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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 25, 2017

NEUROCRINE BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**0-22705**	**33-0525145**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

12780 El Camino Real, San Diego, California	**92130**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 617-7600

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2 (b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4 (c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 1.01 Entry into a Material Definitive Agreement.

The Patheon Agreements and Packaging Agreement (each as defined below) described below were not material to Neurocrine Biosciences, Inc. (the "***Company***") when executed, but became material to the Company during the quarter ending June 30, 2017.

Master Manufacturing Services Agreement and Product Agreement

On November 28, 2016, the Company and Patheon UK Limited ("***Patheon***") entered into a Master Manufacturing Services Agreement (the "***Services Agreement***") and a related Product Agreement (the "***Product Agreement***" and together with the Services Agreement, the "***Patheon Agreements***") for Patheon's manufacture of commercial supplies of INGREZZA™ (valbenazine) at Patheon's manufacturing site. Under the terms of the Services Agreement, the Company is responsible for supplying the active pharmaceutical ingredients for INGREZZA to Patheon. Patheon is responsible for manufacturing the INGREZZA capsules, conducting quality control, quality assurance, validation activities, stability testing, packaging and providing related services for the manufacture of the INGREZZA capsules.

Pursuant to the Patheon Agreements, the Company has agreed to order from Patheon certain annual binding minimum amounts of INGREZZA capsules in the United States based on an agreed upon pricing schedule. The Patheon Agreements have an initial term ending December 31, 2021, and will automatically renew after the initial term for successive terms of two years, unless either party gives notice of its intention to terminate the Patheon Agreements within at least 18 months prior to the end of the then current term.

The Company may terminate the Product Agreement upon 30 days' prior written notice if any governmental agency takes any action that prevents the Company from importing, exporting, purchasing or selling INGREZZA. Further, the Company must give at least six months' advance notice (or such shorter period if required pursuant to action taken by a governmental agency) if the Company intends to no longer order manufacturing services for INGREZZA due to discontinuance of INGREZZA in the market.

Either party may terminate the Services Agreement or the Product Agreement (a) if the other party has failed to remedy a material breach under the Services Agreement or the Product Agreement within 90 days following receipt of a written notice, (b) immediately upon written notice to the other party in the event that the other party is declared insolvent or bankrupt, a voluntary petition of bankruptcy is filed in any court by such other party or the Patheon Agreements are assigned by such other party for the benefit of creditors, and (c) upon six months written notice if the other party assigns the Services Agreement or the Product Agreement to an assignee that, in the opinion of the non-assigning party acting reasonably, is (i) not a credit worthy substitute for the other party or (ii) a competitor of the non-assigning party.

The Patheon Agreements contain certain representations, warranties, limitations of liabilities, confidentiality and indemnity obligations and other provisions customary for agreements of their type.

The foregoing description of the terms of the Patheon Agreements does not purport to be complete and is qualified in its entirety by reference to the full text of the Services Agreement and the Product Agreement, copies of which are attached to this report as Exhibits 99.1 and 99.2, respectively.

Commercial Packaging Agreement

On December 12, 2016, the Company and AndersonBrecon Inc., doing business as PCI of Illinois ("***PCI***"), entered into a Commercial Packaging Agreement (the "***Packaging Agreement***") for PCI's commercial packaging services. Under the terms of the Packaging Agreement, PCI will be responsible for, among other things, the packaging of certain of the Company's products, tooling purchases and repair, analytical work, stability testing, auditing of suppliers and storage. The Company is responsible for supplying the product materials to PCI. Pursuant to the Packaging Agreement, the Company has agreed to submit rolling forecasts, some of which will be binding on the Company. The Company will compensate PCI for services rendered, based on an agreed upon fee schedule and subject to certain price adjustments.

The Packaging Agreement has an initial term ending September 30, 2019, unless earlier terminated in accordance with its terms. The Packaging Agreement will automatically renew after the initial term for successive terms of two years, unless either party gives notice of its intention to terminate the Packaging Agreement at least one year prior to the end of the then current term.

Either party may terminate the Packaging Agreement (a) if the other party has failed to remedy a material breach within 60 days following receipt of a written notice, or (b) immediately upon written notice to the other party in the event that the other party files a

petition of bankruptcy, enters into an agreement with its creditors, applies for or consents to the appointment of a receiver, trustee or administrator, permits the entry of any order adjudicating it to be bankrupt or insolvent and such order is not discharged within 30 days, or takes any equivalent action in consequence of debt in any jurisdiction. Either party may terminate the Packaging Agreement for any reason or no reason upon 24 months' prior written notice to the other party.

The Packaging Agreement contains certain representations, warranties, limitations of liabilities, confidentiality and indemnity obligations and other provisions customary for agreements of this type.

The foregoing description of the terms of the Packaging Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Packaging Agreement, a copy of which is attached to this report as Exhibit 99.3.

License Agreement

Also attached to this report as Exhibit 99.4 is a copy of the License Agreement between the Company and BIAL – Portela & CA, S.A., dated February 9, 2017, the terms of which are described in the Company's Current Report on Form 8-K that was filed with the Securities and Exchange Commission on February 10, 2017.

Item 2.02 Results of Operations and Financial Condition.

The disclosure contained under the heading "Quarter-End Cash, Investments and Receivables" in Item 8.01 below is incorporated herein by reference.

Item 8.01 Other Events.

Recent Developments

On April 11, 2017, the U.S. Food and Drug Administration (the "***FDA***") approved INGREZZA™ (valbenazine) capsules for the treatment of adults with tardive dyskinesia. INGREZZA, a novel, selective vesicular monoamine transporter 2 (VMAT2) inhibitor, is the first and only FDA-approved product indicated for the treatment of adults with tardive dyskinesia.

The Company has established the wholesale acquisition cost ("***WAC***") for a 30-count bottle of INGREZZA 40mg capsules at $5,275. The Company anticipates obtaining FDA approval for an 80mg capsule formulation of INGREZZA by the end of 2017, and expects the WAC price for a 30-count bottle of the 80 mg capsule formulation of INGREZZA to be priced substantially similar to the price of a 30-count bottle of INGREZZA 40 mg capsules.

Quarter-End Cash, Investments and Receivables

The Company expects to end the first quarter of 2017 with cash, investments and receivables totaling approximately $274 million. The Company's financial statements for the quarter ended March 31, 2017 have not yet been completed and could result in changes to these anticipated financial results.

Convertible Senior Notes

On April 25, 2017, the Company issued a press release announcing its proposed plans to offer, subject to market and other conditions, up to approximately $450 million in aggregate principal amount of convertible senior notes due 2024 (the "notes") in a private offering to qualified institutional buyers pursuant to Rule 144A of the Securities Act of 1933, as amended (the "***Securities Act***"). The Company also expects to grant the initial purchasers for the offering a 30-day option to purchase up to an additional $67.5 million principal amount of notes. A copy of the press release is attached hereto as Exhibit 99.5 and incorporated by reference herein.

This Form 8-K does not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any offer, solicitation or sale of these securities in any state in which such offer, solicitation or sale would be unlawful. Any offers of the securities would be made only by means of a confidential offering circular. These securities have not been registered under the Securities Act, or any state securities laws and, unless so registered, may not be offered or sold in the United States except pursuant to an exemption from the registration requirements of the Securities Act and applicable state laws.

Special Note Regarding Forward-Looking Statements

This Current Report on Form 8-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements relate to future events and involve known and unknown risks, uncertainties and other factors which may cause the Company's actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may", "will", "should", "could", "would", "expects", "plans", "anticipates", "believes", "estimates", "projects", "predicts", "potential" and similar expressions intended to identify forward-looking statements. These statements reflect the Company's current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent the Company's estimates and assumptions only as of the date of this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Master Manufacturing Services Agreement dated November 28, 2016, by and between Patheon UK Limited and Neurocrine Biosciences, Inc.
99.2	Product Agreement dated November 28, 2016, by and between Patheon UK Limited and Neurocrine Biosciences, Inc.
99.3	Commercial Packaging Agreement dated December 12, 2016, by and between AndersonBrecon Inc., d/b/a PCI of Illinois, and Neurocrine Biosciences, Inc.
99.4	License Agreement dated February 9, 2017, by and between Bial – Portela & CA, S.A. and Neurocrine Biosciences, Inc.

99.5 Press release dated April 25, 2017

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 hereunto duly authorized.

Dated: April 25, 2017

NEUROCRINE BIOSCIENCES, INC.

/s/ Darin M. Lippoldt

Darin M. Lippoldt
Chief Legal Officer

Master Manufacturing Services Agreement

28 November 2016

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MASTER MANUFACTURING SERVICES AGREEMENT

THIS MASTER MANUFACTURING SERVICES AGREEMENT (the "Agreement") is made as of 28 November 2016 (the "**Effective Date**")

B E T W E E N:

PATHEON UK LIMITED
a corporation existing under the laws of England
of Kingfisher Drive, Covingham, Swindon, SN3 5BZ
("**Patheon**"),

- and –

NEUROCRINE BIOSCIENCES, INC.,
a corporation existing under the laws of Delaware
of 12780 El Camino Real, San Diego 92130, California, USA, on behalf of itself and its wholly-owned subsidiaries
(collectively "**Client**").

THIS AGREEMENT WITNESSES THAT in consideration of the rights conferred and the obligations assumed herein, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each party), and intending to be legally bound the parties agree as follows:

ARTICLE 1

STRUCTURE OF AGREEMENT AND INTERPRETATION

1.1 Master Agreement.

This Agreement establishes the general terms and conditions under which Patheon or any Affiliate of Patheon may perform Manufacturing Services for Client or any Affiliate of Client, at the manufacturing site where the Affiliate of Patheon resides. This "master" form of agreement is intended to allow the parties, or any of their Affiliates, to contract for the manufacture of multiple Products through Patheon's global network of manufacturing sites through the issuance of site specific Product Agreements without having to re-negotiate the basic terms and conditions contained herein.

1.2 Product Agreements.

This Agreement is structured so that a Product Agreement may be entered into by the parties for the manufacture of a particular Product or multiple Products at a Patheon manufacturing site. Each Product Agreement will be governed by the terms and conditions of this Agreement unless the parties to the Product Agreement expressly modify the terms and conditions of this Agreement in the Product Agreement. Unless otherwise agreed by the parties, each Product Agreement will be in the general form and contain the information set forth in Appendix 1 hereto.

