such enforcement or defense, Myovant shall have the option to reconsider whether it wishes to enforce or defend its Product Trademark. Neither Party shall have the right to settle any claim under this section in a manner that diminishes the rights or interests of the other Party or imposes any liability on the other Party without the prior written consent of such other Party.

11.6.5 Corporate Names. Each Party and its Affiliates will retain all right, title and interest in and to its and their respective house marks, Corporate Names and corporate logos. Each Party shall not, and shall cause its Affiliates and its or their respective Sublicensees not to (a) do any act in connection with this Agreement that endangers, destroys or similarly affects, in any material respect, the value of the goodwill pertaining to the Corporate Names of the other Party or (b) attack, dispute or contest the validity of or ownership of the Corporate Names of the other Party anywhere in the world or any registrations issued or issuing with respect thereto. Each Party shall, and shall cause its Affiliates and its and their respective Sublicensees to, conform (y) to the customary industry standards for the protection of the Corporate Names of the other Party and (z) to maintain the quality standards of the other Party with respect to the goods sold and services provided in connection with the Corporate Names of such other Party.

ARTICLE XII.
CONFIDENTIALITY

Section 12.1 Obligations. Except upon obtaining the other Party's prior written consent to the contrary or, in the case of disclosures, to the extent expressly permitted under this Article XII, each Party agrees that, at all times during the Term and for a period of [***] years thereafter (provided that, in relation to any confidential information of any Existing Myovant Third Party disclosed by Myovant to Pfizer, and identified at such time in writing by Myovant to Pfizer as confidential information of any Existing Myovant Third Party Agreement, if longer), it shall, and shall cause its officers, directors, employees and agents to: (a) maintain in confidence, and not disclose to any Third Party (except as provided in Section 12.2), the other Party's Confidential Information and (b) not use the other Party's Confidential Information, directly or indirectly, for any purpose except as contemplated in this Agreement and the Related Agreements or as reasonably necessary for the performance of, or the exercise of such Party's rights under, this Agreement or a Related Agreement. Joint Other Collaboration IP shall be deemed the Confidential Information of both Parties and each Party shall be deemed the Disclosing Party and the Receiving Party with respect thereto. Product Collaboration IP shall be deemed the Confidential Information of Myovant and Myovant shall be deemed the Disclosing Party with respect thereto. The Parties acknowledge that this Agreement and all of the respective terms of this Agreement will be treated as Confidential Information of both Parties.

Section 12.2 Authorized Disclosure of Confidential Information.

12.2.1 Authorized Disclosure. Each Receiving Party may disclose the Disclosing Party's Confidential Information, without the Disclosing Party's prior written consent, only to the extent necessary or

useful in connection with the performance of its obligations or exercise of its rights as contemplated by this Agreement or a Related Agreement, including (a) filing or prosecution of Patents as permitted by this Agreement; (b) filing of Regulatory Materials in order to obtain or maintain Regulatory Approvals, further subject to Section 12.2.3; (c) complying with Applicable Law or regulation or order of any or court or Governmental Authority; (d) prosecuting or defending litigation as contemplated by this Agreement, further subject to Section 12.2.2; and (e) to its Affiliates' or actual Sublicensees', and with respect to Myovant, the Excluded Affiliates' and the Existing Myovant Third Parties' and such Party's and their Affiliates' respective directors, employees, agents, advisers, attorneys, consultants, contractors, lenders, insurers, prospective settlement parties, and other Third Parties on a "need-to-know" basis in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement or, if applicable, any Existing Myovant Third Party Agreement; *provided* that in clause (e), such Persons shall be bound by confidentiality and non-use obligations that are substantially similar to those set forth in this Article XII.

12.2.2 Disclosure Pursuant to Legal Process. Each Receiving Party may disclose the Disclosing Party's Confidential Information, without the Disclosing Party's prior written consent, to any Person, or Governmental Authority to the extent made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial and local governmental or regulatory body of competent jurisdiction or that, in the reasonable opinion of the Receiving Party's legal counsel, Applicable Law require such disclosure; *provided* that the Receiving Party, to the extent reasonably practicable, promptly notifies the Disclosing Party of the required disclosure in order to provide the Disclosing Party an opportunity to take legal action to prevent or limit such disclosure and, if asked, reasonably assists the Disclosing Party in pursuing such action; *provided, further* that the Receiving Party shall use reasonable efforts to request such court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial and local governmental or regulatory body of competent jurisdiction to afford such Confidential Information confidential protection; *provided, further* that the Confidential Information disclosed in response to such court or governmental order or requirement shall be limited to that information that is legally required to be disclosed in response to such court or governmental order or requirement and shall be disclosed under confidentiality provisions, solely to the extent that such confidentiality provisions are available under Applicable Law. For the avoidance of doubt, the disclosures of this Agreement by reason of compliance with applicable securities law shall be governed by Section 12.3.

12.2.3 Disclosure to Regulatory Authorities. The Regulatory Party may disclose the Disclosing Party's Confidential Information, without the Disclosing Party's prior written consent, to any Governmental Authority in connection with any filing, application or request for Regulatory Approval with respect to any Product in the Field in the Territory, to the extent that such disclosure is necessary for obtaining or maintaining any Regulatory Approval or submitting or amending any Regulatory Materials with respect to such Product in the Territory or to the extent such disclosure is required to satisfy any other regulatory obligation with respect to such Product in the Territory; *provided* that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with Applicable Law.

Section 12.3 Securities Filings. Notwithstanding anything to the contrary in this Article XII, each Party acknowledges and agrees that the other Party may submit this Agreement to, or file this Agreement with, the securities regulators or to other Persons as may be required by Applicable Law. If either Party believes in good faith and based on reasonable advice of counsel that disclosure of any Confidential Information is required by Applicable Law of any stock exchange on which such Party or its Affiliates or, in the case of Myovant, Excluded Affiliates, listed or trades securities and proposes to file this Agreement with the Securities and Exchange Commission or the securities regulators of any state or other jurisdiction (including the NASDAQ and the NYSE), then such Party will advise the other Party before making such disclosure and provide such other party a reasonable opportunity to review and comment on such filing and consider in good faith any comments with respect thereto.

Section 12.4 Use of Name. Each Party shall have the right to use the other Party's name and logo in presentations, such Party's website, collateral materials, corporate overviews, and other public disclosures (a) describing the collaboration and licensing relationship, (b) in connection with exercising its rights or performing its obligations under this Agreement, or (c) making any disclosure identifying the other Party or its Affiliates that is required by Applicable Law.

Section 12.5 Press Releases. The Parties have agreed upon the content of press releases that shall be issued substantially in the forms attached hereto as Exhibit 12.5, the release of which the Parties shall coordinate in order to accomplish such release promptly upon execution of this Agreement. Subject to Section 12.3, neither Party nor any of their Affiliates shall issue any other public announcement, press release or other public disclosure regarding this Agreement or its subject matter or any data or information related to the Compound or Products in the Field in the Territory that has not been publicly disclosed prior to the Effective Date without the other Party's prior written consent, except as expressly permitted hereunder or under any Existing Myovant Third Party Agreements. Neither Party nor its Affiliates shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement or any amendment thereto that has already been publicly disclosed by either Party or its Affiliates in accordance with this Article XII; *provided* that such information remains accurate as of such time and provided the frequency and form of such disclosure are reasonable.

Section 12.6 Publications.

12.6.1 Publications.

(a) Publication Plan. Each Party recognizes that the presentations and publication of papers or manuscripts regarding results of, and other information regarding, activities under this Agreement, including manuscripts, oral presentations, posters and abstracts (collectively, "**Publications**"), may be beneficial to both Parties; *provided* such Publications do not disclose Confidential Information of the other Party and are made in a coordinated manner between the Parties. Accordingly, each Party shall not make any Publications except in a manner consistent with the publication plans with respect to the Products in the Field (the "**Presentation and Publication Plans**") and the terms of this Section 12.6.1. The initial version of the Presentation and Publication Plan with respect to the WH Product(s) in the WH Field is set out in [***], and the initial version of the Presentation and Publication Plan with respect to Oncology Product(s) in the Oncology Field is set out in [***]. The applicable IPOC and JMDRC shall periodically review each Presentation and Publication Plan and propose and approve any appropriate amendments with respect thereto.

(b) Each Party shall have the right to review and approve (such approval not to be unreasonably withheld, conditioned or delayed) any proposed Publication by the other Party that contains clinical data or pertains to results of Clinical Trials, Other Studies or other studies with respect to either Product in the Field or that includes Confidential Information of such Party, *provided* that the Party that generated any clinical data shall be responsible for preparing Publications containing such clinical data, unless otherwise mutually agreed by both Parties. With respect to any proposed Publication that is a paper or manuscript, before it is submitted, the publishing Party shall deliver a then-current copy of the proposed Publication to the other Party and the IPOC at least [***] days prior to submitting the paper or manuscript to a publisher. The other Party and the IPOC shall review any such proposed Publication and give its comments to the publishing Party within [***] days of the delivery of such proposed Publication to the other Party and the IPOC. With respect to proposed Publications that are oral presentation materials, posters or abstracts, the presenting Party shall deliver a then-current copy of the proposed Publication for the other Party and the IPOC at least [***] days prior to making the presentation or making such proposed Publication public and the other Party and the IPOC shall make reasonable efforts to expedite review of such presentation materials, posters or abstracts, and shall return such proposed Publication as soon as practicable to the publishing or presenting Party with appropriate comments, if any, but in no event later than [***] days from the date of delivery to the other Party. Failure to respond within such [***] days shall be deemed approval to publish or present. If such proposed Publication is not approved, either Party may refer the matter to the applicable JSC for resolution together with the reasons for withholding approval. The publishing or presenting Party shall comply with the other Party's request to delete references to such other Party's Confidential Information in any such paper and shall withhold publication of any proposed Publication for an additional [***] days in order to permit the Parties to obtain Patent protection if either Party or the IPOC deems it reasonably necessary. Any Publication shall include recognition of the contributions of the other Party according to standard practice for assigning scientific credit, either through authorship or acknowledgement, as may be appropriate. Each Party shall use [***] to cause investigators and institutions participating in Clinical Trials or Other Studies with which it contracts, to agree to terms substantially similar to those set forth in this Section 12.6, which efforts shall satisfy such Party's obligations under this Section 12.6 with respect to such investigators and institutions.

12.6.2 Publication Guidelines. All Publications relating to the Products in the Field shall be prepared, presented, and published in accordance with the publishing Party's internal guidelines and

pharmaceutical industry accepted guidelines including: (a) International Committee of Medical Journal Editors (ICMJE) guidelines, (b) Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication, (c) Pharmaceutical Research and Manufacturers of America (PhRMA) guidelines, and (d) Principles on Conduct of Clinical Trials Publication and Listing of Clinical Trials. The Parties shall discuss and reasonably cooperate with each other in order to facilitate and ensure publication of any summaries of Clinical Trial data and results as required under Applicable Law on the Clinical Trial registry of each respective Party.

ARTICLE XIII.
REPRESENTATIONS, WARRANTIES AND COVENANTS

Section 13.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as of the Effective Date that:

13.1.1 Such Party is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated or formed.

13.1.2 Such Party: (a) has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (b) 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, and, in all material respects, does not conflict with any agreement, written or oral, between such Party and any Affiliate or Third Party.

