

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

**FORM 10-Q/A
(Amendment No. 1)**

(Mark One)

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

For the quarterly period ended June 30, 2018
or

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

For the transition period from _____ to _____
Commission file number 001-37929

Myovant Sciences Ltd.

(Exact name of registrant as specified in its charter)

Bermuda
(State or other jurisdiction of
incorporation or organization)

98-1343578
(I.R.S. Employer
Identification No.)

Suite 1, 3rd Floor
11-12 St. James's Square
London
SW1Y 4LB
United Kingdom
(Address of principal executive offices)

Not Applicable
(Zip Code)

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

(former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

Emerging growth company

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

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

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

EXPLANATORY NOTE

Myovant Sciences Ltd. (“Myovant”) is filing this Amendment No. 1 to Quarterly Report on Form 10-Q/A (this “Amendment”) to amend Myovant’s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2018, as filed with the Securities and Exchange Commission (the “SEC”) on August 7, 2018 (the “Form 10-Q”). This Amendment is an exhibit-only filing. This Amendment is being filed solely to re-file a revised redacted version of Exhibit 10.5 to the Form 10-Q to reflect changes to Myovant’s confidential treatment request with respect to certain portions of Exhibit 10.5. Except for the changes to Exhibit 10.5, this Amendment does not otherwise update any exhibits as originally filed or previously amended.

No attempt has been made in this Amendment to modify or update the other disclosures presented in the Form 10-Q. This Amendment does not reflect events occurring after the filing of the Form 10-Q or modify or update those disclosures that may be affected by subsequent events. Accordingly, this Amendment should be read in conjunction with the Form 10-Q and Myovant’s other filings with the SEC.

In addition, as required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended, new certifications by Myovant’s principal executive officer and principal financial officer are filed as exhibits to this Amendment (Exhibits 31.3 and 31.4). Myovant is not including certifications pursuant to Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350) as no financial statements are being filed with this Amendment.

Item 6. Exhibits.

<u>Exhibit Number</u>	<u>Description of Document</u>	<u>Schedule / Form</u>	<u>File No.</u>	<u>Exhibit No.</u>	<u>Filing Date</u>
3.1	Certificate of Incorporation.	S-1	333-213891	3.1	09/30/2016
3.2	Memorandum of Association.	S-1	333-213891	3.2	09/30/2016
3.3	Third Amended and Restated Bye-laws.	8-K	001-37929	3.1	02/09/2018
10.1	Sales Agreement, dated as of April 2, 2018, between Myovant Sciences Ltd. and Cowen and Company, LLC.	8-K	001-37929	1.1	04/03/2018
10.2	Share Purchase Agreement, dated as of April 2, 2018, between Myovant Sciences Ltd. and Roivant Sciences Ltd.	8-K	001-37929	99.1	04/03/2018
10.3	Waiver and Amendment to the Securities Purchase Agreement, dated as of March 28, 2018, by and among the Registrant, Myovant Holdings Limited, Myovant Sciences GmbH, Myovant Sciences Ireland Limited, Myovant Sciences, Inc., the Purchasers (as defined therein) and NovaQuest Pharma Opportunities Fund IV, L.P.	10-Q	001-37929	10.3	08/07/2018
10.4	Second Waiver and Amendment to the Securities Purchase Agreement, dated as of March 30, 2018, dated October 16, 2017, by and among the Registrant, Myovant Holdings Limited, Myovant Sciences GmbH, Myovant Sciences Ireland Limited, Myovant Sciences, Inc., the Purchasers (as defined therein) and NovaQuest Pharma Opportunities Fund IV, L.P.	10-Q	001-37929	10.4	08/07/2018
10.5*†	Commercial Manufacturing & Supply Agreement, effective as of May 30, 2018, by and between Myovant Sciences GmbH and Takeda Pharmaceutical Company Limited.				
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	10-Q	001-37929	13.1	08/07/2018
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	10-Q	001-37929	31.2	08/07/2018
31.3†	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Form 10-Q/A)				
31.4†	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Form 10-Q/A)				
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.	10-Q	001-37929	32.1	08/07/2018
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.	10-Q	001-37929	32.2	08/07/2018
101.INS XBRL+	Instance Document				
101.SCH XBRL+	Taxonomy Extension Schema				
101.CAL XBRL+	Taxonomy Extension Calculation Linkbase				
101.DEF XBRL+	Taxonomy Extension Definition Linkbase				
101.LAB XBRL+	Taxonomy Extension Label Linkbase				
101.PRE XBRL+	Taxonomy Extension Presentation Linkbase				

† Filed herewith.

+ Previously filed with the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2018, as filed on August 7, 2018.

* Confidential treatment has been requested for portions omitted from this exhibit (indicated by asterisks) and those portions have been separately filed with the SEC.