1.3 Definitions.

The following terms will, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of these terms will have corresponding meanings:

"**Active Materials**", **"Active Pharmaceutical Ingredients"** or **"API"** means the materials listed in a Product Agreement on Schedule D;

"**Active Materials Credit Value**" means the value of the Active Materials for certain purposes of this Agreement, as set forth in a Product Agreement on Schedule D;

"**Actual Annual Yield**" or "**AAY**" has the meaning specified in Section 2.3(a);

"**Actual Yearly Volume**" or "**AYV**" has the meaning specified in Section 4.2.1;

"**Affiliate**" means:

(a) a business entity which owns, directly or indirectly, a controlling interest in a party to this Agreement, by stock ownership or otherwise; or

(b) a business entity which is controlled by a party to this Agreement, either directly or indirectly, by stock ownership or otherwise; or

(c) a business entity, the controlling interest of which is directly or indirectly common to the majority ownership of a party to this Agreement;

For this definition, "control" means the ownership of shares carrying at least a majority of the votes for the election of the directors of a corporation;

"Annual Product Review Report" means the annual product review report prepared by Patheon or an Affiliate of Patheon as described in Title 21 of the United States Code of Federal Regulations, Section 211.180(e);

"**Annual Report"** means the annual report to the FDA which is required to be prepared and filed by Client regarding the Product as described in Title 21 of the United States Code of Federal Regulations, Section 314.81(b)(2);

"**Annual Volume**" means the minimum volume of Product to be manufactured in any Year of this Agreement as set forth in a Product Agreement on Schedule B;

"**Applicable Laws**" means (i) for Patheon, the Laws of the jurisdiction where the Manufacturing Site is located; and (ii) for Client, the Laws of all jurisdictions where the Products are manufactured, distributed, and marketed as these are agreed and understood by the parties in this Agreement;

"**Authority**" means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether federal, state, provincial, county or municipal;

"**Breach Notice**" has the meaning specified in Section 8.2(a);

"**Business Day**" means a day other than a Saturday, Sunday or a day that is a statutory holiday in the United States, United Kingdom or the jurisdiction where the Manufacturing Site is located.;

"**Capital Equipment Agreement**" means a separate agreement that the parties may enter into that will address responsibility for the purchase of capital equipment and facility modifications that may be required to perform the Manufacturing Services under a particular Product Agreement;

"**cGMPs**" means, as applicable, current good manufacturing practices as described in:

(a) Parts 210 and 211 of Title 21 of the United States' Code of Federal Regulations;

(b) EC Directive 2003/94/EC;

(c) Division 2 of Part C of the *Food and Drug Regulations* (Canada); and

(d) Similar current good manufacturing practices for countries/political entities other than those described above as may be agreed to by the Parties in any Product Agreement.

together with the latest Health Canada, FDA and EMA guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time;

"Client Intellectual Property" means Intellectual Property generated or derived by Client before entering into this Agreement, or by Patheon while performing any Manufacturing Services or otherwise generated or derived by Patheon in its business which Intellectual Property is specific to, or dependent upon, Client's Active Material or Product;

"**Client Property**" has the meaning specified in Section 8.3(a)(v);

"**Client-Supplied Components**" means those Components to be supplied by Client or that have been supplied by Client;

"**Change Control Procedure**" has the meaning specified in Section 6.10(a);

"**Components**" means, collectively, all packaging components, raw materials, ingredients, and other materials (including labels, product inserts and other labelling for the Products) required to manufacture the Products in accordance with the Specifications, other than the Active Materials;

"**Confidential Information**" has the meaning specified in Section 11.1;

"**Conversion Fee**" means the Price for performing the Manufacturing Services excluding the cost of Components;

"**CTD**" has the meaning specified in Section 7.9(c);

"C-TPAT" has the meaning specified in Section 2.1(f);

"**Deficiencies**" have the meaning specified in Section 7.9(d);

"**Deficiency Notice**" has the meaning specified in Section 6.1(a);

"Delivery Date" means the date scheduled for shipment of Product under a Firm Order as set forth in Section 5.1(d);

"Disclosing Party" has the meaning specified in Section 11.1;

"**EMA**" means the European Medicines Agency;

"**FDA**" means the United States Food and Drug Administration;

"**Firm Orders**" have the meaning specified in Section 5.1(c);

"**Force Majeure Event**" has the meaning specified in Section 13.7;

"**GST**" has the meaning specified in Section 13.16(a)(iii);

"**Health Canada**" means the section of the Canadian Government known as Health Canada and includes, among other departments, the Therapeutic Products Directorate and the Health Products and Food Branch Inspectorate;

"**Importer of Record**" has the meaning specified in Section 3.2(a);

"**Initial Product Term**" has the meaning specified in Section 8.1;

"**Initial Term**" has the meaning specified in Section 8.1;

"**Intellectual Property**" includes, without limitation, rights in patents, patent applications, formulae, trademarks, trademark applications, trade-names, Inventions, copyrights, industrial designs, trade secrets, and know how;

"**Invention**" means information about any innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable;

"**Inventory**" means all inventories of Components and work-in-process produced or held by Patheon for the manufacture of the Products but, for greater certainty, does not include the Active Materials;

"**Laws**" means all laws, statutes, ordinances, regulations, rules, by-laws, judgments, decrees or orders of any Authority;

"Long Term Forecast" has the meaning specified in Section 5.1(a);

"**Manufacturing Services**" means the commercial manufacturing, quality control, quality assurance, stability testing, packaging, and related services, as set forth in this Agreement, required to manufacture Product or Products using the Active Materials and Materials.

"**Manufacturing Site**" means the facility owned and operated by Patheon or an Affiliate of Patheon where the Manufacturing Services will be performed as identified in a Product Agreement;

"Materials" means all Components and other materials routinely required to manufacture the Products in accordance with the Specifications, other than the Active Materials;

"**Maximum Credit Value**" means the maximum value of Active Materials that may be credited by Patheon under this Agreement, as set forth in a Product Agreement on Schedule D;

"**Minimum Order Quantity**" means the minimum number of batches of a Product to be produced during the same cycle of manufacturing as set forth in a Product Agreement on Schedule B;

"**Obsolete Stock**" has the meaning specified in Section 5.2(b);

"**Patheon Competitor**" means a business that derives greater than […***…]% of its revenues from performing contract pharmaceutical development or commercial manufacturing services;

"Patheon Intellectual Property" means Intellectual Property generated or derived by Patheon before performing any Manufacturing Services, developed by Patheon while performing the Manufacturing Services, or otherwise generated or derived by Patheon in its business which Intellectual Property is not specific to, or dependent upon, Client's Active Material or Product including, without limitation, Inventions and Intellectual Property which may apply to manufacturing processes or the formulation or development of drug products, drug product dosage forms or drug delivery systems unrelated to the specific requirements of the Product(s);

"Price" means the fees to be charged by Patheon for performing the Manufacturing Services, and includes the cost of Components (other than Client-Supplied Components), certain cost items as set forth in a Product Agreement on Schedule B, and annual stability testing fees as set forth in a Product Agreement on Schedule C;

"**Product(s)**" means the product(s) listed in a Product Agreement on Schedule A;

"**Product Agreement**" means the agreement between Patheon and Client issued under this Agreement in the form set forth in Appendix 1 (including Schedules A to D) under which Patheon will perform Manufacturing Services at a particular Manufacturing Site;

"**Product Claims**" have the meaning specified in Section 6.3(c);

"**Quality Agreement**" means the agreement between the parties entering into a Product Agreement, or between the applicable Affiliate of Patheon and Client if the Manufacturing Services are subcontracted to such Affiliate by Patheon, that sets out the quality assurance standards for the Manufacturing Services to be performed by Patheon for Client;

"**Recall**" has the meaning specified in Section 6.2(a);

"**Recipient**" has the meaning specified in Section 11.1;

"**Regulatory Approval**" has the meaning specified in Section 7.9(a);

"**Regulatory Authority**" means the FDA, EMA, and Health Canada and any other foreign regulatory agencies competent to grant marketing approvals for pharmaceutical products including the Products in the Territory;

"**Remediation Period**" has the meaning specified in Section 8.2(a);

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"**Representatives**" means a party's directors, officers, employees, advisers, agents, consultants, subcontractors, service partners, professional advisors, or representatives;

"Resident Jurisdiction" has the meaning specified in Section 13.16(a)(i);

"**Shortfall**" has the meaning specified in Section 2.3(b);

"**Specifications**" means the file, for each Product, which is given by Client to Patheon in accordance with the procedures listed in a Product Agreement on Schedule A and which contains documents relating to each Product, including, without limitation:

(a) specifications for Active Materials and Components;

(b) manufacturing specifications, directions, and processes;

(c) storage requirements;

(d) all environmental, health and safety information for each Product including material safety data sheets; and

(e) the finished Product specifications, packaging specifications and shipping requirements for each Product;

all as updated, amended and revised from time to time by Client in accordance with the terms of this Agreement;

"Surplus" has the meaning specified in Section 2.3(c);

"**Target Yield**" has the meaning specified in Section 2.3(a);

"**Target Yield Determination Batches**" has the meaning specified in Section 2.3(a);

"**Tax**" or "**Taxes**" have the meaning specified in Section 13.16(a);

"**Technical Dispute**" has the meaning specified in Section 12.2;

"**Technology Transfer and Scale-Up Services**" means the technology transfer and scale-up services specified in Exhibit D and referred to in Section 2.2.

"**Territory**" means the geographic area described in a Product Agreement where Products manufactured by Patheon will be distributed by Client;

"**Third Party Rights**" means the Intellectual Property of any third party;

"**VAT**" has the meaning specified in Section 13.16(d);

"**Year**" means in the first year of this Agreement or in the first year of a Product Agreement, the period from the Effective Date up to and including December 31 of the same calendar year, and thereafter will mean a calendar year; and

"**Yearly Forecast Volume**" or "**YFV**" has the meaning specified in Section 4.2.1.

1.4 Currency.

Unless otherwise agreed in a Product Agreement, all monetary amounts expressed in this Agreement are in US Dollars.

1.5 Sections and Headings.

The division of this Agreement into Articles, Sections, Subsections, an Appendix, Schedules and Exhibits and the insertion of headings are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section, Appendix, Schedule or Exhibit refers to the specified Section, Appendix, Schedule or Exhibit to this Agreement. In this Agreement, the terms "**this Agreement**", "**hereof**", "**herein**", "**hereunder**" and similar expressions refer to this Agreement as a whole and not to any particular part, Section, Appendix, Schedule or Exhibit of this Agreement.

1.6 Singular Terms.

Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa.

1.7 Appendix 1, Schedules and Exhibits.

Appendix 1 (including the Schedules thereto) and the following Exhibits are attached to, incorporated in, and form part of this Agreement:

Appendix 1	-	Form of Product Agreement (Including Schedules A to D)
Exhibit A	-	Technical Dispute Resolution
Exhibit B	-	Quarterly Active Materials Inventory Report
Exhibit C	-	Report of Annual Active Materials Inventory Reconciliation and Calculation of Actual Annual Yield
Exhibit D	-	Technology Transfer and Scale-Up Services

ARTICLE 2

PATHEON'S MANUFACTURING SERVICES

2.1 Manufacturing Services.

Patheon will perform the Manufacturing Services for the Territory for the Price specified in a Product Agreement in Schedules B and C to manufacture Products for Client. Schedule B to a Product Agreement sets forth a list of cost items that are included in the Price for Products; all cost items that are not included in the Price are subject to additional fees to be paid by Client which will be the subject of a written agreement between the Parties. Patheon may amend the fees set out in Schedules B and C to a Product Agreement as set forth in Article 4. Patheon may change the Manufacturing Site for the Products only with the prior written consent of Client, this consent not to be unreasonably withheld, provided, however, Patheon acknowledges that avoidance of a cost increase is a valid reason for Client to withhold consent. In performing the Manufacturing Services, Patheon and Client agree that:

(a) Conversion of Active Materials and Components. Patheon will convert Active Materials and Components into Product.

(b) Quality Control and Quality Assurance. Patheon will perform the quality control and quality assurance testing specified in the Quality Agreement. Batch review and release to Client will be the responsibility of Patheon's quality assurance group. Patheon will perform its batch review and release responsibilities in accordance with Patheon's standard operating procedures. Each time Patheon ships Products to Client, it will give Client a certificate of analysis and certificate of compliance including a statement that the batch has been manufactured and tested in accordance with Specifications and cGMPs. Client will have sole responsibility for the release of Products to the market. The form and style of batch documents, including, but not limited to, batch production records, lot packaging records, equipment set up control, operating parameters, and data printouts, raw material data, and laboratory notebooks are the exclusive property of Patheon. Specific Product related information contained in those batch documents is Client property.

(c) Components. Patheon will purchase and test all Components (with the exception of Client-Supplied Components) at Patheon's expense and as required by the Specifications.

(d) Stability Testing. Patheon will conduct stability testing on the Products in accordance with the protocols set out in the Specifications for the separate fees and during the time periods set out in Schedule C to a Product Agreement. Patheon will not make any changes to these testing protocols without prior written approval from Client. If a confirmed stability test failure occurs, Patheon will notify Client within […***…], after which Patheon and Client will jointly determine the proceedings and methods to be undertaken to investigate the cause of the failure, including which party will bear the cost of the investigation. Patheon will not be liable for these costs unless it has failed to perform the Manufacturing Services in accordance with the Specifications and cGMPs. Patheon will give Client all stability test data and results at Client's request.