13.1.3 Neither it nor any of its Affiliates has been debarred by the FDA, is not subject to any similar sanction of other Regulatory Authorities, and neither such Party nor any of its Affiliates has used, or will engage, in any capacity, in connection with this Agreement, any Person who either has been debarred by such a Regulatory Authority, or is the subject of a conviction described in Section 306 of the FFDCA. Such Party shall inform the other Party in writing promptly if it or any Person engaged by it or any of its Affiliates who is performing services under this Agreement is debarred or is the subject of a conviction described in Section 306 of the FFDCA, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to such Party's Knowledge, is threatened, relating to the debarment or conviction of such Party, any of its Affiliates or any such Person performing services hereunder or thereunder.

13.1.4 This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement, and compliance with its terms and provisions, and the consummation of the transaction contemplated hereby, by such Party shall not conflict, interfere or be inconsistent with, result in any breach of or constitute a default under, any agreement, instrument or understanding, oral or written, to which it, or any of its Affiliates, is a party or by which it, or any of its Affiliates, is bound, nor to its Knowledge violate any Applicable Law. The person or persons executing this Agreement on such Party’s behalf have been duly authorized to do so by all requisite corporate action.

13.1.5 Consistent with the ‘Compliance Program Guidance for Pharmaceutical Manufacturers’ published by the Office of Inspector General, U.S. Department of Health and Human Services (the “**OIG Guidance**”), each Party has implemented a compliance program, policies, and an adequate internal audit program with respect to its Detailing and other Commercialization activities in the United States in connection with this Agreement, containing all of the elements described in such guidance document.

13.1.6 Each Party has implemented a compliance and ethics program containing adequate systems, policies, and procedures for the detection, investigation, documentation, and remediation of any allegations, reports, or findings related to a potential violation of Applicable Law with respect to the its obligations under this Agreement with respect to the Products in the Field or payments under this Agreement. Such policies and procedures should set out rules governing interactions with HCPs and Government Officials, the engagement of third parties, and where appropriate, conducting due diligence, and the investigation, documentation, and remediation of any allegations, reports, or findings related to a potential violation of Applicable Law.

13.1.7 Each Party has implemented adequate policies and procedures describing the materials and information that may be distributed or discussed by Party's employees, contractors, subcontractors, or agents related to the Products in the Field, and the manner in which such persons should handle unsolicited requests for information related to off-label uses of the Products in the Field in the Territory. Such policies and procedures should be designed to ensure compliance with Applicable Laws and regulations and consistency with applicable FDA requirements and restrictions.

13.1.8 Each Party has implemented adequate systems, policies, and procedures to screen before hire, and regularly thereafter, all prospective and current employees, contractors, subcontractors, or agents engaged in Covered functions in connection with this Agreement against (i) the List of Excluded Individuals/Entities compiled by the Office of the Inspector General in the Department of Health and Human Services, and (ii) the General Services Administration's List of Parties Excluded from Federal Programs. Such policies and procedures shall require each Party's prospective and current employees, contractors, subcontractors, or agents to disclose to the Party any exclusion, debarment, suspension, or declaration of ineligibility from participation in federal health care programs or federal procurement or non-procurement programs, and any investigation or indictment which may result in an exclusion, debarment, suspension, or declaration of ineligibility.

13.1.9 Each Party has implemented a system of internal accounting controls designed to ensure the making and keeping of fair and accurate books, records, and accounts with respect to its obligations related to any Products in the Field in the Territory or payments provided under this Agreement, and each Party regularly monitors and audits its business activities to ensure compliance with its Policies and the adequacy of internal controls, and implements remediation in response to identified issues.

Section 13.2 Additional Representations and Warranties of Myovant. Myovant hereby represents and warrants to Pfizer as of the Effective Date:

13.2.1 to Myovant's Knowledge, neither of the Products in the Field in the Territory existing as of the Effective Date, nor the use of such Products in the applicable Field in the Territory in accordance with this Agreement, infringes any Patent rights of any Third Party in the Territory;

13.2.2 to Myovant's Knowledge, Myovant Controls the Myovant Background Patents set out in [***] and has a right to grant the licenses to Pfizer under Section 10.1;

13.2.3 to Myovant's Knowledge, all filing, application and renewal fees with respect to the Myovant Background Patents have been duly paid, and Myovant has taken all material steps required for the maintenance and prosecution of the Myovant Background Patents Controlled by Myovant in accordance with Applicable Law;

13.2.4 Myovant has no Knowledge of any actual infringement or threatened infringement of any Myovant Background Patent by any Person;

13.2.5 Myovant has not received any written communication from, or written demand of, any claims or litigation that has been brought or threatened by any Person alleging that any Myovant Background Patent is invalid or unenforceable;

13.2.6 Myovant has not, prior to the Effective Date, received any written communication from, or written demand of, any Third Party that the Development, Manufacture, use or Commercialization of the Products in the Field infringed or misappropriated any intellectual property rights of such Third Party;

13.2.7 (i) Except for the Existing Myovant Third Party Agreements, none of Myovant Background Patents existing as of the Effective Date that is being licensed to Pfizer under this Agreement or that has been or is being used in the Development, Manufacture or Commercialization of the Compound or Products in the Field in the Territory, is, as of the Effective Date, Controlled by Myovant or its Affiliates pursuant to any agreement with a Third Party, (ii) the Existing Myovant Third Party Agreements are in full force and effect and a true and complete copy of each Existing Myovant Third Party Agreements (including any and all amendments thereto) has been provided to Pfizer, (iii) Myovant has obtained any and all consents required in order for Myovant to sublicense the rights granted to Myovant or any of its Affiliates under any such Existing Myovant Third Party Agreements to Pfizer as contemplated in this Agreement and has provided a copy of such consents to Pfizer, (iv)

to its Knowledge, Myovant, its Affiliates and the other party to any of such Existing Myovant Third Party Agreements each are not, and have not been, in material breach of the applicable Existing Myovant Third Party Agreements, and (v) the only material obligations Myovant has to the licensors or to the owners of the patents and technology licensed under the Existing Myovant Third Party Agreements with respect to the Development, Manufacture or Commercialization of the Compound or the Products in the Field in the Territory are obligations set forth in the copies of the Existing Myovant Third Party Agreements provided to Pfizer prior to the Effective Date;

13.2.8 There are no judgments or settlements against or owed by Myovant or any of its Affiliates and no pending litigation in relation to the Myovant Background Patents, or to its Knowledge, claims that have been threatened in writing relating to Myovant Background Patents;

13.2.9 to Myovant's Knowledge, all information provided by or on behalf of Myovant during pre-contractual due diligence, including all information provided in response to due diligence requests, is complete, truthful and accurate in all material respects;

13.2.10 to Myovant's Knowledge, there is no pending product liability action in relation to any Compound or Product in the Field in the Territory. For the purposes of this Section 13.2.10, "product liability action" does not include claims for reimbursement of medical expenses for the treatment of any injury or illness related to administration of a Product in the Field in the Territory in or participation in a clinical study or trial;

13.2.11 Myovant or its Affiliates have made available to Pfizer (i) all information that Myovant or its Affiliates have in their possession or otherwise to which Myovant or its Affiliates have a right of access (e.g. information at Myovant's contract research organization which Myovant has a right to access) that is material to the safety or efficacy of the Compound and Products in the Field in the Territory and (ii) true and correct copies of the following: (a) all Major Regulatory Filings for Products in the Field in the Territory (including all INDs); (b) all material correspondence with Governmental Authorities with respect to such Major Regulatory Filings; (c) all minutes of any material meetings, telephone conferences or discussions with Governmental Authorities with respect to such Major Regulatory Filings; and (d) all final clinical trial reports, in each case with respect to the Products in the Field in the Territory and to the extent in existence as of the Effective Date;

13.2.12 Myovant or its Affiliates are the sole owners of all the Major Regulatory Filings for the Compound and Products in the Field in the Territory;

13.2.13 except as would not be reasonably expected to have a material adverse effect on the development, Manufacture or commercialization of Products in the Field in the Territory, Myovant or its Affiliates have filed with the relevant Governmental Authorities all required notices, amendments and annual reports, as well as Adverse Event reports, with respect to the Major Regulatory Filings for the Compound and Products in the Field in the Territory;

13.2.14 to Myovant's Knowledge, there is no pending action or action threatened in writing by relevant Governmental Authorities to place a clinical hold order on, or otherwise terminate or suspend, any of the Major Regulatory Filings for a Product in the Field in the Territory in existence as of the Effective Date; and

13.2.15 to Myovant's Knowledge, the use Myovant's Product Trademarks in the Field in the Co-Promotion Territory do not infringe the trademark rights of any Third Party in the Co-Promotion Territory.

Section 13.3 Mutual Covenants. Each Party hereby covenants to the other Party as of the Effective Date, that:

13.3.1 Each Party agrees, at all times during the Term, to comply in all material respects with Applicable Laws and accepted applicable pharmaceutical industry business practices in connection with its activities under this Agreement. Consistent with the OIG Guidance, each Party agrees to maintain and enforce a compliance program, policies, and an adequate internal audit program with respect to its Detailing and other Commercialization activities in the United States in connection with this Agreement, containing all of the elements described in such guidance document, as well as completing any required reporting to any Governmental Authority;

13.3.2 Each Party agrees, at all times during the Term, to maintain and enforce a compliance and ethics program containing adequate systems, policies, and procedures for the detection, investigation, documentation, and remediation of any allegations, reports, or findings related to a potential violation of Applicable Law with respect to the Products in the Field in the Territory and payments under this Agreement. Such policies and procedures should set out rules governing interactions with HCPs and Government Officials, the engagement of third parties, and where appropriate, conducting due diligence, and the investigation, documentation, and remediation of any allegations, reports, or findings related to a potential violation of Applicable Law;

13.3.3 Each Party agrees, at all times during the Term, to maintain and enforce adequate policies and procedures describing the materials and information that may be distributed or discussed by Party's employees, contractors, subcontractors, or agents related to the Products in the Field in the Territory, and the manner in which such persons should handle unsolicited requests for information related to off-label uses of the Products in the Field in the Territory. Such policies and procedures should be designed to ensure compliance with Applicable Laws and regulations and consistency with applicable FDA requirements and restrictions;

13.3.4 Each Party agrees, at all times during the Term, to maintain and enforce adequate systems, policies, and procedures to screen before hire, and regularly thereafter, all prospective and current employees, contractors, subcontractors, or agents engaged in covered functions against (i) the List of Excluded Individuals/Entities compiled by the Office of the Inspector General in the Department of Health and Human Services, and (ii) the General Services Administration's List of Parties Excluded from Federal Programs. Such policies and procedures shall require each Party's prospective and current employees, contractors, subcontractors, or agents to disclose to the Party any exclusion, debarment, suspension, or declaration of ineligibility from participation in federal health care programs or federal procurement or non-procurement programs, and any investigation or indictment which may result in an exclusion, debarment, suspension, or declaration of ineligibility;

13.3.5 Each Party agrees, at all times during the Term, to maintain and enforce a system of internal accounting controls designed to ensure the making and keeping of fair and accurate books, records, and accounts with respect to its obligations under this Agreement with respect to any Products in the Field in the Territory or payments provided under this Agreement, and each Party agrees, during the term of this Agreement, to regularly monitor and audit its business activities to ensure compliance with its policies and the adequacy of internal controls, and implements remediation in response to identified issues;

13.3.6 Each Party agrees, at all times during the Term, to: (i) maintain truthful and complete documentation supporting, in reasonable detail, the work performed and any expenses incurred in connection with this Agreement; and (ii) maintain financial books and records that timely, fairly, accurately, and completely reflect all financial transactions under this Agreement, in accordance with all Applicable Laws, including applicable Anti-Corruption Laws (for example, invoices, reports, statements, books, and other records), and shall maintain such books and records during the Term and for [***] years after final payment has been made under this Agreement;