** These certifications were previously furnished solely to accompany the Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, and are not 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.

Date: September 17, 2018

By: /s/ Frank Karbe

Frank Karbe

(Duly Authorized Officer and Principal Financial and Accounting Officer)

COMMERCIAL MANUFACTURING & SUPPLY AGREEMENT

BY AND BETWEEN

TAKEDA PHARMACEUTICAL COMPANY LIMITED

AND

MYOVANT SCIENCES GMBH

DATE: MAY 30, 2018

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

COMMERCIAL MANUFACTURING & SUPPLY AGREEMENT

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

RECITALS

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

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

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

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

ARTICLE 1 DEFINITIONS

The following capitalized terms used in this Agreement shall have the meanings specified below; and all other capitalized terms used but not otherwise defined in this Agreement shall have their respective meanings set forth in the License Agreement, provided that solely with respect to such terms in the License Agreement, (i) all references to “Licensee” and “Takeda” in such other capitalized terms shall be deemed to refer to Myovant and Takeda hereunder (respectively) and all references to “Affiliate” in any such capitalized terms shall refer to “Affiliate” as defined below, (ii) all references to a “Party” and the “Parties” in any such capitalized terms shall be deemed to refer to a Party and the Parties hereunder (respectively), (iii) all references to the “Effective Date” and the “Agreement” in any such capitalized terms shall be deemed to refer

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to the Effective Date hereunder and this Agreement (respectively), (iv) all references to the “Term” in any such capitalized terms shall be deemed to refer to the Term hereunder. For convenience, a glossary of such capitalized terms from the License Agreement that are used herein, as excerpted and redacted for the purposes hereof, is attached hereto as Exhibit D; provided, however, that if there is any inadvertent conflict between the terms on such Exhibit D and the same terms in the License Agreement, the terms in the License Agreement shall control unless the context duly requires otherwise.

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

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

1.3 “Detectable Defect” shall have the meaning set forth in Section 9.1 hereof.

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

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

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

1.7 “Firm Order” is defined in Section 6.1.2(b) hereof.

1.8 “Firm Order Period” is defined in Section 6.1.2(b) hereof.

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

1.10 “FTE Rate” is defined in Schedule 4.2.3 hereto.

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

1.12 “Initial Firm Order” is defined in Section 6.1.2(a) hereof.

1.13 “Initial Firm Order Period” is defined in Section 6.1.2(a) hereof.

1.14 “JPY” means Japanese Yen.

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

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

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

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

1.19 “Project Work Order” shall have the meaning set forth in Section 12.1 hereof.

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

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

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

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

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

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

ARTICLE 2 DRUG SUBSTANCE SUPPLY; GOVERNANCE

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

2.2 Governance.

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

2.3 Joint Manufacturing Working Group.

2.3.1 Establishment; Responsibilities. The Parties have established, under the License Agreement, a joint manufacturing working group (the “**Joint Manufacturing Working Group**” or “**JMWG**”), which shall have, with respect to this Agreement, the responsibilities set forth in this Section 2.3. For clarity, Section 4.1 of the License Agreement and

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the “Transition Plan” described therein shall remain in full force and effect for Licensed Compounds including the Drug Substance under this Agreement; *provided, however*, that the disclaimers set forth in Section 4.2.2 (Takeda Materials Disclaimer) of the License Agreement will not negate any express warranties made by Takeda in this Agreement. The JMWG shall be responsible for overseeing, reviewing and coordinating activities related to the supply of Drug Substance under this Agreement and operational decisions with respect thereto, including as follows:

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

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

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

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

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

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

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

ARTICLE 3 PRICE

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

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

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

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

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

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

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

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

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

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

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

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

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**ARTICLE 4
TECHNOLOGY TRANSFER**

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

4.2 Technology Transfer.

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

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

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

4.2.4 Additional Transition Services. With respect to any Transition Services outside the scope of the Drug Substance Transition Plan, at the reasonable written request of Myovant, Takeda shall negotiate in good-faith, and may (in any event, shall not be obligated, but will not unreasonably refuse, to) provide such additional Transition Services, as reasonably needed and available, in order to support transfer of Manufacturing technology and additional Takeda Materials, including without limitation by providing documentation, information and other materials reasonably available and necessary for the Manufacture of Drug Substance or taking any action(s) reasonably available and necessary to comply with any request or demand of any Regulatory Authority, to Myovant or the Qualified Designees (“**Additional Transition Services**”). For clarity, Takeda shall not be obligated (but will not unreasonably refuse) to conduct hereunder any experiments and studies whatsoever for the data and information on the Drug Substance not

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available to Takeda then. Myovant shall reimburse Takeda for such Additional Transition Services under the same terms as provided in Section 4.2.3 hereof. At the reasonable written request of Myovant for any Additional Transition Services for the transfer of documentation, information and other materials reasonably available and necessary for the Manufacture of Drug Product, further, the Parties shall negotiate in good-faith, and may (as for Takeda, in any event, shall not be obligated to) enter into a subsequent transition plan therefor (the “**Drug Product Transition Plan**”). The Drug Product Transition Plan so entered shall set forth the timelines, obligations, deliverables and other duties of each Party with respect to the transfer of Takeda Materials reasonably available and necessary for the Manufacture of Drug Product. In any event, Takeda shall not be required to conduct any of the Additional Transition Services hereunder for [***].