In the event that Client requests a stability program to be terminated early, any costs associated with the disposal of any remaining drug product or shipment of any remaining drug product back to Client will be charged to Client at a price to be agreed in good faith between the parties.

(e) Packaging and Artwork. Patheon will package the Products in accordance with the Specifications. Client will be responsible for the cost of artwork development. Patheon

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will determine and imprint the batch numbers and expiration dates for each Product shipped. The batch numbers and expiration dates will be affixed on the Products and on the shipping carton of each Product as outlined in the Specifications and as required by cGMPs. Client may, in its sole discretion, make changes as the case may be, to labels, product inserts, and any other packaging for the Products. Those changes will be submitted by Client to all applicable Regulatory Authorities as required and other third parties responsible for the approval of the Products. Client will be responsible for the cost of labelling obsolescence when changes occur, as contemplated in Section 4.3. Patheon's name will not appear on the label or anywhere else on the Products unless: (i) required by any Laws; or (ii) Patheon consents in writing to the use of its name. At least […***…] days prior to the Delivery Date of Product for which new or modified artwork is required, Client will provide at no cost to Patheon, final camera ready artwork for all packaging Components to be used in the manufacture of the Product that meet the Specifications. For the avoidance of doubt, the parties acknowledge and agree that Client will be responsible for complying with any and all regulatory requirements for the labeling of the Product.

(f) Active Materials and Client-Supplied Components. At least […***…] days before the scheduled production date, Client will deliver the Active Materials and any Client-Supplied Components to the Manufacturing Site DDP (Incoterms 2010), at no cost to Patheon, with any VAT paid by Client, in sufficient quantity to enable Patheon to manufacture the desired quantities of Product and to ship Product on the Delivery Date. If the Active Materials and/or Client-Supplied Components are not received […***…] days before the scheduled production date, Patheon may delay the shipment of Product by the same number of days as the delay in receipt of the Active Materials and/or Client-Supplied Components. But if Patheon is unable to manufacture Product to meet this new shipment date due to prior third party production commitments, Patheon may delay the shipment until a later date as agreed to by the parties, but in no event later than the next available slot in the binding part of the Yearly Forecast Volume. All shipments of Active Material will be accompanied by certificate(s) of analysis from the Active Material manufacturer and Client, confirming the identity and purity of the Active Materials and its compliance with the Active Material specifications. For Active Materials or Client-Supplied Components which may be subject to import or export, Client agrees that its vendors and carriers will comply with applicable requirements of the U.S. Customs and Border Protection Service and the Customs Trade Partnership Against Terrorism ("**C-TPAT**").

2.2 Technology Transfer and Scale-Up Services and Additional Services

(a) Validation Activities (if applicable). Patheon may assist in the development and approval of the validation protocols for analytical methods and manufacturing procedures (including packaging procedures) for the Products. The fees for this service are not included in the Price and will be set out separately in Schedule C to a Product Agreement.

(b) Additional Services. If Client requests services other than those expressly set forth herein or in any Product Agreement (such as qualification of a new packaging configuration or shipping studies, new stability studies, or validation of alternative batch sizes), Patheon will provide a good faith and reasonable written quote of the fee for the additional services and Client will advise Patheon whether it wishes to have the additional services performed by Patheon. Such Additional Services shall be set out separately on an new Schedule E to any Product Agreement and shall be subject to Section 6.10.

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(c) Technology Transfer and Scale-Up Services. Patheon shall perform the Technology Transfer and Scale-Up Services set out in Exhibit D pursuant to, and following execution of, the Technology Transfer Services Agreements to be agreed and entered into by the parties. The performance of the Technology Transfer and Scale-Up Services and the parties' rights and obligations in relation to the Technology Transfer and Scale-Up Services shall be governed by the terms and conditions of the applicable Technology Transfer Services Agreement and shall not be subject to the terms and conditions of this Agreement; provided, however, that any Product manufactured while performing the Technology Transfer and Scale-Up Services which is mutually agreed by the Parties to be available for commercial use (i.e., successful validation batches) shall be subject to the terms of this Agreement and the applicable Product Agreement following quality release by Patheon.

2.3 Active Material Yield.

(a) Reporting. Patheon will give Client a […***…] inventory report of the Active Materials held by Patheon using the inventory report form set out in Exhibit B, which will contain the following information for the […***…]:

Quantity Received: The total quantity of Active Materials and Client-Supplied Components that complies with the Specifications and is received at the Manufacturing Site during the applicable period.

Quantity Dispensed: The total quantity of Active Materials and Client-Supplied Components dispensed at the Manufacturing Site during the applicable period. The Quantity Dispensed is calculated by adding the Quantity Received to the inventory of Active Materials that complies with the Specifications held at the beginning of the applicable period, less the inventory of Active Materials that complies with the Specifications held at the end of the period. The Quantity Dispensed will only include Active Materials received and dispensed in commercial manufacturing of Products, and will not include any (i) Active Materials that must be retained by Patheon as samples, (ii) Active Materials contained in Product that must be retained as samples, (iii) Active Materials used in testing (if applicable), and (iv) Active Materials received or dispensed in technical transfer activities or development activities during the applicable period, including without limitation, any regulatory, stability, validation or test batches manufactured during the applicable period.

Quantity Converted: The total amount of Active Materials and Client-Supplied Components contained in the Products manufactured with the Quantity Dispensed (including any additional Products produced in accordance with Section 6.3(a) or 6.3(b), delivered by Patheon, and not rejected, recalled or returned in accordance with Sections 6.1 or 6.2 because of Patheon's failure to perform the Manufacturing Services in accordance with Specifications, cGMPs, and Applicable Laws.

Within […***…] days after the end of each Year, Patheon will prepare an annual reconciliation of Active Materials and Client-Supplied Components on the reconciliation report form set forth in Exhibit C including the calculation of the "**Actual Annual Yield**" or "**AAY**" for the Product at the Manufacturing Site during the Year. AAY is the percentage of the Quantity Dispensed that was converted to Products and is calculated as follows:

$$\frac{\text{Quantity Converted during the Year}}{\text{Quantity Dispensed during the Year}} \times 100\%$$

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After Patheon has produced a minimum of […***…] successful commercial production batches of Product and has produced commercial production batches for at least […***…] at the Manufacturing Site (collectively, the "**Target Yield Determination Batches**"), the parties will agree on the target yield for the Product at the Manufacturing Site (each, a "**Target Yield**"). The Target Yield will be revised annually to reflect the actual manufacturing experience as agreed to by the parties.

(b) Shortfall Calculation. If the Actual Annual Yield falls more than […***…]% below the respective Target Yield in a Year, then the shortfall for the Year (the "**Shortfall**") will be calculated as follows:

Shortfall = [(Target Yield – […***…]%) – AAY] * Active Materials Credit Value * Quantity Dispensed

(c) Surplus Calculation. If the Actual Annual Yield is more than the respective Target Yield in a Year, then the surplus for that Year (the "**Surplus**") will be determined based on the following calculation:

Surplus = [AAY — Target Yield] * Active Materials Credit Value * Quantity Dispensed

(d) Credits

(i) Shortfall Credit. If there is a Shortfall for a Product in a Year, then Patheon will credit Client's account for the amount of the Shortfall not later than […***…] days after the end of each Year.

(ii) Surplus Credit. If there is a Surplus for a Product in a Year, then Patheon will be entitled to apply the amount of the Surplus as a credit against any Shortfall for that Product which may occur in the next Year. If there is no Shortfall in the next Year the Surplus credit will expire.

Each credit under this Section 2.3 will be summarized on the reconciliation report prepared in the form set forth in Exhibit C. Upon expiration or termination of a Product Agreement, any remaining Shortfall credit amount owing under this Section 2.3 will be paid to Client.

(e) Maximum Credit. Patheon's liability for Active Materials calculated in accordance with this Section 2.3 for any Product in a Year will not exceed, in the aggregate, the Maximum Credit Value set forth in Schedule D to a Product Agreement.

(f) No Material Breach. It will not be a material breach of this Agreement by Patheon under Section 8.2(a) if the Actual Annual Yield is less than the Target Yield.

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ARTICLE 3

CLIENT'S OBLIGATIONS

3.1 Payment.

Client will pay Patheon for performing the Manufacturing Services and the Additional Services according to the Prices specified in Schedules B and C in a Product Agreement. These Prices may be subject to adjustment under other parts of this Agreement. Client will also pay Patheon for performing the Technology Transfer and Scale-Up Services according to the Prices specified in the applicable Technology Transfer Services Agreement (as described in Section 2.2(c)).

3.2 Active Materials and Qualification of Additional Sources of Supply.

(a) Client will at its sole cost and expense deliver the Active Materials to Patheon in accordance with Section 2.1(f). If applicable, Patheon and Client will reasonably cooperate to permit the import of the Active Materials to the Manufacturing Site. Client's obligation will include obtaining the proper release of the Active Materials from the applicable Customs Agency and Regulatory Authority. Client or Client's designated broker will be the "**Importer of Record**" for Active Materials imported to the Manufacturing Site. The Active Materials will be held by Patheon on behalf of Client as set forth in this Agreement. Title to the Active Materials will at all times remain the property of Client. Any Active Materials received by Patheon will only be used by Patheon to perform the Manufacturing Services. Client will be responsible for paying for all rejected Product that arises from defects in the Active Materials which could not be reasonably discoverable by Patheon using the test methods set forth in the Specifications.

(b) If Client asks Patheon to qualify an additional source for the Active Material or any Component, Patheon may agree to evaluate the Active Material or Component to be supplied by the additional source to determine if it is suitable for use in the Product. The parties will agree on the scope of work to be performed by Patheon at Client's cost subject to Section 6.10. For an Active Material, this work at a minimum will include: (i) laboratory testing to confirm the Active Material meets existing specifications; (ii) manufacture of an experimental batch of Product that will be placed on […***…] accelerated stability; and (iii) manufacture of […***…] full-scale validation batches that will be placed on concurrent stability (one batch may be the registration batch if manufactured at full scale).

(c) Patheon will promptly advise Client if it encounters supply problems, including delays and/or delivery of non-conforming Active Material or Components from a Client designated additional source. Patheon and Client will cooperate to reduce or eliminate any supply problems from these additional sources of supply. Client will be obligated to certify all Client designated sources of supply on an annual basis at its expense and will provide Patheon with copies of these annual certifications. If Patheon agrees to certify a Client designated additional sources of supply on behalf of Client, it will do so at Client's expense.

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ARTICLE 4

CONVERSION FEES AND COMPONENT COSTS

4.1 First Year Pricing.

The Price for the first Year listed in Schedules B and C in a Product Agreement will be subject to the adjustments set forth in Sections 4.2 and 4.3. The Price may also be increased or decreased by Patheon at any time upon written notice to Client if there are changes to the underlying manufacturing, packaging or testing assumptions as agreed by the Parties, subject to the Change Control Procedure outline in Section 6.10 and set forth in a revised Schedule B of the Product Agreement.

4.2 Price Adjustments – Subsequent Years' Pricing.

After the first Year of the Product Agreement, Patheon may adjust the Price effective January 1st of each Year as follows:

(a) Manufacturing and Stability Testing Costs. Patheon may adjust the conversion component of the Price and the annual stability testing costs for inflation, based upon the preliminary number for any increase in the inflation index stated in the Product Agreement in June of the preceding Year compared to the final number for the same month of the Year prior to that (based on the […***…]), unless the parties otherwise agree in writing. Patheon will give Client a statement setting forth the calculation for the inflation adjustment to be applied in calculating the Price for the next Year.

(b) Component Costs. If Patheon incurs an increase in Component costs during the Year, it may increase the Price for the next Year to pass through the additional Component costs at Patheon's cost. Patheon will give Client information about the increase in Component costs which will be applied to the calculation of the Price for the next Year to reasonably demonstrate that the Price increase is justified.