13.3.7 Each Party agrees to permit, during the Term and for [***] years after final payment has been made under this Agreement, the other Party's external auditors access to any relevant books, documents, papers, and records of Party involving transactions related to the Products in the Field in the Territory or payments provided, in each case, under this Agreement, and each Party agrees to cooperate fully in any audit or in connection with any investigation regarding any potential violations of Applicable Laws in connection with its obligations under this Agreement with respect to the Products in the Field in the Territory or payments provided under this Agreement;

13.3.8 Each Party shall ensure that it and every agent, contractor, or subcontractor performing services in connection with this Agreement agrees to comply with and be bound by the provisions of this Agreement to the extent applicable to such services;

13.3.9 With respect to the activities relating to Products in the Field in the Territory under this Agreement, a Party's Alliance Manager shall promptly notify the other Party in the event that a Party becomes aware of a potential material violation by the other Party of: (a) the other Party's policies or procedures applicable to such activities; (b) any criminal, civil, or administrative laws or regulations applicable to any federal health care program or for which penalties or exclusion may be authorized; or (c) the applicable

regulatory guidance promulgated by such agencies related to the Products in the Field in the Territory or payments provided under this Agreement;

13.3.10 If a Party finds, following an investigation, credible evidence of a Significant Violation of any applicable policies and procedures that are designed to ensure compliance with: (i) any Applicable Laws, including any criminal, civil, or administrative laws or regulations; or (ii) the applicable regulatory requirements and guidance related to the Products in the Field in the Territory or payments provided under this Agreement (an "**Occurrence**"), Party's Alliance Manager shall promptly inform the other Party of the Occurrence and the steps taken by Party to remediate the Occurrence, except to the extent that the disclosing Party's counsel reasonably believes that such disclosure to the other Party could violate applicable privacy laws or have a significant adverse impact on the disclosing Party's legal position or defense (including the loss of attorney-client privilege) with respect to any such Occurrence. In the event that a Party determines that disclosure could violate applicable privacy laws or have a significant adverse impact on its legal position or defense, Party shall promptly notify the other Party that it is exercising its right not to disclose an Occurrence. In the event that a Party engages in conduct that constitutes a Significant Violation of any applicable policies and procedures designed to ensure compliance with Applicable Laws, such Party shall perform a diligent investigation of the facts of the breach, appropriate disciplinary and remedial action by Party up to an including termination of employment or relationship with any person involved in the breach or any relationship obtained through improper means, and confirmation to the other Party that Party has taken appropriate remedial action;

13.3.11 Every year during the Term that coincides with the term of the Corporate Integrity Agreement ("**CIA**") entered into on May 23, 2018 between Pfizer and the United States Department of Health and Human Services, Office of Inspector General, Pfizer will send a letter to Myovant that: (a) summarizes Pfizer's obligations under the CIA, (b) expresses Pfizer's commitment to full compliance with all federal health care program requirements, (c) describes the Pfizer Compliance Program and (d) includes a copy of (or includes a link to) Pfizer's code of conduct (referred to as the Blue Book). Within [***] days of receipt of this letter, Myovant shall respond in writing to the contact information included in Pfizer's letter that Myovant shall: (i) make Pfizer's code of conduct and a description of the Pfizer Compliance Program available to its employees engaged in activities related to this Agreement or (ii) represent to Pfizer that it has and enforces a substantially comparable code of conduct and Compliance Program for its employees who have responsibilities related to this Agreement; and

13.3.12 With respect to any Products in the Field in the Territory or payments, provided under this Agreement, the Parties acknowledge and agree that each Party shall independently determine whether to provide charitable donations to independent charities that provide financial assistance to patients ("**Independent Charity PAPs**") in meeting the cost of clinical care, including drug therapy, and what donation amounts to provide. Neither Party shall provide funding to the other Party for such donations, including sharing costs associated with such donations; provide information to the other Party concerning its own such donations; or seek to obtain information about such donations from the other Party. Each Party shall maintain and enforce appropriate policies and procedures to ensure that such donations comply with Applicable Law and current government guidance, including without limitation, guidance issued by the U.S. Department of Health and Human Services, Office of Inspector General, and shall operate consistent with those policies and procedures. Unless a Party does not and will not make such donations during the term of this Agreement, if a Party does not have appropriate policies and procedures in place on the Effective Date, the Party must implement such policies and procedures within [***] days of the Effective Date. Either Party may request copies of such policies and procedures of the other Party in order to confirm compliance with the requirements of this Section 13.3.12.

Section 13.4 Additional Covenants of Myovant. In addition to the covenants made by Myovant elsewhere in this Agreement, Myovant hereby covenants to Pfizer that, from the Effective Date until expiration or termination of this Agreement:

13.4.1 Myovant will not, and will cause its Affiliates not to (a) license, sell, assign (other than in a connection with a permitted assignment of this Agreement by Myovant pursuant to Section 18.2) or otherwise transfer to any person or Third Party (other than Pfizer or its Affiliates or Sublicensees pursuant to the terms of this Agreement) any Myovant Background IP or Product Collaboration IP (or agree to do any of the foregoing) or (b) incur or permit to exist, with respect to any Myovant Background IP or Product Collaboration IP, any lien, encumbrance, charge, security interest, mortgage, liability, assignment, grant of license or other Binding

Obligation, in each case ((a) and (b)) that is or will be inconsistent with the licenses and other rights granted (or that may be granted) to Pfizer or its Affiliates under this Agreement;

13.4.2 Subject to the terms of this Agreement, Myovant will not (a) take any action that diminishes the rights granted (or that would be granted if the Option was exercised) to Pfizer hereunder or (b) fail to take any action that is reasonably necessary to avoid diminishing the rights under the Myovant Background IP or Product Collaboration IP to Pfizer or Pfizer's Affiliates under this Agreement;

13.4.3 Myovant will (a) not enter into any agreement with a Third Party that is inconsistent with (i) the rights granted (or that may be granted) to Pfizer, Pfizer's Affiliates or Sublicensees hereunder or (ii) Myovant's obligations hereunder; (b) not amend or otherwise modify any Existing Myovant Third Party Agreement or consent or waive rights with respect thereto in any manner that is inconsistent with (A) the rights granted (or that may be granted) to Pfizer or Pfizer's Affiliates or Sublicensees hereunder or (B) Myovant's obligations hereunder; (c) remain, and cause its Affiliates to remain, in compliance in all material respects with all Existing Myovant Third Party Agreements; (d) provide to Pfizer copies of all written notices received by Myovant or its Affiliates from the other party under the applicable Existing Myovant Third Party Agreement relating to any alleged breach or default by Myovant or its Representatives under any Existing Myovant Third Party Agreement within [***] Business Days after receipt thereof; and (e) provide to Pfizer copies of all amendments, solely as permitted pursuant to (b) above, of Existing Myovant Third Party Agreements entered into after the Effective Date to the extent such amendments concern the Development or Commercialization of the Products in the Field in the Territory under this Agreement.

Section 13.5 Additional Covenants of Pfizer. In addition to the covenants made by Pfizer elsewhere in this Agreement, Pfizer hereby covenants to Myovant that, from the Effective Date until expiration or termination of this Agreement: Pfizer will (i) not enter into any agreement with a Third Party that is inconsistent with Pfizer's obligations hereunder; and (ii) not amend or otherwise modify any Third Party License or consent or waive rights with respect thereto in any manner that is inconsistent with Pfizer's obligations hereunder.

Section 13.6 DISCLAIMER OF WARRANTIES. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

ARTICLE XIV.
INDEMNIFICATION

Section 14.1 Indemnification by Myovant. Myovant shall defend, indemnify and hold harmless Pfizer, its Affiliates, and its and their respective directors, officers, employees and agents (the "**Pfizer Indemnitees**") and defend and save each of them harmless, from and against any and all losses, damages, liabilities, taxes, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") in connection with (a) any and all suits, investigations, claims or demands of Third Parties (collectively, "**Third Party Claims**") arising from or occurring as a result of: (i) the breach by Myovant of this Agreement; (ii) the gross negligence or willful misconduct on the part of any Myovant Indemnitee in performing its or their obligations under this Agreement; (iii) Third Party Infringement Claims arising from the practice of Myovant Background IP to Exploit the Products for which Myovant is defending under Section 14.4.2 in the Co-Promotion Territory, (iv) any activities conducted by or on behalf of Myovant or its Affiliates in relation to the Compound or Product in the Field prior to the Effective Date in the Territory or (v) subject to Section 11.4, the Exploitation of any Product in the Field in the Territory by or on behalf of Myovant or any of its Affiliates (but not by Pfizer or any of its Affiliates) in the Co-Promotion Territory, except, in each case ((i) through (v)), for those Losses for which Pfizer has an obligation to indemnify an Myovant Indemnitee pursuant to Section 14.2, as to which Losses each Party shall indemnify the other Party to the extent of its respective liability for the Losses, and (b) the successful enforcement of Pfizer's rights under this Section 14.1; *provided* that if Pfizer asserts against Myovant any claim for indemnification under this Section 14.1 and it is determined pursuant to

Section 17.2 that Myovant is not to be obligated to provide such indemnification under this Section 14.1, then Pfizer promptly shall reimburse Myovant for all Losses incurred by Myovant in defending such claim for indemnification.

Section 14.2 Indemnification by Pfizer. Pfizer shall indemnify Myovant, its Affiliates, Excluded Affiliates, and its and their respective directors, officers, employees and agents (the "**Myovant Indemnitees**") and defend and save each of them harmless, from and against any and all Losses in connection with (a) any and all Third Party Claims arising from or occurring as a result of: (i) the breach by Pfizer of this Agreement; (ii) the gross negligence or willful misconduct on the part of any Pfizer Indemnitee in performing its obligations under this Agreement; or (iii) subject to Section 11.4, the Exploitation of any Product in the Field by or on behalf of Pfizer or any of its Affiliates (but not by Myovant or any of its Affiliates) in the Territory, except, in each case ((i) through (iii)), for those Losses for which Myovant has an obligation to indemnify a Pfizer Indemnitee pursuant to Section 14.1, as to which Losses each Party shall indemnify the other to the extent of its respective liability for the Losses, and (b) the successful enforcement of Myovant's rights under this Section 14.2; *provided* that if Myovant asserts against Pfizer any claim for indemnification under this Section 14.2 and it is determined pursuant to Section 17.2 that Pfizer is not to be obligated to provide such indemnification under this Section 14.2, then Myovant promptly shall reimburse Pfizer for all Losses incurred by Pfizer in defending such claim for indemnification.

Section 14.3 Losses.

14.3.1 Except with respect to Losses (a) for which indemnification is provided in Section 14.1 or Section 14.2, (b) otherwise included within Allowable Expenses or (c) arising from or in connection with any employment or other similar claim brought by any employee or individual independent contractor of either Party or its Affiliates or, in the case of Myovant, Excluded Affiliates (which, for clarity, shall be the sole responsibility of such Party), any Losses arising from or incurred in connection with any Third Party Claim brought against either Party or any of its Affiliates**,** or, in the case of Myovant, Excluded Affiliates, arising from or occurring as a result of the Exploitation of the Products in the Field in the Co-Promotion Territory in accordance with this Agreement or any Related Agreement, including any Third Party Claims for product liability (such Losses, "**Shared Losses**"), shall be shared by the Parties [***]. Myovant shall be responsible for [***] of any Losses arising in connection with any Third Party Infringement Claim arising from the practice of Myovant Background IP to Exploit the Products for which Myovant is defending under Section 14.4.2 in the Co-Promotion Territory. Each Party shall give the other Party prompt written notice of any Shared Loss or discovery of fact that may reasonably be expected to give rise to a Shared Loss. Shared Losses, with respect to Pfizer, shall not include any Losses arising in connection with any Third Party Infringement Claim arising from the practice of Myovant Background IP to Exploit the Products for which Myovant is defending under Section 14.4.2 in the Co-Promotion Territory.