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

ARTICLE 5 REGULATORY ACTIVITIES AND RESPONSIBILITIES

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

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

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

ARTICLE 6 FORECASTING AND ORDERING

6.1 Forecasts and Purchase Orders.

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

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6.1.2 Binding Quantities.

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

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

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

6.1.3 Purchase Orders.

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

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

6.1.4 [*].**

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

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

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

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

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

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

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

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

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

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

ARTICLE 7 MANUFACTURING

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

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

7.2.1 Modifications Required by Regulatory Authorities in Myovant Territory. Notwithstanding anything to the contrary herein, if any Regulatory Authority in the Licensee Territory requires, even before, upon or after its Regulatory Approval as applicable to the Drug Substance supplied hereunder, that Myovant implement a Manufacturing Change (each, a “**Required Modification**”), then Takeda shall, upon receipt of written notice from Myovant describing in reasonable detail such Required Modification, discuss in good faith such Required Modification, including its [***], and prepare and deliver to Myovant, as soon as possible but no later than [***] days after such notice, a written reasonable estimate of (a) [***] for implementing such Required Modification, (b) a [***] such Required Modification, (c) any [***] to fulfill Firm Orders and (d) [***] substantially in connection with such Required Modification (collectively, the “**Estimate**”). The Parties shall discuss with each other such Estimate in good faith to reach

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agreement thereon, including but not limited to any change in Firm Orders [***] Myovant shall pay for Drug Substance, as well as any regulatory impacts on the TAK-385 Licensed Product or TAK-385 Licensed Compound for the Takeda Territory. Upon the mutual written agreement on any terms and conditions as applicable (the “**Manufacturing Change Order**”), both Parties shall duly: (i) implement the applicable Regulatory Modification(s) in accordance with the Manufacturing Change Order; and (ii) provide each other with all Regulatory Materials that are required by Regulatory Authorities in the Licensee Territory and Takeda Territory in connection with such Required Modification.

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

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

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

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

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**ARTICLE 8
DELIVERY, TITLE AND RISK OF LOSS**

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

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

**ARTICLE 9
NON-CONFORMING PRODUCT/RETURNS**

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

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

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

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

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

ARTICLE 10 STORAGE, HANDLING AND TRANSPORT

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

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

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

**ARTICLE 11
RECALL**

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

**ARTICLE 12
TECHNICAL SUPPORT SERVICES**

[Intentionally left blank]

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

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

ARTICLE 13 PAYMENT TERMS

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

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

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

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

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**ARTICLE 14
INTELLECTUAL PROPERTY**

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

**ARTICLE 15
CONFIDENTIALITY**

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

**ARTICLE 16
REPRESENTATIONS AND WARRANTIES**

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

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

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

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

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16.2 Further Takeda Representations, Warranties and Covenants.

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

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

- (a) will have been Manufactured, tested, released, stored, supplied and otherwise handled in accordance with all Applicable Laws and GMPs, and the applicable Specifications;
- (b) will have been Manufactured in facilities that are in compliance with Applicable Laws;
- (c) will have been Manufactured in accordance with the Quality Agreement and will conform with the certificates provided pursuant to the Quality Agreement;
- (d) shall not be adulterated or misbranded within the meaning of the FFDCA; and
- (e) may be introduced into interstate commerce pursuant to the FFDCA.

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

16.4 Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, THERE ARE NO REPRESENTATIONS OR WARRANTIES OR COVENANTS OF ANY KIND, EXPRESS OR IMPLIED, WRITTEN OR ORAL, MADE BY TAKEDA (OR ANY OF ITS AFFILIATES), WITH RESPECT TO THE DRUG SUBSTANCE OR OTHERWISE, INCLUDING: (A) ANY IMPLIED WARRANTIES OF

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MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE; (B) ANY IMPLIED WARRANTIES ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE IN THE TRADE; (C) ANY WARRANTY OF DESCRIPTION OR OTHERWISE CREATED BY ANY AFFIRMATION OF FACT OR PROMISE OR SAMPLE OR MODEL; OR (D) NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