(c) Pricing Basis. Client acknowledges that the Price in any Year is quoted based upon the Minimum Order Quantity and the Annual Volume specified in Schedule B to a Product Agreement. The Price is subject to change if the specified Minimum Order Quantity changes or if the Annual Volume is not ordered in a Year. For greater certainty, if Patheon and Client agree that the Minimum Order Quantity will be reduced or the Annual Volume in the lowest tier will not be ordered in a Year, then Patheon may propose an increase in the Price by an amount sufficient to absorb its documented increased costs subject to discussion and agreement by Client. Patheon will give Client a statement setting forth the information to be applied in calculating those cost increases for the next Year.

(d) Tier Pricing (if applicable). The pricing in Schedule B of a Product Agreement is set forth in Annual Volume tiers based upon Client's volume forecasts under Section 5.1. Client will be invoiced during the Year for the unit price set forth in the Annual Volume tier based on the […***…] forecast provided in September of the previous Year. Within […***…] days after the end of each Year or of the termination of the Agreement, Patheon will send Client a reconciliation of the actual volume of Product ordered by Client during the Year with the pricing tiers. If Client has overpaid during the Year, Patheon will issue a credit to Client for the amount of the overpayment within […***…] days after the end of the Year or will issue payment to Client for the overpayment within […***…] days after the termination of the Agreement. If Client has underpaid during the Year, Patheon will issue

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an invoice to Client under Section 5.5 for the amount of the underpayment within […***…] days after the end of the Year or termination of the Agreement. If Client disagrees with the reconciliation, the parties will work in good faith to resolve the disagreement amicably. If the parties are unable to resolve the disagreement within […***…] days, the matter will be handled under Section 12.1.

(e) For all Price adjustments under this Section 4.2, Patheon will deliver to Client on or about […***…] but no later than […***…] of each Year a proposed revised Schedule B to the Product Agreement to be effective for Product delivered on or after the […***…] day of the next Year. The Parties agree to meet, discuss, and agree any such Price increase proposals prior to any changes to Schedule B for Product delivered on or after the […***…] day of the next Year.

4.2.1 Yearly Forecast Volumes and Binding Committments.

On the execution of a Product Agreement, Client will give to Patheon a forecast, by […***…], of the volume of Product required for the first […***…] of the Product Agreement (the "**Yearly Forecast Volume**" or "**YFV**") that will become part of the Product Agreement. The Yearly Forecast Volume shall be updated on a […***…] basis as provided in Section 5.1(c). The first […***…] of the Yearly Forecast Volume will be binding upon Client; the next […***…] will be binding upon Client at […***…]%, the next […***…will be binding upon Client at […***…]% and the final […***…] will be binding upon Client at […***…]%. Upon receipt of a Yearly Forecast Volume, Patheon shall reserve capacity to the extent required by the binding commitment.

4.2.2 Minimum Annual Revenue

Client shall be obliged to order and purchase an annual binding minimum amount of Product equal to USD$[…***…] (based on small scale commercial manufacturing) or USD$[…***…] (based on full scale commercial manufacturing) as applicable. If in any Year the amount of Product purchased by Client is less than USD$[…***…] or USD$[…***…] as applicable (i.e. payments of the Price received by Patheon) ("**Actual Annual Purchase Amount**") then Client shall pay Patheon the shortfall between USD$[…***…] or USD$[…***…] as applicable and the Actual Annual Purchase Amount. Patheon shall be entitled to invoice Client for any shortfall following 31 December of each Year.

4.3 Adjustments Due to Technical Changes or Regulatory Authority Requirements.

Amendments to the Specifications or the Quality Agreement requested by Client will be implemented only following a technical and cost review that Patheon will perform subject to Section 6.10. Amendments to the Specifications, the Quality Agreement, or the Manufacturing Site requested by Patheon will only be implemented following the written approval of Client subject to Section 6.10. If Client accepts a proposed Price change, the proposed change in the Specifications or the Quality Agreement and the associated scope of work will be implemented at Client's cost, and the Price change will become effective, only for those orders of Product that are manufactured under the revised Specifications. In addition, Client agrees to purchase, at the price paid by Patheon (including all costs incurred by Patheon for the purchase, handling, and transport of the Inventory), all Inventory held under the "old" Specifications and purchased or maintained by Patheon in order to fill Firm Orders or under Section 5.2, if the Inventory can no longer be used under the revised Specifications. Open purchase orders for Components no longer required under any revised Specifications that were placed by Patheon with suppliers in order to fill Firm Orders or under Section 5.2 will be cancelled where possible, but if the orders may not be cancelled without penalty, they will be assigned to and paid for by Client. Additional

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payments or price increases may also be required to compensate Patheon for fees and other expenses incurred by Patheon to comply with Regulatory Authority requirements or changes in Applicable Laws which apply solely to the Manufacturing Services provided herein.

4.4 Multi-Country Packaging Requirements.

If Client decides to have Patheon perform Manufacturing Services for the Product for countries outside the Territory, then Client will inform Patheon of the packaging requirements for each new country and Patheon will prepare a quotation for consideration by Client of any additional costs for Components (other than Client-Supplied Components). The agreed additional packaging requirements and related packaging costs and change over fees will be set out in a written amendment to this Agreement.

4.5 Cost Improvement Measures

The Parties agree to share cost improvement measures related to the Manufacturing Services. All cost improvement investments specific for such Product shall require consent. Patheon shall be entitled to receive reimbursement for reasonable costs which it incurred in developing such cost improvements. Cost improvement benefits concerning such Manufacturing Services shall be allocated equitably between the parties to be reflected in the Price. Client shall pay such Price to Patheon in accordance with the provisions as set forth in this Agreement.

ARTICLE 5

ORDERS, SHIPMENT, INVOICING, PAYMENT

5.1 Orders and Forecasts.

(a) Long Term Forecast. When each Product Agreement is executed, Client will give Patheon a non-binding […***…] forecast of Client's volume requirements for the Product for […***…] during the term of the Product Agreement (the "**Long Term Forecast**"). The Long Term Forecast will thereafter be updated every […***…] (as of […***…] and […***…]) during the Initial Product Term. If Patheon is unable to accommodate any portion of the Long Term Forecast, it will notify Client and the parties will agree on any revisions to the forecast.

(b) Rolling […***…] Forecast. When each Product Agreement is executed, Client will give Patheon a non-binding […***…] forecast of the volume of Product that Client expects to order in the first […***…] of commercial manufacture of the Product. This forecast will then be updated by Client on or before the […***…] of each […***…] on a rolling forward basis. Client will update the forecast forthwith if it determines that the volumes estimated in the most recent forecast have changed by more than […***…]%. The most recent […***…] forecast will prevail. These forecasts should be consistent with the Long Term Forecast.

(c) Firm Orders. On a rolling basis during the term of the Product Agreement, Client will issue an updated Yearly Forecast Volume on or before the […***…] of each […***…]. This YFV will start on the […***…] of the next […***…]. Unless otherwise agreed in the Product Agreement, the YFV will be considered binding in accordance with Section 4.2.1. Client will order Product on a […***…] basis. Concurrent with the delivery of the YFV, Client will issue a new firm written order in the form of a purchase order or otherwise ("**Firm Order**") by Client to purchase and, when accepted by Patheon, for Patheon to manufacture and deliver the agreed quantity of the Products. The Delivery Date will not

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be less than […***…] days from the […***…] following the date that the Firm Order is submitted. Firm Orders submitted to Patheon will specify Client's purchase order number, quantities by Product type, monthly delivery schedule, and any other elements necessary to ensure the timely manufacture and shipment of the Products. The quantities of Products ordered in those written orders will be firm and binding on Client and may not be reduced by Client. Expedited Firm Orders will be subject to additional fees.

(d) Acceptance of Firm Order. Patheon will accept Firm Orders by sending an acknowledgement to Client within […***…] Business Days of its receipt of the Firm Order. The acknowledgement will include, subject to confirmation from Client, the Delivery Date for the Product ordered or delivery month for any Firm Orders that do not relate to the first […***…] of the […***…] forecast. The Delivery Date may be amended by agreement of the parties. If Patheon fails to acknowledge receipt of a Firm Order within the […***…] Business Day period, the Firm Order will be deemed to have been accepted by Patheon.

(e) Cancellation of a Firm Order. If Client cancels a Firm Order, Client will pay Patheon for […***…], for the Firm Order.

(f) Controlled Substance Quota Requirements (if applicable). Client will give Patheon the information set forth below for obtaining any required DEA or equivalent agency quotas needed to perform the Manufacturing Services. Patheon will be responsible for routine management of DEA quota information in accordance with DEA regulations. Patheon and Client will cooperate to communicate the information and to assist each other in DEA information requirements related to the Product as follows: (i) as of […***…] of each Year for the applicable Product, Client will provide to Patheon the next Year's annual quota requirements for the Product; (ii) as of […***…] of each Year, Client will provide to Patheon any changes to the next Year's quota requirements; (iii) Client will pro-actively communicate any changes to the quota requirements for the then-current Year in sufficient time to allow Patheon to file and finalize DEA filings supporting the changes; (iv) upon Patheon receiving the necessary forecast information from Client in order to request additional quota, Patheon will submit to the DEA, on a timely basis, all filings necessary to obtain DEA or equivalent agency quotas for Active Materials and will use commercially reasonable efforts to secure sufficient quota from the DEA so as to achieve Delivery Dates for Product as set forth in applicable purchase orders and forecasts submitted to Patheon by Client or its designee; and (v) Patheon will not be responsible for DEA's refusal or failure to grant sufficient quota for reasons beyond the reasonable control of Patheon.

5.2 Reliance by Patheon.

(a) Client understands and acknowledges that Patheon will rely on the Firm Orders and rolling forecasts submitted under Sections 5.1(a), and (b) in ordering the Components (other than Client-Supplied Components) required to meet the Firm Orders. In addition, Client understands that to ensure an orderly supply of the Components**,** Patheon may want to purchase the Components in sufficient volumes to meet the production requirements for Products during part or all of the forecasted periods referred to in Section 5.1(a) or to meet the production requirements of any longer period agreed to by Patheon and Client. Accordingly, Client authorizes Patheon to purchase Components to satisfy the Manufacturing Services requirements for Products for the first […***…] contemplated in the most recent forecast given by Client under Section 5.1(a). Patheon may make other purchases of Components to meet Manufacturing Services requirements for longer periods if agreed to in writing by the parties.

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Client will give Patheon written authorization to order Components for any launch quantities of Product requested by Client which will be considered a Firm Order when accepted by Patheon.

(b) Client will reimburse Patheon for the cost of Components ordered by Patheon under Firm Orders or under Section 5.2(a) that are not included in finished Products manufactured for Client within […***…] after the forecasted […***…] for which the purchases have been made (or for a longer period as the parties may agree) or if the Components have expired or are rendered obsolete due to changes in artwork or applicable regulations during the period (collectively, "**Obsolete Stock**"). This reimbursement will include Patheon's cost to purchase (plus a […***…]% handling fee) and destroy the Obsolete Stock. If any non-expired Components are used in Products subsequently manufactured for Client or in third party products manufactured by Patheon, Client will receive credit for any costs of those Components previously paid to Patheon by Client.

(c) If Client fails to take possession or arrange for the destruction of non-expired Components within […***…] of purchase or, in the case of the delivery of conforming finished Product not accepted by Client within […***…] of manufacture, Client will pay Patheon USD$[…***…] per pallet, per month thereafter for storing the Components or finished Product. Storage fees for Components or Product which contain controlled substances or require refrigeration will be charged at USD$[…***…] per pallet per month. Storage fees are subject to a one pallet minimum charge per month. Patheon may ship finished Product held by it longer than […***…] to Client at Client's expense on […***…] days' written notice to Client.

5.3 **Minimum Orders**.