14.3.2 Myovant shall have the first right, but not the obligation, to control the defense of any such Third Party Claim with respect to any Shared Losses, and in the event that it elects not to control the defense, Pfizer shall have the right to do so.

14.3.3 The controlling Party may appoint as lead counsel in the defense of such Third Party Claim any legal counsel selected by the controlling Party; *provided* that it obtains the prior written consent of the non-controlling Party (which consent shall not be unreasonably withheld, conditioned or delayed). The non-controlling Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; *provided* that such employment shall be at the non-controlling Party's sole cost and expense.

14.3.4 With respect to each such Third Party Claim, regardless of which Party is the controlling Party, the Parties shall cooperate and consult fully with each other in strategizing, preparing, presenting and conducting the defense of such Third Party Claim and to help drive efficiencies in defense costs. The Parties shall seek in good faith to agree on all matters regarding such Third Party Claim. In case such agreement cannot be reached within an appropriate time period (recognizing that certain decisions with respect to strategizing, preparing, presenting and conducting the defense of such Third Party Claim may be time sensitive), the controlling Party shall have the final decision; *provided* that the controlling Party shall not settle any such Third Party Claim without the prior written consent of the non-controlling Party, which consent shall not be unreasonably withheld, conditioned or delayed. The non-controlling Party shall provide the controlling Party

with reasonable assistance in connection with the defense of all such Third Party Claims. Neither Party shall have the right to settle any Third Party Claim under this Section 14.3.4 in a manner that diminishes the rights or interests of the other Party or imposes any liability on the other Party without the prior written consent of such other Party.

14.3.5 Notwithstanding anything in Section 14.1 or Section 14.2 to the contrary, all Losses from any Third Party Claim relating to product liability in the Co-Promotion Territory (a "**Product Liability Claim**") shall constitute Shared Losses unless it is ultimately determined by clear and convincing evidence pursuant to Section 17.2.2 that any such Product Liability Claim solely and directly was caused by or resulted from the actual gross negligence of, actual willful misconduct of, or actual violation of Applicable Law by, only one Party (the "**At-Fault Party**") or any of its Affiliates or its or their subcontractors in performing any activity contemplated by this Agreement, or any actual breach by the At-Fault Party (or any of its Affiliates) of this Agreement or any Related Agreement, and the actions or omissions of the other Party (the "**Non-Fault Party**") or any of its Affiliates or its or their subcontractors did not in any way contribute to the events and circumstances leading to such Product Liability Claim (an "**At-Fault Claim**"). The At-Fault Party with respect to an At-Fault Claim shall bear [***] of all Losses from such At-Fault Claim and shall reimburse the Non-Fault Party for any Losses incurred by the Non-Fault Party in connection with such At-Fault Claim (if not previously reimbursed), and if such determination is the result of an arbitration proceeding initiated by the Non-Fault Party pursuant to Section 17.2.2, then the At-Fault Party also shall reimburse the Non-Fault Party for all of the reasonable and verifiable costs and expenses (including reasonable attorneys' fees and costs of arbitration) incurred by the Non-Fault Party directly in connection with such arbitration proceeding.

Section 14.4 Indemnification Procedures.

14.4.1 Notice of Claim. All indemnification claims in respect of a Party and its Indemnitees shall be made solely by such Party (the "**Indemnified Party**"). The Indemnified Party shall give the indemnifying Party prompt written notice (an "**Indemnification Claim Notice**") of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under this Article XIV, but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims.

14.4.2 Control of Defense. At its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within [***] days after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party or its Indemnitees in respect of such Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's or its Indemnitees' claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of such Third Party Claim any legal counsel selected by the indemnifying Party; *provided* that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party or any of its Indemnitees in connection with such Third Party Claim. If the indemnifying Party assumes the defense of a Third Party Claim, except as provided in Section 14.4.3, the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party or any of its Indemnitees in connection with the analysis, defense or settlement of such Third Party Claim unless the expenses were incurred by the Indemnified Party at the request of the indemnifying Party. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party or its Indemnitees from and against the Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any and all costs and expenses (including attorneys' fees and costs of suit) and any Losses incurred by the indemnifying Party in its defense of the Third Party Claim.

14.4.3 Right to Participate in Defense. Any Indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose;

provided that such employment shall be at the Indemnified Party's sole cost and expense unless (a) the employment thereof has been specifically authorized by the indemnifying Party in advance in writing, (b) the indemnifying Party has notified the Indemnified Party is not going to assume or failed to assume the defense and employ counsel in accordance with Section 14.4.2 (in which case the Indemnified Party shall control the defense) or (c) the interests of the applicable Indemnitees and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law, ethical rules or equitable principles.

14.4.4 Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that shall not result in the applicable Indemnitee's becoming subject to injunctive or other relief or otherwise adversely affecting the business of the applicable Indemnitee in any manner or the admission or attribution of liability by or to the Indemnified Party or any Indemnitee and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the applicable Indemnitee hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 14.4.2, the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; *provided* that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). If the indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided above, the Indemnified Party may defend against such Third Party Claim; *provided, further,* that the Indemnified Party shall not settle any Third Party Claim without the prior written consent of the indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed).

14.4.5 Cooperation. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall and shall cause each Indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the indemnifying Party to and reasonable retention by the Indemnified Party and Indemnitees of, records and information that are reasonably relevant to such Third Party Claim and making Indemnitees and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable and verifiable out-of-pocket expenses in connection therewith. Notwithstanding the foregoing, the Indemnified Party shall not be required to provide the tax returns or tax records of such Indemnified Party or its Affiliates (or, in the case of Myovant, Excluded Affiliates) unless and to the extent that the indemnifying Party can reasonably demonstrate that such tax returns or tax records are essential to defending a Third Party Claim.

14.4.6 Special, Indirect, Consequential and Other Losses. EXCEPT IN CIRCUMSTANCES OF GROSS NEGLIGENCE OR WILLFUL MISCONDUCT BY A PARTY OR ITS AFFILIATES (OR, IN RESPECT OF MYOVANT, EXCLUDED AFFILIATES), OR WITH RESPECT TO A BREACH OF Article XVI OR Article XIII, NEITHER PARTY NOR ANY OF THEIR RESPECTIVE AFFILIATES (OR, IN RESPECT OF MYOVANT, EXCLUDED AFFILIATES) SHALL BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, OR LOST PROFITS, WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, ARISING OUT OF ANY BREACH OF OR FAILURE TO PERFORM ANY OF THE PROVISIONS OF THIS AGREEMENT. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 14.4.6 LIMITS OR RESTRICTS THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY PURSUANT TO SECTION 14.1 THROUGH SECTION 14.3 WITH RESPECT TO LOSSES PAYABLE TO THIRD PARTIES ASSERTING CLAIMS SUBJECT TO SUCH RIGHTS OR OBLIGATIONS.

Section 14.5 Insurance. Each Party shall, and shall cause its Affiliates to, at their own respective expense (and not subject to cost sharing hereunder) have and maintain such types and amounts of liability insurance (or self-insurance) to cover liabilities related to its activities under this Agreement as is normal and customary in the pharmaceutical industry generally for Persons similarly situated, and shall upon request

provide to the other Party evidence of its insurance coverage. Such policies shall remain in effect throughout the Term and for a period of [***] years thereafter.

ARTICLE XV.
TERM AND TERMINATION

Section 15.1 Term.

15.1.1 Term. The term of this Agreement shall commence on the Effective Date and, unless earlier terminated in accordance with the terms hereof, shall expire (a) in the case of the Co-Promotion Territory on the date in which no Products in the Field are sold in the Co-Promotion Territory and all Development activities for the Products in the Field in the Co-Promotion Territory have terminated, and (b) in the case of the Pfizer Territory, on the expiration of the last to expire Royalty Term with respect to a country in the Pfizer Territory (for each such portion of the Territory, the "**Term**").

Section 15.2 Effect of Expiration of Royalty Term.

15.2.1 Following the Option Closing (if it occurs), after expiration of the Royalty Term (but not after early termination of this Agreement) with respect to any country within the Pfizer Territory, with respect to any Oncology Product and Pediatric Product in their respective Fields, Pfizer shall have an exclusive, fully-paid, royalty-free right and license, with the right to grant sublicenses through multiple tiers (in accordance with Section 10.1.2), under the Myovant Background IP, Myovant Other Collaboration IP, Myovant's interest in the Joint Other Collaboration IP and Product Collaboration IP to Exploit such Oncology Product in the Field in such country.

15.2.2 The licenses granted to Myovant under Section 10.2 and the sublicenses granted by Myovant or its Sublicensees under Section 10.2 shall survive any such expiration.

Section 15.3 Termination by Either Party for Breach or Insolvency.

15.3.1 Breach.

(a) In the event that either Party (the "**Breaching Party**") materially breaches this Agreement, in addition to any other right or remedy the other Party (the "**Non-Breaching Party**") may have, the Non-Breaching Party may terminate this Agreement: (i) with respect to the Product (the WH Product or the Oncology Product) to which the material breach pertains; (ii) with respect to the Region, the United States or Canada to which the material breach pertains; or (iii) in its entirety if such material breach pertains to both the WH Product and the Oncology Product and all Regions, the United States or Canada within the Territory, in each case, by providing [***] days' prior written notice (or [***] days' prior written notice with respect to any breach of any payment obligation hereunder) (the "**Termination Notice Period**") to the Breaching Party specifying the nature of the breach and stating its intention to terminate this Agreement for the applicable Product, applicable Region or in its entirety if such breach is not cured (the "**Termination Notice**; (ii) the termination shall not become effective at the end of the Termination Notice Period if the Breaching Party cures the breach specified in the Termination Notice during the Termination Notice Period (or, if such breach (other than a payment breach) cannot be cured within the Termination Notice Period, if the Breaching Party commences actions to cure such breach within the Termination Notice Period and thereafter diligently continues such actions; *provided, further,* that such breach is cured within [***] year after the receipt of the Termination Notice), (ii) in the event of a good faith dispute as to whether performance has been made by either Party pursuant to this Agreement, including any good faith dispute as to payments due under this Agreement (other than the payment required pursuant to Section 8.1), the relevant cure period with respect thereto will be tolled from the date the Breaching Party notifies the Non-Breaching Party of such good faith dispute and through the resolution of such dispute in accordance with the applicable provisions of this Agreement (*provided,* that if such dispute relates to payment, the cure period will only apply with respect to payment of disputed amounts, and not with respect to undisputed amounts); and (iii) it is understood and agreed that during the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder, and, if the material breach in question is cured by the end of the tolled cure period (*i.e.* prior to resolution of such dispute in accordance with such applicable provisions), then the non-breaching Party shall no longer have a right to termination under this Section 15.3.1(a) with respect

to such material breach. The Termination Notice Period with respect to any payment breach shall be [***] days and the Breaching Party shall have the right to cure a payment breach only within the applicable Termination Notice Period, subject to the tolling provision of this Section 15.3.1(a); *provided* that the tolling provision of this Section 15.3.1(a) shall not apply to any breach of Section 8.1.