ARTICLE 17
INDEMNIFICATION; NO CONSEQUENTIAL DAMAGES; INSURANCE

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

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

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

ARTICLE 18
TERM AND TERMINATION

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

18.2 Termination.

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

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

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

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

18.3 Consequences of Termination.

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

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

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

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

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

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

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

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

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

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

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

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

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ARTICLE 19
GENERAL PROVISIONS

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

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

If to Takeda:

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

If to Myovant:

Myovant Sciences GmbH
Viaduktstrasse 8
4051 Basel
Switzerland

Copy to:

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

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

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

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

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

19.7 Assignment. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective heirs, successors and permitted assigns. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, which consent shall not be unreasonably withheld, delayed or conditions;

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provided, however, that Myovant may, without Takeda's prior written consent (but with a written notice to Takeda in a timely manner): (a) assign its rights and obligations under this Agreement in whole or in part to one or more of its Affiliates; and (b) assign this Agreement in connection with the sale or other transfer of all or substantially all of the assets of the business to which this Agreement relates (whether such transaction occurs by way of a sale of assets, merger, consolidation or similar transaction); *provided, further*, that any assignment by Myovant shall be permitted only if such assignment is consistent with Sections 5.5 and 5.6 of the License Agreement. Any successor or assignee of rights or obligations permitted hereunder will, in writing to the other Party, expressly assume performance of such rights or obligations. Any permitted assignment will be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 19.7 will be null, void and of no legal effect.

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

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

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

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

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

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

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

[Signature Page Follows.]

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

MYOVANT SCIENCES GMBH

Signature: /s/ Mark Altmeyer
Name: Mark Altmeyer
Title: Director
Date: June 1, 2018

TAKEDA PHARMACEUTICAL COMPANY LIMITED

Signature: /s/ Hideki Fujiwara
Name: Hideki Fujiwara
Title: Head of [***]
Date: 28. May. 2018

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EXHIBIT B

TRANSITION PLAN

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

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<u>Activities</u>	<u>Comments</u>	<u>Timeline</u>
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***

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EXHIBIT C

FORM OF PROJECT WORK ORDER

PWO #*[INSERT]*

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

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

[Signature page follows.]

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

MYOVANT SCIENCES GMBH

TAKEDA PHARMACEUTICAL COMPANY LIMITED

Signature: _____
Name: _____
Title: _____
Date: _____

Signature: _____
Name: _____
Title: _____
Date: _____

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EXHIBIT D

GLOSSARY

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

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

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

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

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

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

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

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

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

“**Control**” means, with respect to any Information, Patent Right, Trademark or other Intellectual Property Right, ownership or possession by a Party, including its Affiliates, of the ability (without taking into account any rights granted

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by one Party to the other Party under the terms of this Agreement) to grant access, a license, or a sublicense to such Information, Patent Right, Trademark or other Intellectual Property Right without (a) violating the terms of any agreement or other arrangement with, (b) being required to make any payment to, or (c) necessitating the consent of, in each case (a) – (c), any Third Party, at such time that the Party would be first required under this Agreement to grant the other Party such access, license, or sublicense. [See License Agreement Section 1.29]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

“**Takeda Know-How**” means (a) all Information and Inventions Controlled by Takeda or its Affiliates as of the Effective Date that are necessary or reasonably useful to Exploit a Licensed Compound or a Licensed Product and (b) all Information and Inventions developed after the Effective Date and Controlled by Takeda or its Affiliates (other than Licensee Know-How and Joint

Know-How) during the Term that are necessary to Exploit a Licensed Compound or a Licensed Product. Takeda Know-How excludes any Information contained within or Inventions Covered by a published Takeda Patent Right. [See License Agreement Section 1.147]

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

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

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

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

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

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

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

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

Schedule 1.17

Chemical Composition:

Specification:

<u>Item</u>	<u>Specification</u>
***	***
***	***

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

Schedule 3.1

Prices

[***]

[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

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

Schedule 4.2.3

Fee Schedule for Transition Services

[***]

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

Schedule 6.1.1

Takeda Recipient of Rolling Forecasts

Takeda Contact:

[***]

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

Initial Binding Order

***	***	***	***	***	***
***	***	***	***	***	***

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

CERTIFICATION

I, Lynn Seely, certify that:

1. I have reviewed this Amendment No. 1 on Form 10-Q/A of Myovant Sciences Ltd.; and
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.

Date: September 17, 2018

/s/ Lynn Seely

Lynn Seely

Principal Executive Officer

CERTIFICATION

I, Frank Karbe, certify that:

1. I have reviewed this Amendment No. 1 on Form 10-Q/A of Myovant Sciences Ltd.; and
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.

Date: September 17, 2018

/s/ Frank Karbe

Frank Karbe

Principal Financial and Accounting Officer