Client may order Manufacturing Services for batches of Products only in multiples of the Minimum Order Quantities as set out in Schedule B to a Product Agreement.

5.4 **Delivery and Shipping**.

Delivery of Products will be made EXW (Incoterms 2010) packaged ready for export, including such items required to confirm shipment of goods under controlled condition such as temp tales, documentation suitable for export of the supplied product under controlled conditions and other measures required to satisfy EC Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01) and other Regulatory Authority's guidance. Title and risk of loss will pass to Client when Products are delivered to the carrier at the Facility. All Products must be free and clear of any liens and encumbrances. In amplification of the provisions regarding EXW Incoterms® 2010, and not in limitation thereof, Patheon shall directly or indirectly through Client, upon reasonable request of Client and at Client 's cost and risk (and as agent for Client), provide assistance in the following (but the following shall remain obligations of Client) (i) addressing special shipping requirements, (ii) obtaining licenses, official authorizations, clearances, customs, or any other documents and/or Information, including security related Information that Client may require for the export, import or transport of the Products to the final destination; and/or (iii) making a contract for carriage and/or insurance. Patheon shall also assist in loading the packed Products in any container, collecting vehicle or other means of transport at the Facility. Client shall, upon request of Patheon, provide Information required for taxation or reporting purposes in respect of the export of the Products.

5.5 **Invoices and Payment.**

Invoices will be sent by email to the email address given by Client to Patheon. Invoices will be issued when the Product is released by Patheon. Patheon will also submit to Client, with each shipment of Products, a duplicate copy of the invoice covering the shipment. Patheon will also give Client an invoice covering any Inventory or Components which are to be purchased by Client under Section 5.2 of this Agreement. Each invoice will, to the extent applicable, identify Client's Manufacturing Services

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purchase order number, Product numbers, names and quantities, unit price, freight charges, and the total amount to be paid by Client. Client will pay all invoices within […***…] days of the date thereof; provided, however, if Client rejects any portion of a shipment pursuant to Section 6.1, no payment shall be required until resolution of the rejected shipment has been reached. If any portion of an invoice is disputed, Client will pay Patheon for the undisputed amount and the parties will use good faith efforts to reconcile the disputed amount as soon as practicable. Interest on undisputed past due accounts will accrue at […***…]% per month which is equal to an annual rate of […***…]%.

ARTICLE 6

QUALITY MANAGEMENT

6.1 Non-Compliance of Product.

(a) Product Claims. Client has the right to reject any portion of any shipment of Product that was not manufactured in accordance with the Specifications, cGMPs, or Applicable Laws, without invalidating any remainder of the shipment. Client will inspect the Product manufactured by Patheon immediately upon receipt and will give Patheon written notice (a "**Deficiency Notice**") of all claims for Product that was not manufactured in accordance with the Specifications, cGMPs, or Applicable Laws, within […***…] days after Client's receipt thereof (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, such defect to be defined as a "Latent Defect", within […***…] days after discovery by Client, but not after the expiration date of the Product). If Client fails to give Patheon the Deficiency Notice within the applicable […***…] day period, then the delivery will be deemed to have been accepted by Client on the […***…] day after delivery or discovery, as applicable. Patheon will have no liability for any deficiency for which it has not received notice within the applicable […***…] day period.

(b) Determination of Deficiency. Upon receipt of a Deficiency Notice, Patheon will have […***…] days to advise Client by notice in writing if it disagrees with the contents of the Deficiency Notice. If Client and Patheon fail to agree within […***…] days after Patheon's notice to Client as to whether any Product identified in the Deficiency Notice was not manufactured in accordance with the Specifications, cGMPs, or Applicable Laws, the parties will proceed as follows: (i) if the issue is believed to be caused by a raw material deficiency, laboratory error or a suspect analytical method, representatives from both parties will jointly test the Product and/or materials side by side in the same laboratory to determine if a raw material or testing deficiency is the root cause and whether the Product and/or materials is acceptable; or (ii) if the issue is believed to be process related, representatives from both parties will jointly evaluate the Patheon deviation report to determine if any other investigation could identify the root cause and proceed as determined. If, after the joint testing or investigation has been performed, the parties still cannot agree on the root cause, executives from both parties will meet and use good faith efforts to resolve the deficiency and liability issues. If the parties' executives are unable to resolve the dispute within […***…] days, the dispute will be handled as a Technical Dispute under Section 12.2.

(c) Shortages and Price Disputes. Claims for shortages in the amount of Product shipped by Patheon or a Price dispute will be dealt with by reasonable agreement of the parties. Any claim for a shortage or a Price dispute will be deemed waived if it has not been presented within […***…] days of the date of invoice, with the exception of Product subject to a Latent Defect which shall be notified […***…] days from discovery.

(d) Product Rejection for Finished Product Specification Failure. Internal process specifications will be defined and agreed upon and set out in Schedule A of a Product Agreement. If after a full investigation as set forth in Section 6.1(b), it is determined that Patheon manufactured Product in accordance with (i) the agreed upon process specifications, (ii) the batch production record, (iii) Patheon's standard operating procedures for manufacturing (including requirements relating to maintenance and operation of equipment), (iv) cGMPs and (v) Applicable Laws, and, despite the manufacturing being

performed by Patheon in accordance with all of the foregoing, a batch or portion of batch of Product does not meet a finished Product specification, and no root cause is determined for the out of specification result following the full investigation a set forth in Section 6.1(b), Client will pay Patheon the applicable fee per unit for the non-conforming Product if it has not been released for shipment by Patheon. Patheon shall not release for shipment any Product that does not meet a finished Product specification and Client shall not be obliged to pay for any such released Product. The API in the non-conforming Product will be included in the "Quantity Converted" for purposes of calculating the "Actual Annual Yield" under Section 2.3(a).

6.2 Product Recalls and Returns.

(a) Records and Notice. Patheon and Client will each maintain records necessary to permit a Recall of any Product delivered to Client or customers of Client. Each party will promptly notify the other by telephone (to be confirmed in writing) of any information which might affect the marketability, safety or effectiveness of the Product or which might result in the Recall or seizure of the Product. Upon receiving this notice or upon this discovery, each party will stop making any further shipments of any Product in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, will be made and implemented by Client. "**Recall**" will mean any action (i) by Client to recover title to or possession of quantities of the Product sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Product from the market); or (ii) by any regulatory authorities to detain or destroy any of the Product. Recall will also include any action by either party to refrain from selling or shipping quantities of the Product to third parties which would be subject to a Recall if sold or shipped.

(b) Recalls. If (i) any Regulatory Authority issues a directive, order or, following the issuance of a safety warning or alert about a Product, a written request that any Product be Recalled, (ii) a court of competent jurisdiction orders a Recall, or (iii) Client determines that any Product should be Recalled or that a "Dear Doctor" letter is required relating the restrictions on the use of any Product, Patheon will co-operate as reasonably required by Client, having regard to all Applicable Laws and regulations.

(c) Product Returns. Client will have the responsibility for handling customer returns of the Product. Patheon will give Client any assistance that Client may reasonably require to handle the returns.

6.3 Patheon's Responsibility for Defective and Recalled Products.

(a) Defective Product. If Client rejects Product under Section 6.1 and the deficiency is determined to have arisen from Patheon's failure to provide the Manufacturing Services in accordance with the Specifications, cGMPs or Applicable Laws, Patheon will credit Client's account for Patheon's invoice price for the defective Product. If Client previously paid for the defective Product, Patheon will promptly, at Client's election, either: (i) refund the invoice price for the defective Product; (ii) offset the amount paid against other amounts due to Patheon hereunder; or (iii) replace the Product with conforming Product, (if Patheon is able to manufacture the replacement Product at the same Manufacturing Site as that of the rejected Product), without Client being liable for payment therefor under Section 3.1, contingent upon the receipt from Client of all Active Materials and Client-Supplied Components required for the manufacture of the replacement Product. For greater certainty, Patheon's responsibility for any loss of Active Materials in defective Product will be captured and calculated in the Active Materials Yield under Section 2.3.

(b) Recalled Product. If a Recall or return results from, or arises out of, a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs, or Applicable Laws, Patheon will be responsible for the documented out-of-pocket expenses of the Recall or return and will use its commercially reasonable efforts to replace the Recalled or returned Products with new Products, contingent upon the receipt from Client of all Active Materials and Client-Supplied Components required

for the manufacture of the replacement Products. For greater certainty, Patheon's responsibility for any loss of Active Materials in Recalled Product will be captured and calculated in the Active Materials Yield under Section 2.3. If Patheon is unable to replace the Recalled or returned Products (except where this inability results from a failure to receive the required Active Materials and Client-Supplied Components), then Client may request Patheon to reimburse Client for the price that Client paid to Patheon for Manufacturing Services for the affected Products. In all other circumstances, Recalls, returns, or other corrective actions will be made at Client's cost and expense.

(c) Except as set forth in Sections 6.3(a) and (b) above and Sections 6.4,6.5. and 6.6 and 10.1 and 10.2 below, Patheon will not be liable to Client nor have any responsibility to Client for any deficiencies in, or other liabilities associated with, any Product manufactured by it, (collectively, "**Product Claims**"). For greater certainty but not limitation, Patheon will have no obligation for any Product Claims to the extent the Product Claim (i) is caused by deficiencies in the Specifications, the safety, efficacy, or marketability of the Product or any distribution thereof, (ii) results from a defect in a Component that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications prior to use of the applicable Component in the performance of the Manufacturing Services, (iii) results from a defect in the Active Materials, Client-Supplied Components or Components supplied by a Client designated additional source that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications, (iv) is caused by actions of Client or third parties occurring after the Product is shipped by Patheon under Section 5.4, (v) is due to packaging design or labelling defects or omissions for which Patheon has no responsibility, (vi) is due to any unascertainable reason despite Patheon having performed the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws, or (vii) is due to any other breach by Client of its obligations under this Agreement.

(d) Patheon will only be required to replace or refund any batch or portion of a batch of recalled Product and will only be liable for Active Material contained therein to the extent (i) the Product is unsold, returned, destroyed or otherwise disposed of by Client in accordance with the terms of this Agreement or (ii) the Product has been recalled by Client for a Latent Defect (as described in Section 6.1(a)) and such Product has been placed on the market and cannot be recovered and the Latent Defect could not have been detected by Client. The quantity of API contained in this Product will be included in the Quantity Dispensed but not in the Quantity Converted for purposes of calculating the Shortfall in Section 2.3(b).

6.4 **Disposition of Defective or Recalled Products**.

Client will not dispose of any damaged, defective, returned, or Recalled Products for which it intends to assert a claim against Patheon without Patheon's prior written authorization to do so. Alternatively, Patheon may instruct Client to return the Products to Patheon. Patheon will bear the cost of transportation and disposition for any damaged, defective, returned or Recalled Products for which it bears responsibility under Section 6.3. In all other circumstances, Client will bear the cost of disposition, including all applicable fees for Manufacturing Services, for any damaged, defective, returned, or Recalled Products.

6.5 **Healthcare Provider or Patient Questions and Complaints**.

Client will have the sole responsibility for responding to questions and complaints from its customers. Questions or complaints received by Patheon from Client's customers, healthcare providers or patients will be promptly referred to Client. Patheon will co-operate as reasonably required to allow Client to determine the cause of and resolve any questions and complaints. This assistance will include follow-up investigations, including testing. In addition, Patheon will give Client all agreed upon information that will enable Client to respond properly to questions or complaints about the Product as set forth in the Quality Agreement. Unless it is determined that the cause of the complaint resulted from a

failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws, all costs incurred under this Section 6.5 will be borne by Client.

6.6 Sole Remedy.

Except for the indemnity set forth in Section 10.3 and subject to the limitations set forth in Sections 10.1 and 10.2, the remedies described in this Article 6 will be Client's sole remedy in contract, tort, equity or otherwise for any failure by Patheon to provide the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws.