(b) "**Termination Product**" means the Product(s) that is/are subject to expiration or termination pursuant to this Article XV or Article XVI.

(c) "**Termination Effective Date**" means the effective date of termination with respect to the applicable Terminated Product(s) in the applicable Terminated Territory (which shall include termination in accordance with Section 16.3.3)).

(d) "**Terminated Territory**" means, with respect to a specific Terminated Product, (i) the country or Region that has been terminated with respect to such specific Terminated Product; or (ii) in the event of termination of this Agreement in its entirety, the entire Territory.

15.3.2 Insolvency. Each of Myovant and Pfizer may terminate this Agreement in its entirety immediately upon notice if an Insolvency Event occurs in relation to the other Party. In any event, when a Party first becomes aware of the likely occurrence of any Insolvency Event with respect to such Party, such Party shall promptly notify the other Party in sufficient time to give the other Party sufficient notice to protect such other Party's interests under this Agreement.

Section 15.4 Termination at Will by Pfizer.

(a) Entire Agreement or Co-Promotion Territory. Pfizer, without cause, for any or no reason, may terminate this Agreement (i) in its entirety, (ii) with respect to the Oncology Product in the Co-Promotion Territory, or (iii) with respect to the WH Product in the Co-Promotion Territory by providing Myovant with at least [***] days' prior written notice of such termination, provided that Pfizer may only provide such written notice to Myovant on or after the [***] anniversary of the Effective Date.

(b) Pfizer Territory. Pfizer, without cause, for any or no reason, may terminate this Agreement on a Region by Region basis for all Oncology Products with respect solely to the rights granted to Pfizer under this Agreement for such Region by providing [***] days' prior written notice of such termination to Myovant if there has been no First Commercial Sale of such Oncology Product by Pfizer, its Affiliates or Sublicensees in such Region, or [***] days' prior written notice to Myovant following the First Commercial Sale of such Oncology Product by Pfizer, its Affiliates or Sublicensees in such Region.

If Pfizer terminates this Agreement with respect to the United States or to a Region under this Section 15.4, such Region or the United States shall be deemed to be a "**Terminated Territory**" under this Agreement.

Section 15.5 Canada Termination.

15.5.1 Pfizer, without cause, for any or no reason, may terminate this Agreement solely with respect to the rights granted to Pfizer under this Agreement for Canada:

(a) for the Oncology Product in the Oncology Field by notifying Myovant of such termination at any time following the Effective Date through [***] days following the filing of the first Drug Approval Application for the Oncology Product in the Oncology Field with the Regulatory Authority in Canada. Such termination shall be effective with immediate effect upon such notice to Myovant;

(b) for the WH Product in the WH Field by notifying Myovant of such termination with respect to the WH Product(s) in the WH Field at any time following the Effective Date through [***] days following the filing of the first Drug Approval Application for the WH Product(s) in the WH Field with the Regulatory Authority in Canada. Such termination shall be effective with immediate effect upon such notice to Myovant; or

(c) following the receipt of Regulatory Approval, including the establishment of pricing for the Oncology Product or WH Product, as applicable, [***], either Party (the "**Terminating Party**") may terminate the rights of the other Party (the "**Non-Terminating Party**") with respect to the applicable Product in the Field in Canada to the extent the Non-Terminating Party or its Affiliates (or, in the case of Myovant as Non-Terminating Party, its Excluded Affiliates) is not [***] in at least: (i) [***] or (ii) [***] (together, the "**Commercialization Minimum**") by providing the Non-Terminating Party [***] days' written notice (the

"**Canadian Termination Notice Period**") specifying the lack of applicable Commercialization by the Non-Terminating Party and stating its intention to terminate this Agreement for the applicable Product solely with respect to Canada if the Non-Terminating Party [***] (the "**Canadian Termination Notice**"); provided that the termination shall not become effective at the end of the Canadian Termination Notice Period if [***], the relevant cure period with respect thereto will be tolled from the date the Non-Terminating Party notifies the Terminating Party of such good faith dispute and through the resolution of such dispute in accordance with the applicable provisions of this Agreement; and (iii) it is understood and agreed that during the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder, and, if [***], then the Terminating Party shall no longer have a right to terminate with respect to the applicable Product in the Field in Canada under this Section 15.5.1(c).

In the event of a termination of a Product in Canada pursuant to this Section 15.5.1(c) by Pfizer [***]: (i) Canada will be deemed to be [***] but will be [***]; and (ii) Canada shall be [***], including [***] and [***], where such [***] must include at least the lesser of (x) [***] or (y) [***]. Termination by a Terminating Party pursuant to this Section 15.5.1(c) for the applicable Product in Canada will be the [***].

If Pfizer terminates this Agreement with respect to a Product with respect to Canada pursuant to Section 15.5.1(a) or Section 15.5.1(b) or Myovant terminates this Agreement with respect to a Product with respect to Canada pursuant to Section 15.5.1(c), Canada shall be deemed to be a "**Terminated Territory**" for the applicable Product under this Agreement.

Section 15.6 Termination of [***] Agreement. In the event of any termination of the [***] Agreement, this Agreement shall automatically terminate in its entirety on the effective date of such termination of the [***] Agreement.

Section 15.7 Cessation of Commercialization or Regulatory Approval Activities.

15.7.1 Pfizer Territory. Following Option Closing (if any), in the event Pfizer: (a) fails to file any Drug Approval Application for the Oncology Product in the Oncology Field in at least [***] Major Country in a given Region within [***] months of Pfizer's provision of the Option Exercise Notice to Myovant; (b) fails to Commercialize the Oncology Product in the Oncology Field in at least [***] Major Country in a given Region within [***] months after approval of the Drug Approval Application for the Oncology Product in the Oncology Field by the Regulatory Authority in such Major Country, (c) thereafter ceases to Commercialize in at least [***] Major Country in a given Region for a period of [***] months or more, (d) no longer maintains at least [***] Drug Approval Application for the Oncology Product in the Oncology Field in at least [***] Major Country in such Region or (e) determines that it will not conduct or ceases the performance of any Required Study for the Oncology Product in the Oncology Field in at least [***] Major Country in a given Region, Pfizer shall promptly notify Myovant thereof. Whether or not such notice is delivered, Myovant may terminate this Agreement with respect to such Region effective upon delivery of a notice to Pfizer or such later date as is specified by Myovant in such notice, in which case the Pfizer Territory shall no longer include such Region (and such Region shall be deemed a "**Terminated Territory**").

15.7.2 Required Studies in the Co-Promotion Territory. If Pfizer objects to the inclusion of any Required Study for a WH Product in the WH Field or an Oncology Product in the Oncology Field in the United States or Canada within the [***] day period pursuant to Section 2.10.3(c)(iii), then Myovant shall have the right to conduct such Required Study and terminate this Agreement with respect to the WH Product(s) (in the case in which Pfizer declines to include a Required Study for a WH Product) or the Oncology Product(s) (in the case in which Pfizer declines to include a Required Study for an Oncology Product) in the United States or Canada, as applicable, for which the Required Study is required, with immediate effect upon notice to the objecting Party (and such country shall be deemed a "**Terminated Territory**" for the applicable Product).

15.7.3 Termination by Myovant for Patent Challenge. Except to the extent the following is unenforceable under the Applicable Law of a particular jurisdiction where a Patent application within the [***] is pending or a Patent within [***] is issued ("[***] **Patents**"), if Pfizer, its Affiliates or Sublicensees, directly or indirectly through assistance granted to a Third Party, commences any interference or opposition proceeding, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary certificate with respect to such [***] Patents in the Territory, Myovant shall, in its sole discretion, have the right to terminate this Agreement in its entirety effective upon [***]-day written notice of termination to Pfizer;

provided that Pfizer shall have a period [***] days from written notice of such termination in which to withdraw or terminate such action with prejudice.

Section 15.8 Effects of Termination.

15.8.1 Termination in Entirety or in Part for Any Reason (Except for [***]). In the event this Agreement is terminated in its entirety for any reason, other than under Section 15.6 for the termination of a [***] Agreement caused by reasons other than any of Pfizer's performance of or the failure to perform activities to which [***] notice to Myovant relates under Section 15.8.3(a), then:

(a) All rights and licenses granted by each Party hereunder, other than the licenses granted in or stated to survive such termination under this Article XV, shall immediately terminate for the Terminated Product in the Terminated Territory, including, for clarity, any sublicenses granted pursuant to Section 10.1.2.

(b) The license granted by Pfizer to Myovant under Section 10.2 and any sublicenses granted under Section 10.2 shall survive such termination.

(c) Myovant shall automatically and immediately have the exclusive right to Develop and Commercialize the Terminated Products in the Terminated Territory.

(d) Pfizer shall pay for its share of Allowable Expenses for the Terminated Product(s) for such Terminated Territory(ies) for any notice period prior to the Termination Effective Date and Pfizer will continue to receive its share of Net Sales for such notice period with respect to such Terminated Product as set forth in this Agreement.

(e) In the case of a termination of this Agreement with respect to the Co-Promotion Territory, in whole or for a Terminated Product, the Parties shall co-operate to reconcile the Allowable Expenses and Net Sales already incurred by the Parties for the Terminated Product with respect to the Terminated Territory as of such termination and not already shared by the Parties under Section 8.5.1, to achieve [***] sharing of the resulting Net Profits or Net Losses for the applicable period and Terminated Product for the Co-Promotion Territory consistent with Section 8.5.1. Following such reconciliation, the applicable Party shall pay to the other Party a reconciliation payment to achieve the foregoing share of Net Profits or Net Losses for the Terminated Product, if applicable.

(f) At Myovant's written request:

(i) In the case of a termination of the WH Product(s) or the Oncology Product(s) with respect to the Co-Promotion Territory (or this Agreement in its entirety with respect to such Product(s), in whole or in part), with respect to any Clinical Trial being performed by or on behalf of Pfizer under any Joint Medical Affairs and Development Plan and Budget relating to such Terminated Product as of the effective date of such termination for such Terminated Product, unless expressly prohibited by any Regulatory Authority, at Myovant's written request, Pfizer shall and hereby does, and shall cause its Affiliates to, at Myovant's discretion, (i) unless expressly prohibited by any Regulatory Authority, transfer control to Myovant (or its designee) or wind-down such Clinical Trial in an orderly fashion; or (ii) continue to conduct such Clinical Trial to completion in each case (i) and (ii), in accordance with all Applicable Law and the applicable Joint Medical Affairs and Development Plan and Budget.

(ii) In the case of a termination of the Oncology Product(s) with respect to the Pfizer Territory (or this Agreement in its entirety with respect to such Oncology Product(s), in whole or in part), with respect to any Clinical Trial being performed by or on behalf of Pfizer for such Terminated Product as of the Termination Effective Date, at Myovant's written request, Pfizer shall and hereby does, and shall cause its Affiliates to, at Myovant's discretion, (i) unless expressly prohibited by any Regulatory Authority, transfer control to Myovant (or its designee) of such Clinical Trial or wind-down such Clinical Trial in an orderly fashion or (ii) if such transfer is prohibited by any Regulatory Authority, Pfizer shall continue to conduct such Clinical Trial to completion, in each case (i) and (ii), in accordance with all Applicable Law and the applicable Joint Medical Affairs and Development Plan and Budget.