6.7 Quality Agreement.

A Quality Agreement shall be executed within […***…] days following the execution of a Product Schedule. The Client and Patheon's Affiliate shall in good faith negotiate and execute a Quality Agreement concerning the Products and Markets, covering the appropriate activities under this Agreement. Upon execution and delivery of the Quality Agreement by both Client and Patheon's Affiliate, the Quality Agreement shall automatically become part of this Agreement.

6.8 Quality Agreement Terms.

The terms contained in the Quality Agreement are intended to complement the terms of this Agreement, and they shall be interpreted as complementary to the extent possible. In the event of a conflict between the terms of the Quality Agreement and the terms of this Agreement, the terms of this Agreement shall control with respect to business, financial and legal matters, and the terms of the Quality Agreement shall control with respect to quality control and quality assurance matters related to the Product (including, without limitation, manufacturing, testing, storage, release, change management and validation activities); provided, however, that the inclusion of a particular term or level of detail in the Quality Agreement where such term or level of detail is absent from this Agreement shall not be deemed to constitute a conflict between the two agreements. Only where competing terms in the two agreements conflict in terms of the principal focus of an express prescription or prohibition in the agreements shall a conflict between the two agreements be deemed to exist.

6.9 Breach of Quality Agreement

Any breach of the Quality Agreement shall be deemed a breach of this Agreement.

6.10 Specification Changes

(a) Client Requested Changes. Client shall be entitled to change the Specifications for a Product from time to time, and Patheon shall make all revisions to the Specifications requested by Client, in accordance with the change control procedure set forth in the Quality Agreement (the "**Change Control Procedure**"). Client retains the right and responsibility for final approval of the Specifications for the Products. Except to the extent provided in Section 6.10(b) below, Client shall pay Patheon the amounts incurred in implementing a change to the Specifications requested by Client under this Section 6.10(a), as determined in accordance with the Change Control Procedure. Client shall reimburse Patheon for the agreed Price with Client's prior written approval in implementing a change to the Specifications requested by Client under this Section 6.10(a). Patheon agrees to use commercially reasonable efforts to minimize its costs associated with any Specification change. At the request of Client, Patheon shall evaluate the estimated costs and timing of potential revisions to the Specifications.

(b) Patheon Changes. Patheon shall not make any revisions to the Specifications without prior written consent of Client in accordance with the Change Control Procedure. Client retains the right and responsibility for final approval of the Specifications for Products. All requests by Patheon for such revisions shall be submitted in writing to Client. Patheon shall notify Client, in writing and in reasonable

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detail, of (i) Patheon's suggested change; (ii) the reasons for the suggested change; (iii) the perceived benefits of the suggested change to Patheon and Client, respectively; and (iv) the estimated costs and timing of implementing such change. If the Parties implement a change in the Specifications hereunder, they shall negotiate any changes in any affected Firm Order to provide reasonable accommodation for changed circumstances. Responsibility for documenting all revisions to the Specifications, subject to Client's approval, will be identified in accordance with the Change Control Procedure, as applicable.

(c) Payment for Certain Changes. Either Party may request a Specifications change intended to maintain high standards or compliance with Regulatory Acts and Applicable Laws or to bring the Specifications into compliance with high standards or Regulatory Acts and Applicable Laws. Payment for changes required for compliance with Regulatory Acts or Applicable Laws will be made per the following standards:

i. The costs of revisions requested by either Party in order to maintain the Specifications in conformity with that Product's Drug Application, applicable cGMPs, applicable Regulatory Acts, laws or Applicable Laws (including with respect to any of the Materials used in that Product), and not generally applicable to the manufacture of pharmaceutical products or types of dosage forms generally, shall be borne by CLIENT.

ii. The costs of revisions (including any capital expenditure incurred to implement any revision, costs of additional materials and one-time expenditures) requested by either Party to maintain the Specifications in conformity with cGMPs, laws, Regulatory Acts or Applicable Laws that are applicable to the general manufacture of pharmaceutical products or an applicable dosage form shall be discussed and agreed by the Parties.

(d) Changes in Labeling and Packaging. From time to time CLIENT may require labeling or packaging changes that will affect the Product. These changes may either be initiated by CLIENT, pursuant to Section 6.10(a) above, or may be a requirement resulting from cGMPs changes. Payment will be subject to 6.10(a) and (b) above.

ARTICLE 7

CO-OPERATION

7.1 Steering Committee.

The Parties shall establish a steering committee, consisting of at least one business executive and one senior technical executive from both Parties ("Steering Committee"). The Steering Committee will meet at least quarterly, through face-to-face meetings at a mutually convenient location or via telephone conferences and/or videoconferences, at times to be mutually agreed. The Steering Committee will discuss and resolve any overarching questions or issues and discuss future plans and the relationship between the Parties. The Steering Committee shall not have the authority to modify, supplement, amend or terminate this Agreement. If the Steering Committee is unable to resolve any such differences, the matter(s) shall be escalated to the Chief Financial Officer for the client and a Vice President for Patheon (the "**Senior Executives**"). If the Senior Executives are unable to resolve any such differences, the matter shall be handled pursuant to Article 12.0 of this Agreement.

7.2 Relationship Manager and Quarterly Reviews

Upon execution of this Agreement, each party will appoint one of its employees to be a "**Relationship Manager**" responsible for liaison between the parties with respect to the Manufacturing Services covered

under the relevant Product Agreement and the and Technology Transfer and Scale-Up Services under the relevant Technology Transfer Services Agreement (as described in Section 2.2(c)). The Relationship Managers and appropriate quality assurance and technical personnel from both Parties agree to meet no less than quarterly to review the business relationship including but not limited to, supply, demand, process deviations, metrics, change controls, and project status.

7.3 **Governmental Agencies**.

Subject to Section 7.9, each party may communicate with any governmental agency, including but not limited to governmental agencies responsible for granting Regulatory Approval for the Products, regarding the Products if, in the opinion of that party's counsel, the communication is necessary to comply with the terms of this Agreement or the requirements of any law, governmental order or regulation. Unless, in the reasonable opinion of its counsel, there is a legal prohibition against doing so, a party will permit the other party to accompany and take part in any communications with the agency, and to receive copies of all communications from the agency.

7.4 **Records and Accounting by Patheon**.

Patheon will keep records of the manufacture, testing, and shipping of the Products, and retain samples of the Products as are necessary to comply with Applicable Laws, as well as to assist with resolving Product complaints and other similar investigations. Unless otherwise agreed to in the Quality Agreement, copies of the records and samples will be retained for one year following the date of Product expiry, or longer if required by law or regulation, following which time Client will be contacted concerning the delivery and destruction of the documents and/or samples of Products. Patheon reserves the right to destroy or return to Client, at Client's sole expense, any document or samples for which the retention period has expired if Client fails to arrange for destruction or return within […***…] days of receipt of notice from Patheon. Client is responsible for retaining samples of the Products necessary to comply with the legal/regulatory requirements applicable to Client.

7.5 **Inspection**.

Client may inspect Patheon reports and records relating to this Agreement during normal business hours and with reasonable advance notice, but a Patheon representative must be present during the inspection.

7.6 **Access**.

Patheon will give Client reasonable access at agreed times to the areas of the Manufacturing Site in which the Products are manufactured, stored, handled, or shipped to permit Client to verify that the Manufacturing Services are being performed in accordance with the Specifications, cGMPs, and Applicable Laws. But, with the exception of "for-cause" audits, Client will be limited each Year to the following: i) […***…] cGMP-type audit, lasting no more than […***…] days, and involving no more than […***…] auditors; and ii) […***…] physical inventory to inspect and count Active Materials and Client-Supplied Materials. Client may request additional cGMP-type audits, additional audit days, or the participation of additional auditors subject to payment to Patheon of a fee of USD$[…***…] for each additional audit day and USD$[…***…] per audit day for each additional auditor. The right of access set forth in Sections 7.5 and 7.6 will not include a right to access or inspect Patheon's financial records. Patheon will support the first Pre- Approval Inspection ("PAI") of the FDA or equivalent regulatory inspection for other jurisdictions (where applicable) and provide a copy of the resulting report to Client at no cost . Additional PAI or equivalent support will be subject to additional fees.

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7.7 Notification of Regulatory Inspections.

Patheon will notify Client within […***…] of any inspections by any governmental agency specifically involving the Products, and Client will have the right to be present at the Manufacturing Site (but not to participate in the inspection unless requested by the applicable authority) for all such inspections. Patheon will also notify Client of receipt of any form 483s or warning letters or any other significant regulatory action which Patheon's quality assurance group determines could impact the regulatory status of the Products.

7.8 Reports.

Patheon will supply on an annual basis no fewer than […***…] days prior to the date the Annual Report is due by client, the data required to be in the Annual Product Review Report, which includes all Product data in its control, including release test results, complaint test results, and all investigations (in manufacturing, testing, and storage), that Client reasonably requires in order to complete any filing under any applicable regulatory regime, including any Annual Report that Client is required to file with the FDA. Any additional data or report requested by Client beyond the scope of cGMPs and customary FDA requirements, including Continuous Process Verification data, will be subject to an additional fee to be agreed upon between Patheon and Client.

7.9 Regulatory Filings.

(a) Regulatory Authority. Client will have the sole responsibility at Client's expense for filing all documents with all Regulatory Authorities and taking any other actions that may be required for the receipt and/or maintenance of Regulatory Authority approval for the commercial manufacture, distribution and sale of the Products ("**Regulatory Approval**") and will provide copies thereof to Patheon on request. Patheon will assist Client, to the extent consistent with Patheon's obligations under this Agreement, to obtain Regulatory Authority approval for the commercial manufacture, distribution and sale of all Products as quickly as reasonably possible.

(b) Verification of Data. Prior to filing any documents with any Regulatory Authority that incorporate data generated by Patheon, Client will give Patheon a copy of the documents incorporating this data to give Patheon the opportunity to verify the accuracy and regulatory validity of those documents as they relate to Patheon generated data. Patheon generally requires […***…] days to perform this review but the parties (i) may agree to a shorter time for the review as needed or (ii) shall agree to a shorter time for the review if submission to a Regulatory Authority is required prior to the […***…] day period expiration.

(c) Verification of CTD. Prior to filing with any Regulatory Authority any documentation which is or is equivalent to the Quality Module (Drug Product Section) of the Common Technical Document (all such documentation herein referred to as "**CTD**") related to any Marketing Authorization, such as a US New Drug Application, US Abbreviated New Drug Application, US Biologics Licence Application, or EU Marketing Authorisation Application, Client will give Patheon a copy of the CTD as well as all supporting documents which have been relied upon to prepare the CTD. This disclosure will permit Patheon to verify that the CTD accurately describes the validation or scale-up work that Patheon has performed and the manufacturing processes that Patheon will perform under this Agreement. Patheon requires […***…] days to perform this review but the parties may agree to a shorter time for the review as needed. Client will give Patheon copies of all relevant filings at the time of submission which contain CTD information regarding the Product.

(d) Deficiencies. If, in Patheon's sole discretion, acting reasonably, Patheon determines that any of the information given by Client under clauses (b) and (c) above is inaccurate or deficient in any manner whatsoever (the "**Deficiencies**"), Patheon will notify Client in writing of the Deficiencies. The parties will work together to have the Deficiencies resolved prior to the date of filing of the relevant

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application and in any event before any pre-approval inspection or before the Product is placed on the market if a pre-approval inspection is not performed.

(e) Client Responsibility. In reviewing the documents referred to in clause (b) above, Patheon's role will be limited to verifying the accuracy of the description of the work undertaken or to be undertaken by Patheon. Subject to the foregoing, Patheon will not assume any responsibility for the accuracy of any application for receipt of an approval by a Regulatory Authority. Client is solely responsible for the preparation and filing of the application for approval by the Regulatory Authority and any relevant costs will be borne by Client.