(g) At Myovant's written request, Pfizer shall, and shall cause its Affiliates to, assign to Myovant any or all Third Party agreements for services or supplies used in connection with the Development, Manufacturing or Commercialization of any Terminated Product in the Terminated Territory by or on behalf of

Pfizer, including any contract research organization agreements, Clinical Trial agreements and contract manufacturing agreements, unless any such agreement expressly prohibits such assignment or also pertains to activities other than the Development, Manufacturing or Commercialization of such Terminated Product, in which case, Pfizer shall, and shall cause its Affiliates to, obtain for Myovant substantially all of the practical benefit and burden under such agreement, including by (a) entering into appropriate and reasonable alternative arrangements on terms mutually agreeable to Myovant and Pfizer (or such Affiliate) and (b) subject to the consent and control of Myovant, enforcing, at Myovant's cost and expense and for the account of Myovant, any and all rights of Pfizer (or such Affiliate) against the other Party thereto arising out of the breach or cancellation thereof by such other party or otherwise.

(h) Pfizer shall promptly (a) destroy or, at Myovant's election, transfer to Myovant all Promotional and Educational Materials and materials relating to the Advertising Plan for the Terminated Product in the Terminated Territory Pfizer's or its Affiliates' its possession as of the effective date of termination, and, in the case of such destruction, shall certify to Myovant in writing as to such destruction within [***] days after the effective date of such termination, subject to Applicable Law and Pfizer's standard document retention policies and (b) return to Myovant all Samples in its possession as of the effective date of termination.

(i) Upon completion pursuant or wind-down pursuant to Section 15.8.1(f) of the Clinical Trials or Other Studies ongoing as of the effective date of such termination for a Terminated Product, as soon as reasonably practical after the Termination Effective Date, Pfizer will provide to Myovant, as applicable and to the extent permitted under any applicable Third Party contract (i) any Know-How, including copies of all Clinical Trial data and results, developed by or for the benefit of Myovant relating to the Terminated Product(s) in the Terminated Territory and (ii) other documents to the extent relating to the Terminated Product in the Terminated Territory that are necessary in the continued Exploitation of a Terminated Product in the Terminated Territory (including material documents and agreements relating to the sourcing and Manufacture of a Terminated Product in the Terminated Territory for sale, promotion, distribution, or use of such Terminated Product in the Terminated Territory) throughout the Terminated Territory.

(j) Pfizer will and hereby does, and will cause its Affiliates and its Sublicensees to, (i) effective as of the effective date of termination, assign to Myovant for the Terminated Product in the Terminated Territories all of its rights, title, and interests in and to all INDs, Drug Approval Applications, other Regulatory Approvals, and other Regulatory Materials for each Terminated Product in the Territory, to the extent allowed under Applicable Law, pertaining to such Terminated Product then Controlled by Pfizer or any of its Affiliates or its Sublicensees and (ii) to the extent assignment pursuant to clause (i) is delayed or not permitted by the applicable Regulatory Authority, permit Myovant, its Affiliates, licensees or [***] to cross-reference and rely upon any Regulatory Materials and Regulatory Approvals filed by Pfizer with respect to any Product. As soon as practicable after such transfer, Pfizer will take all steps necessary to transfer ownership of all such assigned Regulatory Materials and Regulatory Approvals to Myovant, including submitting to each applicable Regulatory Authority a letter or other necessary documentation (with a copy to Myovant) notifying such Regulatory Authority of the transfer of such ownership of each Regulatory Approval, including by making such filings as may be required with Regulatory Authorities and other Governmental Authorities in the Territory that may be necessary to record such assignment or effect such transfer.

(k) Effective as of the Termination Effective Date, Pfizer will and hereby does assign to Myovant all of its rights, title, and interests in and to all Product Trademarks that pertain to the Terminated Product in the Terminated Territory, including all associated goodwill. Pfizer will provide all cooperation reasonably requested by Myovant in any effort of Myovant to establish, perfect, or defend its rights in such Product Trademarks, including the execution of assignments, releases, or other documentation, and the provision of good faith testimony by declaration, by affidavit or in-person. Myovant shall be responsible for preparing and filing all instruments and documents necessary to effect the assignment of such trademarks from Pfizer or its Affiliates to Myovant or its Affiliates, including all costs and expenses of preparing and recording country-specific assignments and legalization of signatures (where required).

(l) Pfizer shall use good faith efforts to effect a seamless, timely transition to Myovant of all Development and Commercialization activities and responsibilities for the Terminated Product in the Terminated Territory under this Agreement.

(m) For any Clinical Trials or Other Studies in the Co-Promotion Territory that continue beyond termination or is wound down after Termination Effective Date for a Terminated Product(s), the Development Costs associated with such continuation or wind-down, even if incurred after termination of this

Agreement, shall be shared equally. For any Clinical Trial in the Pfizer Territory that continues beyond such termination or is wound down after such termination, the Development Costs associated with such continuation or wind-down, even if incurred after termination of this Agreement, shall be fully borne by Pfizer.

(n) Myovant will have the right to assume all Prosecution and Maintenance, enforcement and defense activities under Article XI with respect to Myovant Patents. Parties shall discuss such responsibilities with respect to Joint Other Collaboration Patents in good faith after the termination or expiration. For each Myovant Patent with respect to which Pfizer was in charge of the Prosecution and Maintenance, enforcement or defense activities prior to the effective date of termination or expiration of this Agreement, Pfizer, if requested in writing by Myovant, will use reasonable efforts to transfer such responsibilities and provide assistance, including providing any and all (a) material correspondences or submissions with the applicable patent offices or Governmental Authority pertaining to Pfizer's Prosecution and Maintenance, enforcement or defense of such Myovant Patent to the extent not previously provided to Myovant during the course of this Agreement and (b) a report detailing the status of all such Myovant Patents at the effective date of termination or expiration of this Agreement.

15.8.2 Additional Termination Consequences for Material Breach by Myovant.

(a) In addition to the termination consequences under Section 15.8.1, Myovant shall pay to Pfizer an amount equal to [***] of [***] (the "[***]") as agreed by the Parties or as determined in accordance with subclause (b) below. In the event the Parties are unable to agree on the [***] within [***] days following the effective date of termination pursuant to Section 15.8.1, each Party will provide the other Party with their determination of the [***] (the "[***]") and any applicable supporting materials. The Parties shall use good faith efforts to negotiate and agree on the [***] within [***] days following receipt of the other Party's [***]. If the difference between the two [***] is [***] or less the [***] shall be the average of the two [***]. If, following the [***] days following receipt of the other Party's [***] the Parties are unable to agree on the [***] and the difference is more than [***], then within an additional [***] days each Party shall select an independent investment bank of international repute and these two banks will select a third independent Third Party of international repute (the "**Deciding Bank**"). Following such selection of the Deciding Bank, each Party will supply the Deciding Bank with their final determination of the [***] (the "[***]") and any applicable supporting materials necessary for the Deciding Bank. The Deciding Bank will be informed that the [***] provided by the two parties [***]. [***]. The cash flows will be independent of any economic or other transaction terms contained within the Agreement. The Deciding Bank will have [***] days to determine which of the [***] is more appropriate. Such determination of the [***] shall be final and Myovant shall pay to Pfizer an amount equal to [***] of such [***] in accordance with Section 15.8.2(b) below.

(b) Myovant shall pay such amount as set forth in Section 15.8.2(a) above, at Myovant's election, either: (i) within [***] days after such determination of the [***], or (ii) as [***] separate and equal payments, with the first payment payable within [***] days after such determination and the other two payments payable on, respectively, the first and second anniversary of the due date for such first payment.

(c) In addition, if the uncured material breach of this Agreement by Myovant giving rise to Pfizer's right to termination of this Agreement in its entirety occurred prior to the [***] of the Effective Date, Myovant will pay to Pfizer an amount equal to [***] within [***] days of the effective date of the termination of this Agreement.

15.8.3 Cooperation in relation to termination of [***]; Additional Termination Consequences for termination of [***].

(a) If at any time after the Effective Date Myovant receives notice from [***], and such notice relates to the performance of, or the failure to perform, any activities undertaken or obligated to be undertaken by either Party under this Agreement or any Related Agreement, Myovant shall notify Pfizer thereof, specifying the basis for [***]. The Parties shall cooperate in good faith to avoid termination of [***], including cooperating to cure the applicable breach within the applicable cure period set forth in the [***] and Pfizer affording Myovant reasonable assistance in the effort to avoid such termination.

(b) If this Agreement terminates under Section 15.6 as a result of any termination of the [***], Pfizer may only exercise the [***] (as defined in the [***]) in accordance with the terms of the [***], if such termination is caused by reasons other than Pfizer's performance of, or the failure to perform, activities to which [***]notice to Myovant relates under Section 15.8.3(a). Following any such exercise of the [***] by Pfizer, Pfizer shall pay to Myovant an [***] of all Net Sales of all Terminated Products in the Territory by

Pfizer, its Affiliates or Sublicensees, during the Royalty Term of the Products, on a Product-by-Product and country-by-country basis. Pfizer shall not exercise the [***] if the termination of the [***] is caused by any of Pfizer's performance of or the failure to perform activities to which [***] notice to Myovant relates under Section 15.8.3(a).

Section 15.9 Surviving Obligations.

15.9.1 Survival. Expiration or termination of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such expiration or termination. Such expiration or termination shall not relieve a Party from obligations that are expressly indicated to survive the expiration or termination of this Agreement. Without limiting the foregoing, Sections 3.4.1 (for the duration set out therein), 3.5.2 (with respect to the last reporting period), 3.8.1 (with respect to the right and license to utlize the data obtained from the applicable Co-Administration Studies), 4.6.1, 5.3.3 (with respect to the last reporting period), 5.3.4 (last sentence, Pfizer shall be deemed the Non-Selling Party to the extent Myovant (or its Affiliates and Sublicensees) is booking sales in the Territory), 6.1.3 (for the duration set out in the first sentence), 6.1.4 (with respect to the last reporting period), 6.3.1 (last sentence), 6.3.2 (last sentence), 6.5.6 (with respect to the last reporting period), 8.3.2 (in the case of expiration only), 8.3.4 (with respect to the last reporting period), 8.5 to 8.8 (in each case, for the duration of any outstanding payments under this Agreement), 8.9 (for the duration set out therein), 8.10 and 8.11 (for the [***] year period set out therein, after the last calendar year of the term), 8.12, 8.13, 8.14 (for the duration of any outstanding payments under this Agreement), 9.4 (with respect to the last reporting period), 10.3.1, 10.3.2, 10.3.3, 11.1, 11.6.2 (only to the extent it relates to the ownership of the domain names), 11.6.5 (first sentence), 12.1 to 12.5 (for the duration set out in Section 12.1), 13.6, Sections 14.1, 14.2 and 14.4 (solely as to actions arising during the term of this Agreement, or as to activities conducted in the course of a Party's exercise of licenses surviving under this Agreement (or, in the case of Pfizer, pursuant to the [***]) after such expiration or termination), 14.4.6, 14.5 (for the duration set out therein), 15.2.2 (in the case of such expiration only), 15.7, 15.8, 16.3.3, and Article I (to the extent any defined terms therein are used in any of the surviving provisions listed in this Section 15.9.1), Article XVII and Article XVIII of this Agreement shall survive the expiration or termination of this Agreement for any reason. In addition, without limiting the foregoing, in the event of any expiration of this Agreement, Sections 3.2.2 (solely to the extent either Party is performing any Clinical Trial for Products in the Field in the Territory), 4.4.1 (first sentence), 4.4.2, 10.3.4, 10.3.5 and 15.2, and the Parties shall reasonably agree any reporting obligations required from Pfizer for any ongoing Development and Commercialization activities in order for Myovant to comply with the [***] Agreement to the extent it is still in effect. The foregoing surviving provisions shall be referred to as the "**Surviving Provisions**".

15.9.2 Termination of Terminated Territory. If this Agreement is terminated with respect to a Terminated Territory but not in its entirety, then following such termination the Surviving Provisions shall remain in effect with respect to such Terminated Territory (to the extent they would survive and apply in the event this Agreement were terminated in its entirety or as otherwise necessary for Myovant and its Affiliates and Excluded Affiliates and its and their Sublicensees or Pfizer and its Affiliates and its and their Sublicensees, as applicable, to exercise their rights in such Terminated Territory) and all provisions not surviving in accordance with the foregoing shall terminate with respect to such Terminated Territory upon termination of this Agreement with respect to such Terminated Territory and be of no further force and effect (and for the avoidance of doubt all provisions of this Agreement shall remain in effect with respect to all countries in the Territory other than such Terminated Territory).

15.9.3 Terminated Territory. With respect to any provision that is expressly stated to survive any termination of this Agreement that applies to the Territory, Co-Promotion Territory or Pfizer Territory with respect to any Product(s), such provision shall be construed to continue to apply to the Terminated Territory to the extent included in the Territory, Co-Promotion Territory or Pfizer Territory (as applicable) prior to termination of this Agreement with respect to such Product(s) (and each reference to Territory, Co-Promotion Territory or Pfizer Territory in such surviving provisions (including the definitions therein) shall be construed to include the applicable Terminated Territory with respect to such Product(s)).

15.9.4 No Limitation of Rights. The rights provided in this Article XV shall be in addition and without prejudice to any other rights which the Parties may have with respect to any default or breach of the provisions of this Agreement. Termination is not the sole remedy under this Agreement and, whether or not

termination is effected; all other remedies at equity or law shall remain available to the Parties except as expressly agreed otherwise herein.

ARTICLE XVI.
EXCLUSIVITY; NON-COMPETITION

Section 16.1 Exclusivity. [***].

Section 16.2 Non-Competition. [***].

Section 16.3 Acquiring Party Business Combination.

16.3.1 Business Combination. Notwithstanding Section 16.2, if, at any time after the [***] anniversary of the Effective Date, a Party (such Party, the "**Acquiring Party**") or any of its Affiliates enters into a transaction for a compound or product (the "**Acquired Product**") where (a) [***] or (b) [***], then (i) [***] and (ii) [***]. [***]:

(a) [***];

(b) [***]; or

(c) [***].

16.3.2 Divestiture by the Acquiring Party.

(a) If the Acquiring Party notifies the non-Acquiring Party in writing that it intends to divest such Competing Product under Section 16.3.1(a), then the Acquiring Party shall or shall procure its relevant Affiliate shall (as applicable) use all reasonable efforts to effect such divestiture as quickly as possible. The Acquiring Party shall keep the non-Acquiring Party reasonably informed of its efforts and progress in effecting such divestiture until it is completed.

(b) If the Acquiring Party or its relevant Affiliate effects such divestiture of the Competing Product by way of sale or granting one or more licenses or sublicenses, then the Acquiring Party or its relevant Affiliate, as applicable (i.e., as licensor), shall be entitled to (i) [***] and (ii) [***].

(c) Notwithstanding any provision of this Agreement to the contrary: (i) prior to the date that such divestiture becomes effective, the Acquiring Party shall be free to [***]; (ii) the Acquiring Party shall continue to [***] under this Agreement with respect to the Products in the Field in the Territory. Until the completion of such divestiture, for purposes of determining the Acquiring Party's diligence obligations, the Acquiring Party's [***] shall not take into account [***], and its Development or Commercialization activities for such Competing Product.

(d) Prior to such divestiture by the Acquiring Party, the Acquiring Party shall take reasonable steps to prevent data access and sharing between the Acquiring Party personnel working on the Compound or Product or having access to data from activities performed under this Agreement and Confidential Information on the non-Acquiring Party and personnel of the Acquiring Party working on such Competing Product, including by following commercially reasonable policies and procedures that are no less stringent than those customarily followed in the pharmaceutical industry when establishing firewalls, and provide the non-Acquiring Party with the details of such efforts and demonstrate how it will implement governance, systems and monitoring to avoid the data sharing described in this sentence.

16.3.3 [***]. **[***]**:

(a) [***]:

[***]	**[***]**
[***]	[***] [***]
[***]	[***] [***]
[***]	[***] [***]

[***].

(b) [***]:

(i) [***]

(ii) [***].

(c) For clarity, the termination consequences set out in Section 15.8.1 shall apply with respect to the Terminated Product and the Terminated Territory.

Section 16.4 Reformation. Each of the Parties acknowledges and agrees that (a) Section 16.1, Section 16.2 and Section 16.3 have been negotiated by the Parties, (b) the geographical and time limitations on activities, are reasonable, valid and necessary in light of the circumstances pertaining to the Parties and necessary for the adequate protection of the Products in the Field, and (c) neither Party would have entered in this Agreement without the protection afforded it by Section 16.1, Section 16.2 or Section 16.3. If, however, a court of competent jurisdiction determines that the restrictions set forth in Section 16.1, Section 16.2 or Section 16.3 are too broad or otherwise unreasonable under Applicable Law, including with respect to duration, geographic scope or space, the court is hereby requested and authorized by the Parties to revise the foregoing restriction to include the maximum restrictions allowable under Applicable Law.

Section 16.5 Firewall. Solely in the event that a product being promoted [***] as of the Effective Date (the "[***]") receives approval as [***] (the "[***]"), (a) [***] will put in place reasonable internal firewall provisions to effect a segregation between any such [***], and (b) [***].

ARTICLE XVII.
GOVERNING LAW; DISPUTE RESOLUTION

Section 17.1 Governing Law. This 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.

Section 17.2 Dispute Resolution.

17.2.1 Executive Officers. Except for disputes covered by Section 2.10.3 or Section 18.13, in the event of any controversy or claim arising out of or relating to this Agreement, or the rights or obligations of the Parties hereunder (collectively, a "**Dispute**"), then either Party shall have the right to refer such Dispute to the Executive Officers for attempted resolution by good faith negotiations during a period of [***] Business Days. Any final decision mutually agreed to by the Executive Officers in writing under this Section 17.2.1 shall be conclusive and binding on the Parties.

17.2.2 Arbitration.

(a) If the Executive Officers are unable to resolve any Arbitration Matter pursuant to Section 2.10.3(c) within the [***] Business Day period specified in Section 2.10.3(b) or any Dispute pursuant to Section 17.2.1 within the [***] Business Day period specified therein, and *provided* that such Dispute is not an Excluded Claim, either Party shall be free to institute binding arbitration in accordance with this Section 17.2.2 upon written notice to the other Party (an "**Arbitration Notice**") and seek such remedies as may be available. As used in this Section 17.2.2, the term "**Excluded Claim**" means a dispute, controversy or claim that concerns (i) the validity or infringement of a Patent, Trademark or copyright; or (ii) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.

(b) Upon receipt of an Arbitration Notice by a Party, the applicable Dispute shall be resolved by final and binding arbitration before a panel of [***] experts with relevant industry experience (the "**Arbitrators**"). Each of Pfizer and Myovant shall promptly appoint [***] Arbitrator each, which selections

shall in no event be made later than [***] days after the notice of initiation of arbitration. The third Arbitrator shall be chosen promptly by mutual agreement of the Arbitrator chosen by Pfizer and the Arbitrator chosen by Myovant, but in no event later than [***] days after the date that the last of such Arbitrators was appointed. The arbitration shall be administered by the American Arbitration Association ("**AAA**") (or its successor entity) in accordance with the then current Commercial Rules of the American Arbitration Association including the Procedures for Large, Complex Commercial Disputes (including the Optional Rules for Emergency Measures of Protection), except as modified in this Agreement (the "**AAA Rules**"). The arbitration shall be held in New York, New York and shall be conducted in the English language, and the Parties shall use reasonable efforts to expedite the arbitration if requested by either Party. The Arbitrators shall, within [***] days after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The decision or award rendered by the Arbitrators shall be final and non-appealable, and judgment may be entered upon it in accordance with Applicable Law in any court of competent jurisdiction. The Arbitrators shall be authorized to grant legal and equitable remedies that would be available in any judicial proceeding instituted to resolve a disputed matter under the substantive laws of New York, but shall not be authorized to reform, modify or materially change this Agreement or any other agreements contemplated hereunder.

(c) Neither Party shall be required to produce documents or provide information reflecting communications between the Party and its attorney(s) for the purpose of seeking or providing legal advice or prepared by the Party or its attorney(s) (or retained experts or consultants) in anticipation of litigation or arbitration, the Parties will make their respective employees available for depositions and hearing testimony as reasonably requested by the other Party. Judgment on any arbitral award issued by the Arbitrators may be entered in any court having competent jurisdiction.

(d) The Parties may agree to additional appropriate restrictions or procedures that shall apply to any arbitration under this Section 17.2.2.

17.2.3 Arbitration Costs; Confidentiality. Each Party shall bear its own counsel fees, costs, and disbursements arising out of the dispute resolution procedures described in this Section 17.2, and shall pay an equal share of the fees and costs of the Arbitrators and all other general fees related to any arbitration described in Section 17.2.2; *provided* that the Arbitrators shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party reimbursement for its reasonable counsel fees, costs and disbursements (including expert witness fees and expenses, photocopy charges, and travel expenses), or the fees and costs of the Arbitrators. Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding described in Section 17.2.2 is pending under this Agreement, the Parties shall continue to comply with all those terms and provisions of this Agreement that are not the subject of such pending arbitration proceeding. All arbitration proceedings and decisions of the Arbitrators under Section 17.2.2 shall be deemed Confidential Information of both Parties under Article XII.

17.2.4 Excluded Claims. Either Party may initiate litigation in any court of competent jurisdiction to resolve any Excluded Claim.

ARTICLE XVIII.
MISCELLANEOUS

Section 18.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement, to the extent that such failure or delay is caused by an event of Force Majeure. "**Force Majeure**" means an event that is beyond a non-performing Party's reasonable control, including an act of God, act of the other Party, strike, lock-out or other industrial/labor dispute, war, acts of war (whether war be declared or not) riot, civil commotion, terrorist act, malicious damage, epidemic, pandemic, quarantine, fire, flood, storm, or natural disaster. The non-performing Party shall promptly after the occurrence of the Force Majeure event give written notice to the other Party stating the nature of the Force Majeure event, its anticipated duration and any action being taken to avoid or minimize its effect. Any suspension of performance shall be of no greater scope and of no longer duration than is reasonably required and the non-performing Party shall use [***] to remedy its inability to perform; *provided*, *however*, if the suspension of performance continues for [***] days after the date of the occurrence and such failure to perform would constitute a material breach of this Agreement in the absence of such event of Force Majeure, the Parties shall meet and discuss in good faith an appropriate course of action.