(f) Inspection by Regulatory Authorities. If Client does not give Patheon the documents requested under subsections (b) and (c) above within the time specified and if Patheon reasonably believes that Patheon's standing with a Regulatory Authority may be jeopardized, Patheon may, in its sole discretion, delay or postpone any inspection by the Regulatory Authority until Patheon has reviewed the requested documents and is satisfied with their contents.

(g) Pharmacovigilance. Client will be responsible, at its expense, for all pharmacovigilance obligations for the Products pursuant to Applicable Laws. Unless required by Applicable Law, neither party will be obliged to exchange with the other party any information or data which it compiles pursuant to pharmacovigilance obligations or activities.

(h) No Patheon Responsibility. Patheon will not assume any responsibility for the accuracy or cost of any application for Regulatory Approval. If a Regulatory Authority, or other governmental body, requires Patheon to incur fees, costs or activities in relation to the Products which Patheon considers unexpected and extraordinary, then Patheon will notify Client in writing and the parties will discuss in good faith appropriate mutually acceptable actions, including fee/cost sharing, or termination of all or any part of this Agreement. Patheon will be not be obliged to undertake these activities or to pay for the fees or costs if, in Patheon's sole discretion, doing so is commercially inadvisable for Patheon.

ARTICLE 8

TERM AND TERMINATION

8.1 Initial Term.

This Agreement will become effective as of the Effective Date and will continue until December 31, 2021 (the "**Initial Term**"), unless terminated earlier by one of the parties in accordance herewith. This Agreement will automatically renew after the Initial Term for successive terms of two Years each if there is a Product Agreement in effect, unless either party gives written notice to the other party of its intention to terminate this Agreement at least 18 months prior to the end of the then current term. In any event, the legal terms and conditions of this Agreement will continue to govern any Product Agreement in effect as provided in Section 1.2. Each Product Agreement will have an initial term from the Effective Date of the Product Agreement until December 31 of the Year agreed to by the parties in the Product Agreement (each, an "**Initial Product Term**"). Product Agreements will automatically renew after the Initial Product Term for successive terms of two Years each unless either party gives written notice to the other party of its intention to terminate the Product Agreement at least 18 months prior to the end of the then current term.

8.2 Termination for Cause.

(a) Either party at its sole option may terminate this Agreement or a Product Agreement upon written notice where the other party has failed to remedy a material breach of any of its representations, warranties, or other obligations under this Agreement or the Product Agreement within

90 days following receipt of a written notice (the "**Remediation Period**") of the breach from the aggrieved party that expressly states that it is a notice under this Section 8.2(a) (a "**Breach Notice**"). The aggrieved party's right to terminate this Agreement or a Product Agreement under this Section 8.2(a) may only be exercised for a period of 60 days following the expiry of the Remediation Period (where the breach has not been remedied) and if the termination right is not exercised during this period then the aggrieved party will be deemed to have waived the breach of the representation, warranty, or obligation described in the Breach Notice. The termination of a Product Agreement under this Section 8.2(a) will not affect this Agreement or any other Product Agreements where there has been no material breach of the other Product Agreements.

(b) Either party at its sole option may immediately terminate this Agreement or a Product Agreement upon written notice, but without prior advance notice, to the other party if: (i) the other party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by the other party; or (iii) this Agreement or a Product Agreement is assigned by the other party for the benefit of creditors.

(c) Client may terminate a Product Agreement upon 30 days' prior written notice if any Authority takes any action, or raises any objection, that prevents Client from importing, exporting, purchasing, or selling the Product. But if this occurs, Client must still fulfill all of its obligations under Section 8.3 below and under any Capital Equipment Agreement regarding the Product.

(d) Client may terminate a Product Agreement upon six months' prior written notice if it intends to no longer order Manufacturing Services for a Product due to the Product's discontinuance in the market.

(e) Patheon may terminate this Agreement or a Product Agreement upon six months' prior written notice if Client assigns under Section 13.6 any of its rights under this Agreement or a Product Agreement to an assignee that, in the opinion of Patheon acting reasonably, is: (i) not a credit worthy substitute for Client; or (ii) a Patheon Competitor; or (iii) an entity with whom Patheon has had prior unsatisfactory business relations. Client may terminate this Agreement or a Product Agreement upon six months' prior written notice if Patheon assigns under 13.6 any of its rights under this Agreement or a Product Agreement to an assignee that, in the opinion of Client acting reasonably, is: (i) not a credit worthy substitute for Patheon; or (ii) a Client Competitor, or (iii) an entity with whom Client has had prior unsatisfactory business relations.

8.3 **Obligations on Termination**.

(a) If a Product Agreement is completed, expires, or is terminated in whole or in part for any reason, then:

(i) Client will take delivery of and pay for all undelivered Products that are manufactured and/or packaged in accordance with this Agreement under a Firm Order, at the Price in effect at the time the Firm Order was placed;

(ii) Client will purchase, at Patheon's cost (including all costs incurred by Patheon for the purchase, handling, and processing of the Inventory), the Inventory applicable to the Products which was purchased, maintained or produced by Patheon in contemplation of filling Firm Orders or in accordance with Section 5.2;

(iii) Client will satisfy the purchase price payable under Patheon's orders with suppliers of Components, if the orders were made by Patheon in reliance on Firm Orders or in accordance with Section 5.2;

(iv) Client acknowledges that no Patheon Competitor will be permitted access to the Manufacturing Site; and

(v) Client will make commercially reasonable efforts, at its own expense, to remove from Patheon site(s), within […***…] days, all unused Active Material and Client-Supplied Components, all applicable Inventory and Materials (whether current or obsolete), supplies, undelivered Product, chattels, equipment or other moveable property owned by Client, related to the Agreement and located at a Patheon site or that is otherwise under Patheon's care and control ("**Client Property**"). If Client fails to remove Client Property within […***…] days following the completion, termination, or expiration of the Product Agreement, Client will pay Patheon $[…***…] per pallet, per month, one pallet minimum (except that Client will pay $[…***…] per pallet, per month, one pallet minimum, for any of Client Property that contains controlled substances, requires refrigeration or other special storage requirements) thereafter for storing Client Property and will assume any third party storage charges invoiced to Patheon regarding Client Property. Patheon will invoice Client for the storage charges as set forth in Section 5.5 of this Agreement. If Client fails to remove Client Property within […***…] days following the completion, termination, or expiration of the Product Agreement, Client will assume all risk of loss or damage to the stored Client Property and it will be Client's responsibility to have appropriate insurance coverage in place for this risk. If Client asks Patheon to destroy any Client Property, Client will be responsible for the cost of destruction.

(b) Any completion, termination or expiration of this Agreement or a Product Agreement will not affect any outstanding obligations or payments due prior to the completion, termination or expiration, nor will it prejudice any other remedies that the parties may have under this Agreement or a Product Agreement or any related Capital Equipment Agreement. For greater certainty, completion, termination or expiration of this Agreement or of a Product Agreement for any reason will not affect the obligations and responsibilities of the parties under Articles 10 and 11 and Sections 5.4, 5.5, 8.3, 13.1, 13.2, 13.3 and 13.16, all of which survive any completion, termination or expiration.

ARTICLE 9

REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Authority.

Each party covenants, represents, and warrants that it has the full right and authority to enter into this Agreement and that it is not aware of any impediment that would inhibit its ability to perform its obligations hereunder.

9.2 Client Warranties.

Client covenants, represents, and warrants that:

(a) Non-Infringement.

(i) the Specifications for each of the Products are its or its Affiliate's property and that Client may lawfully disclose the Specifications to Patheon;

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(ii) any Client Intellectual Property, used by Patheon in performing the Manufacturing Services according to the Specifications (A) is Client's or its Affiliate's unencumbered property, (B) may be lawfully used as directed by Client, and (C) does not infringe and will not infringe any Third Party Rights;

(iii) the performance of the Manufacturing Services by Patheon for any Product under this Agreement or any Product Agreement or the use or other disposition of any Product by Patheon as may be required to perform its obligations under this Agreement or under any Product Agreement does not and will not infringe any Third Party Rights;

(iv) there are no actions or other legal proceedings involving Client that concerns the infringement of Third Party Rights related to any of the Specifications, or any of the Active Materials and the Components, or the sale, use, or other disposition of any Product made in accordance with the Specifications;

(b) Quality and Compliance.

(i) the Specifications for all Products conform to all applicable cGMPs and Applicable Laws;

(ii) the Products, if labelled and manufactured in accordance with the Specifications and in compliance with applicable cGMPs and Applicable Laws (i) may be lawfully sold and distributed in every jurisdiction in which Client markets the Products, (ii) will be fit for the purpose intended, and (iii) will be safe for human consumption;

(iii) on the date of shipment, the API will conform to the specifications for the API that Client has given to Patheon and that the API will be adequately contained, packaged, and labelled and will conform to the affirmations of fact on the container.

9.3 **Patheon Warranties**.

Patheon covenants, represents, and warrants that:

(a) it will perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws; and

(b) any Patheon Intellectual Property used by Patheon to perform the Manufacturing Services (i) is Patheon's or its Affiliate's unencumbered property, (ii) may be lawfully used by Patheon, and (iii) does not infringe and will not infringe any Third Party Rights.

(c) it will not in the performance of its obligations under this Agreement use the services of any person it knows is debarred or suspended under 21 U.S.C. §335(a) or (b); and

(d) it does not currently have, and it will not hire, as an officer or an employee any person whom it knows has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the United States *Federal Food, Drug, and Cosmetic Act*.

9.4 Permits.

(a) Client will be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals for the Products or the Specifications, including, without limitation, all marketing and post-marketing approvals.

(b) Patheon will maintain at all relevant times all governmental permits, licenses, approval, and authorities required to enable it to lawfully and properly perform the Manufacturing Services.

9.5 No Warranty.

PATHEON MAKES NO WARRANTY OR CONDITION OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT. PATHEON MAKES NO WARRANTY OR CONDITION OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY WARRANTY OR CONDITION OF MERCHANTABILITY FOR THE PRODUCTS.

ARTICLE 10

REMEDIES AND INDEMNITIES

10.1 Consequential and Other Damages.

Under no circumstances whatsoever will either party be liable to the other in contract, tort, negligence, breach of statutory duty, or otherwise for (i) any (direct or indirect) loss of profits, of production, of anticipated savings, of business, or goodwill or (ii) any reliance damages, including but not limited to costs or expenditures incurred to evaluate the viability of entering into this Agreement or to prepare for performance under this Agreement or (iii) for any other liability, damage, costs, penalty, or expense of any kind incurred by the other party of an indirect or consequential nature, regardless of any notice of the possibility of these damages.

10.2 Limitation of Liability.

(a) Defective or Recalled Product. Patheon's maximum aggregate liability to Client for any obligation to refund, or offset any defective Product under Section 6.3(a) will not exceed […***…]% of the Price for the defective or recalled Product as applicable . This Section 10.2(a) will not be subject to Section 10.2(c).

(b) Active Materials. Except as expressly set forth in Section 2.3, under no circumstances will Patheon be responsible for any loss or damage to the Active Materials. Patheon's maximum responsibility for loss or damage to the Active Materials will not exceed the Maximum Credit Value set forth in Schedule D of a Product Agreement. This Section 10.2(b) will not apply to loss or damage to the Active Materials that occurs during storage at the Manufacturing Site, provided such loss is recoverable under Patheon's insurance policy (subject to any deductible amounts applied by the insurer) and not subject to any policy exclusions, and, more specifically, such Active Materials were not lost or damaged due to an error or errors in processing or manufacturing.