Section 18.2 Successors and Assigns. Neither Party shall sell, transfer, assign, pledge or otherwise dispose of its rights under this Agreement, whether by operation of law or otherwise, in whole or in part without the prior written consent of the other Party, except that (a) each Party shall always have the right, without such consent, to sell, transfer, assign, pledge or otherwise dispose of its rights under this Agreement to any of its Affiliates, or, in the case of Myovant, through any of its Excluded Affiliates, it being agreed that such Party shall cause such assignment to terminate prior to such time, if any, as such Person ceases to be an Affiliate of such Party), or (b) each Party shall have the right, without such consent, to assign this Agreement and its rights and obligations hereunder to its successor entity or acquirer in the event of a merger, consolidation or change of control of such Party or in connection with the purchase of all or substantially all of the assets of such Party; *provided*, *however*, each of Myovant and Pfizer shall remain liable for the performance of its Affiliates and shall ensure that such Affiliate complies with the terms of this Agreement and the Related Agreements in the same manner and to the same extent as if such activity were performed directly by such Party, and any action or omission of such Affiliate shall be deemed and action or omission of such Party for all purposes of this Agreement and the Related Agreements. Any permitted assignee of all of a Party's rights under this Agreement that has also assumed all of such Party's obligations hereunder in writing shall, upon any such assignment and assumption, be deemed to be a Party to this Agreement as though named herein; *provided*, *however*, with respect to an assignment to an Affiliate, such assigning Party shall remain responsible and liable for the performance by such Affiliate of the rights and obligations hereunder. All validly assigned rights of a Party shall inure to the benefit of and be enforceable by, and all validly delegated obligations of such Party shall be binding on and be enforceable against, the permitted successors and assigns of such Party. Any attempted assignment or delegation in violation of this Section 18.2 shall be void. Notwithstanding any other provision of this Section 18.2, the terms of this Agreement may be varied, amended or modified or this Agreement may be suspended, cancelled or terminated without the consent of any assignee or delegate that is not deemed pursuant to the provisions of this Section 18.2 to have become a Party to this Agreement.

Section 18.3 Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it shall not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other Governmental Authority in accordance with Applicable Law.

Section 18.4 Independent Contractors. It is the express intention of Myovant and Pfizer that each Party and its Affiliates perform its responsibilities under this Agreement as an independent contractor of the other Party. Nothing contained in this Agreement shall be construed to create a relationship of partners, principal and agent, employer and employee or joint venturers between Myovant and Pfizer or their respective Affiliates or employees. Nothing contained in this Agreement and the Related Agreements shall be construed to create a "separate entity" or "business entity" within the meaning of the Code or the regulations thereunder and any foreign equivalents thereto. Neither Party, nor its Affiliates or employees, shall have the power or right to bind or obligate the other Party, without the other Party's prior written consent to do so, nor shall either Party or its Affiliates or employees hold itself out as having such authority except as otherwise specified herein or in any Related Agreement.

Section 18.5 Delegation and Subcontracting of Obligations to Third Parties. Each Party (and its Affiliates) shall have the right to subcontract its Development, Manufacturing and Commercialization obligations under this Agreement to one (1) or more Third Parties; *provided* that neither Party (nor its Affiliates) may subcontract (a) the conduct of any Clinical Trial to any contract research organization except as determined by the applicable JMDRC, (b) the performance of any Commercialization activity, except as determined by the applicable JCC, or (c) any Manufacturing obligation to any Third Party manufacturer, except as determined by the JMC. The Party engaging a Third Party subcontractor shall remain responsible for the management of such subcontractor, liable for the performance of such subcontractor and shall ensure that such subcontractor complies with the terms of this Agreement and the Related Agreements in the same manner and to the same extent as if such activity were performed directly by such Party, and any action or omission of such subcontractor shall be deemed an action or omission of such Party for all purposes of this Agreement and the Related Agreements. All compensation, reimbursement of costs and other payments to be made to any such Third Party subcontractor shall be determined solely by the Party engaging such Third Party subcontractor and

such Third Party subcontractor; *provided* that all such arrangements shall be consistent with the applicable Joint Medical Affairs and Development Plan and Budget or Co-Promotion Commercialization Plan and Budget.

Section 18.6 Compliance with Applicable Law. Each of the Parties shall, and shall cause its Affiliates to, in all material respects, comply with all Applicable Law in Developing and Commercializing the Products in the Field in the Territory and performing its other obligations under this Agreement, including the Anti-Corruption Laws; the FFDCA; the Public Health Service Act, as amended; the Prescription Drug Marketing Act of 1987, as amended; the Federal Health Care Program Anti-Kickback Law (42 U.S.C. §§ 1320a-7b), as amended; the Health Insurance Portability and Accountability Act of 1996, as amended; the FDA Guidance for Industry-Supported Scientific and Educational Activities; all federal, state and local "fraud and abuse," consumer protection and false claims statutes and regulations, including the Medicare and State Health Programs Anti-Fraud and Abuse Amendments of the Social Security Act and the "Safe Harbor Regulations" found at 42 C.F.R. §1001.952 et seq.; the Office of the Inspector General's Compliance Guidance Program, 42 U.S.C. 1320a-7h and its implementing regulations (also known as the National Physician Payment Transparency Program and the Open Payments Program) ("**Sunshine Act**"); and all foreign equivalents in the Territory of any of the foregoing; *provided* that with respect to the Sunshine Act, each Party shall be responsible for reporting in connection with payments or other transfers of value actually made by such Party or its Affiliates, and each Party shall use [***] to cooperate with the other Party to coordinate such disclosure.

Section 18.7 Amendment. Any amendment, change, supplement to or other variation of this Agreement shall be valid only if made in writing, mutually agreed to by the Parties and duly executed by authorized representatives of both Parties.

Section 18.8 Notices.

18.8.1 Requirements. All notices under or in connection with this Agreement shall be in writing (which requirement shall also be deemed fulfilled by a facsimile transmission, but not exclusively via electronic communication or electronic transmission), shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by facsimile transmission (with transmission confirmed) or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 18.8.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 18.8.1. Such notice shall be deemed to have been given as of the date delivered by hand or transmitted by facsimile (with transmission confirmed) or on the [***] Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. Any notice delivered by facsimile shall be confirmed by a hard copy delivered as soon as practicable thereafter. This Section 18.8.1 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

18.8.2 Address for Notice.

If to Myovant, to:

Myovant Sciences GmbH
Viaduktstrasse 8
4051 Basel
Switzerland
Attention: Legal Department

With copy to:
Myovant Sciences, Inc.
2000 Sierra Point Parkway, 9th Floor
Brisbane, CA 94005
United States
Attention: Legal Department

If to Pfizer, to:
Pfizer
Pfizer Inc.
235 East 42nd Street
New York, NY 10017
Attention: President, Pfizer Oncology
With copies to:
Pfizer Inc.
235 East 42nd Street
New York, NY 10017
Attention: General Counsel

Pfizer Inc.
235 East 42nd Street
New York, NY 10017
Attention: Senior Vice President, Business Development

Section 18.9 Entire Agreement. This Agreement and the Related Agreements, together with the Schedules, Exhibits and Appendices attached hereto and thereto, 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, including that certain Confidential Disclosure Agreement between Pfizer Inc. and Myovant Sciences Inc., effective as of August 21, 2020. Except for the Related Agreements, there are no ancillary or side agreements, whether written, oral, or otherwise. Each Party confirms that in entering into this Agreement it is not relying on any representations or warranties of the other Party, except as specifically set forth in this Agreement.

Section 18.10 Interpretation. This Agreement shall be construed and interpreted in accordance with the following rules except as expressly otherwise provided herein and except as the context otherwise requires:

18.10.1 Wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. In the case of a defined term, any grammatical form thereof shall have a corresponding meaning. The term "including," "include," or "includes" as used herein shall mean including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto.

18.10.2 Unless specifically stated otherwise, any reference (a) to any Section, Article or Exhibit shall be references to such Section or Article of or Exhibit to this Agreement, (b) in any Section to any clause shall be a reference to such clause of such Section and (c) to any agreement, instrument, or other document in this Agreement shall refer to such agreement, instrument, or other document as originally executed or, if subsequently amended, replaced, or supplemented from time to time, as so amended, replaced, or supplemented and in effect at the relevant time of reference thereto.

18.10.3 A reference to a law, ruling, agreement or other legal instrument shall include all changes, amendments or supplements to such law, agreement or other legal instrument regardless of whether such change, amendment or supplement has occurred prior to, on or after the Effective Date.

18.10.4 In the event of any inconsistency between a Related Agreement and this Agreement, the terms of this Agreement shall govern unless such Related Agreement specifically references a Section of this Agreement and expressly states that such Section is intended to be amended by such Related Agreement.

18.10.5 This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall

not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

Section 18.11 Severability. In the event that any provision of this Agreement is held to be invalid, illegal or unenforceable, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such invalid, illegal or unenforceable provision had never comprised a part hereof, (c) the validity, legality and enforceability of the remaining provisions hereof shall not be affected or impaired thereby and (c) in lieu of such invalid, illegal or unenforceable provision, there shall be added automatically as a part of this Agreement a valid, legal and enforceable provision that (x) achieves, to the maximum extent possible, the Parties' original intent and commercial objectives and (y) is reasonably acceptable to the Parties. It is understood that in any case where a provision is void or unenforceable only in some respects (*e.g.*, only with respect to certain countries) such provision shall continue to be applied in all other respects. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid, or unenforceable in any respect.

Section 18.12 Waivers. 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 (a) shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition and (b) in any one instance shall be construed to be a waiver of such term or provision or any other term or provision in any other instance. All rights, remedies, undertakings and obligations contained herein shall be cumulative, and none of them shall be construed to be a limitation of any other right, remedy, undertaking or obligation.

Section 18.13 Equitable Relief. Each Party acknowledges and agrees that the restrictions set forth in Section 3.3, Article XII and Article XVI are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any provision of such Section or Articles may result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Section or Articles, the non-breaching Party shall be authorized and entitled to seek from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance, and an equitable accounting of all earnings, profits, and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity. Nothing in this Section 18.13 is intended, or should be construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

Section 18.14 Further Assurances. Each Party shall 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, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

Section 18.15 Counterparts. This Agreement may be executed in any number of counterparts and on a separate counterpart by each Party. Each of such counterparts shall, when executed, be deemed to be an original hereof, and all such counterparts together shall be deemed to constitute one and the same document. This Agreement may be executed by facsimile or electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

Section 18.16 No Third Party Beneficiaries. Subject to Section 10.3.4, it is acknowledged and mutually agreed that no provision of this Agreement shall be for the benefit of, or shall be enforceable by, any Third Party, including any creditor of either Party.

Section 18.17 Costs. Except as otherwise set forth herein, each Party shall bear its own costs and expenses in connection with the preparation, execution and implementation of this Agreement.

[Signature page follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement by their duly authorized officers as of the Effective Date.

MYOVANT Sciences GmbH		**PFIZER Inc.**	
By:	/s/ Elke Hunsche	By:	
Name:	Elke Hunsche	Name:	
Title:	Vice President, Global Market Access & HEOR	Title:	

IN WITNESS WHEREOF, the Parties have executed this Agreement by their duly authorized officers as of the Effective Date.

MYOVANT Sciences GmbH	**PFIZER Inc.**
By: _____	By: /s/ John Young
Name:	Name: John Young
Title:	Title: Chief Business Officer

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 we have:

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

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

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

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

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

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

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

Date: February 11, 2021

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

Exhibit 31.2

CERTIFICATION

I, Frank Karbe, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: February 11, 2021

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Myovant Sciences Ltd. (the "Company") for the period ended December 31, 2020 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: February 11, 2021

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 December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Frank Karbe, Principal Financial Officer of the Company, hereby certifies, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and 18 U.S.C. Section 1350, that to the best of his knowledge:

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

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

Date: February 11, 2021

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

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