(c) Maximum Liability. Except for Patheon's obligations to […***…], Patheon's maximum aggregate liability to Client in any Year under this Agreement or any Product Agreement for any reason whatsoever, including, without limitation, any liability arising under Section 6.3(b) relating to the expenses of a Recall or Product return, Sections 2.3 or 10.3 hereof or resulting from

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any and all breaches of its representations, warranties, or any other obligations under this Agreement or any Product Agreement will not exceed on a per Product basis […***…]% of revenues (being payments of the Price) per Year received by Patheon under the applicable Product Agreement during the Year in which the underlying event occurred that gave rise to the liability (e.g. the date of the incident or manufacture) unless the liability arises out of Patheon's […***…], in which case, Patheon's maximum aggregate liability to Client in any Year under this Agreement or any Product Agreement will not exceed on a per Product basis […***…]% of revenues per Year received by Patheon under the applicable Product Agreement during the Year in which the underlying event occurred that gave rise to the liability.

(d) Death, Personal Injury and Fraudulent Misrepresentation. Nothing contained in this Agreement shall act to exclude or limit either party's liability for personal injury or death caused by the negligence of either party or fraudulent misrepresentation.

10.3 Patheon Indemnity.

(a) Patheon agrees to defend and indemnify Client, its officers and employees, against all losses, damages, costs, claims, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) for any claim of personal injury or property damage to the extent that the injury or damage is the result of a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws except to the extent that the losses, damages, costs, claims, demands, judgments, and liability are due to the negligence or wrongful act(s) of Client, its officers, employees, or Affiliates.

(b) If a claim occurs, Client will: (a) promptly notify Patheon of the claim; (b) use commercially reasonable efforts to mitigate the effects of the claim; (c) reasonably cooperate with Patheon in the defense of the claim; and (d) permit Patheon to control the defense and settlement of the claim, all at Patheon's cost and expense.

10.4 Client Indemnity.

(a) Client agrees to defend and indemnify Patheon, its officers and employees, against all losses, damages, costs, claims, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) for any claim of infringement or alleged infringement of any Third Party Rights in the Products, or any portion thereof, or any claim of personal injury or property damage to the extent that the injury or damage arises other than from (i) a breach of the relevant Product Agreement by Patheon or (ii) the gross negligence or wrongful act(s) of Patheon, including, without limitation, any representation or warranty contained herein, except to the extent that the losses, damages, costs, claims, demands, judgments, and liability are due to the negligence or wrongful act(s) of Patheon, its officers, employees, or Affiliates.

(b) If a claim occurs, Patheon will: (a) promptly notify Client of the claim; (b) use commercially reasonable efforts to mitigate the effects of the claim; (c) reasonably cooperate with Client in the defense of the claim; and (d) permit Client to control the defense and settlement of the claim, all at Client's cost and expense.

10.5 Reasonable Allocation of Risk.

This Agreement (including, without limitation, this Article 10) is reasonable and creates a reasonable allocation of risk for the relative profits the parties each expect to derive from the Products. Patheon assumes only a limited degree of risk arising from the manufacture, distribution, and use of the Products because Client has developed and holds the marketing approval for the Products, Client requires Patheon to manufacture and label the Products strictly in accordance with the Specifications,

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and Client, not Patheon, is best positioned to inform and advise potential users about the circumstances and manner of use of the Products.

ARTICLE 11

CONFIDENTIALITY

11.1 Confidential Information.

"Confidential Information" means any information disclosed by the Disclosing Party to the Recipient (whether disclosed in oral, written, electronic or visual form) that is non-public, confidential or proprietary including, without limitation, information relating to the Disclosing Party's patent and trademark applications, process designs, process models, drawings, plans, designs, data, databases and extracts therefrom, formulae, methods, know-how and other intellectual property, its clients or client confidential information, finances, marketing, products and processes and all price quotations, manufacturing or professional services proposals, information relating to composition, proprietary technology, and all other information relating to manufacturing capabilities and operations. In addition, all analyses, compilations, studies, reports or other documents prepared by any party's Representatives containing the Confidential Information will be considered Confidential Information. Samples or materials provided hereunder as well as any and all information derived from the approved analysis of the samples or materials will also constitute Confidential Information. For the purposes of this ARTICLE 11, a party or its Representative receiving Confidential Information under this Agreement is a "Recipient," and a party or its Representative disclosing Confidential Information under this Agreement is the "Disclosing Party."

11.2 Use of Confidential Information.

The Recipient will use the Confidential Information solely for the purpose of meeting its obligations under this Agreement. The Recipient will keep the Confidential Information strictly confidential and will not disclose the Confidential Information in any manner whatsoever, in whole or in part, other than to those of its Representatives who (i) have a need to know the Confidential Information for the purpose of this Agreement; (ii) have been advised of the confidential nature of the Confidential Information and (iii) have obligations of confidentiality and non-use to the Recipient no less restrictive than those of this Agreement. Recipient will protect the Confidential Information disclosed to it by using reasonable precautions to prevent the unauthorized disclosure, dissemination or use of the Confidential Information, which precautions will in no event be less than those exercised by Recipient with respect to its own confidential or proprietary Confidential Information of a similar nature.

11.3 Exclusions.

The obligations of confidentiality will not apply to the extent that the information:

(a) is or becomes publicly known through no breach of this Agreement or fault of the Recipient or its Representatives;

(b) is in the Recipient's possession at the time of disclosure by the Disclosing Party other than as a result of the Recipient's breach of any legal obligation;

(c) is or becomes known to the Recipient on a non-confidential basis through disclosure by sources, other than the Disclosing Party, having the legal right to disclose the Confidential Information, provided that the other source is not known by the Recipient to be bound by any obligations (contractual, legal, fiduciary, or otherwise) of confidentiality to the Disclosing Party with respect to the Confidential Information;

(d) is independently developed by the Recipient without use of or reference to the Disclosing Party's Confidential Information as evidenced by Recipient's written records; or

(e) is expressly authorized for release by the written authorization of the Disclosing Party.

Any combination of information which comprises part of the Confidential Information are not exempt from the obligations of confidentiality merely because individual parts of that Confidential Information were publicly known, in the Recipient's possession, or received by the Recipient, unless the combination itself was publicly known, in the Recipient's possession, or received by the Recipient.

11.4 Photographs and Recordings.

Neither party will take any photographs or videos of the other party's facilities, equipment or processes, nor use any other audio or visual recording equipment (such as camera phones) while at the other party's facilities, without that party's express written consent.

11.5 Permitted Disclosure.

Notwithstanding any other provision of this Agreement, the Recipient may disclose Confidential Information of the Disclosing Party to the extent required, as advised by counsel, in response to a valid order of a court or other governmental body or as required by law, regulation or stock exchange rule. But the Recipient will advise the Disclosing Party in advance of the disclosure to the extent practicable and permissible by the order, law, regulation or stock exchange rule and any other applicable law, will reasonably cooperate with the Disclosing Party, if required, in seeking an appropriate protective order or other remedy, and will otherwise continue to perform its obligations of confidentiality set out herein. If any public disclosure is required by law, the parties will consult concerning the form of announcement prior to the public disclosure being made.

11.6 Marking.

The Disclosing Party will use reasonable efforts to summarize in writing the content of any oral disclosure or other non-tangible disclosure of Confidential Information within […***…] days of the disclosure, but failure to provide this summary will not affect the nature of the Confidential Information disclosed if the Confidential Information was identified as confidential or proprietary when disclosed orally or in any other non-tangible form.

11.7 Return of Confidential Information.

Upon the written request of the Disclosing Party, the Recipient will promptly return the Confidential Information to the Disclosing Party or, if the Disclosing Party directs, destroy all Confidential Information disclosed in or reduced to tangible form including any copies thereof and any summaries, compilations, analyses or other notes derived from the Confidential Information except for one copy which may be maintained by the Recipient for its records. The retained copy will remain subject to all confidentiality provisions contained in this Agreement.

11.8 Remedies.

The parties acknowledge that monetary damages may not be sufficient to remedy a breach by either party of this Article 11 and agree that the non-breaching party will be entitled to seek in any court of competent jurisdiction (notwithstanding Section 13.17 below) specific performance, injunctive and/or other equitable relief to prevent breaches of this Article 11 and to specifically enforce the provisions hereof in addition to any other remedies available at law or in equity. These remedies will not

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be the exclusive remedies for breach of this Article 11 but will be in addition to any and all other remedies available at law or in equity.

ARTICLE 12

DISPUTE RESOLUTION

12.1 Commercial Disputes.

If any dispute arises out of this Agreement or any Product Agreement (other than a dispute under Section 6.1(b) or a Technical Dispute, as defined herein), the parties will first try to resolve it amicably. In that regard, any party may send a notice of dispute to the other, and each party will appoint, within […***…] Business Days from receipt of the notice of dispute, a single representative having full power and authority to resolve the dispute. The representatives will meet as necessary in order to resolve the dispute. If the representatives fail to resolve the matter within one month from their appointment, or if a party fails to appoint a representative within the […***…] Business Day period set forth above, the dispute will immediately be referred to the […***…] (or another officer as he/she may designate) of each party who will meet and discuss as necessary to try to resolve the dispute amicably. Should the parties fail to reach a resolution under this Section 12.1, the dispute will be referred to a court of competent jurisdiction in accordance with Section 13.17.

12.2 Technical Dispute Resolution.

If a dispute arises (other than disputes under Section 12.1) between the parties that is exclusively related to technical aspects of the manufacturing, packaging, labelling, quality control testing, handling, storage, or other activities under this Agreement (a "**Technical Dispute**"), the parties will make all reasonable efforts to resolve the dispute by amicable negotiations. In that regard, […***…] of each party will, as soon as possible and in any event no later than […***…] Business Days after a written request from either party to the other, meet in good faith to resolve any Technical Dispute. If, despite this meeting, the parties are unable to resolve a Technical Dispute within a reasonable time, and in any event within […***…] Business Days of the written request, the Technical Dispute will, at the request of either party, be referred for determination to an expert in accordance with Exhibit A. If the parties cannot agree that a dispute is a Technical Dispute, Section 12.1 will prevail. For greater certainty, the parties agree that the release of the Products for sale or distribution under the applicable marketing approval for the Products will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including Exhibit A) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.

ARTICLE 13

MISCELLANEOUS

13.1 Inventions.

(a) For the term of this Agreement, Client hereby grants to Patheon a non-exclusive, paid-up, royalty-free, non-transferable license of Client's Intellectual Property which Patheon must use in order to perform the Manufacturing Services.

(b) All Client Intellectual Property will be the exclusive property of Client.

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(c) All Patheon Intellectual Property will be the exclusive property of Patheon. Patheon hereby grants to Client a perpetual, irrevocable, non-exclusive, paid-up, royalty-free, transferable license to use the Patheon Intellectual Property used by Patheon to perform the Manufacturing Services to enable Client to manufacture the Product(s).

(d) Each party will be solely responsible for the costs of filing, prosecution, and maintenance of patents and patent applications on its own Inventions.

(e) Either party will give the other party written notice, as promptly as practicable, of all Inventions which can reasonably be deemed to constitute improvements or other modifications of the Products or processes or technology owned or otherwise controlled by the party.

13.2 Intellectual Property.

Neither party has, nor will it acquire, any interest in any of the other party's Intellectual Property unless otherwise expressly agreed to in writing. Neither party will use any Intellectual Property of the other party, except as specifically authorized by the other party or as required for the performance of its obligations under this Agreement.

13.3 Insurance.

Each party will maintain commercial general liability insurance, including blanket contractual liability insurance covering the obligations of that party under this Agreement through the term of this Agreement and for a period of three years thereafter. This insurance will have policy limits of not less than (i) USD$ […***…] for each occurrence for personal injury or property damage liability; and (ii) USD$ […***…] in the aggregate per annum for product and completed operations liability. If requested each party will give the other a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date, and the limits of liability. The insurance certificate will further provide for a minimum of […***…] days' written notice to the insured of a cancellation of, or material change in, the insurance. If a party is unable to maintain the insurance policies required under this Agreement through no fault of its own, then the party will forthwith notify the other party in writing and the parties will in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

13.4 Independent Contractors.

The parties are independent contractors and this Agreement and any Product Agreement will not be construed to create between Patheon and Client any other relationship such as, by way of example only, that of employer-employee, principal agent, joint-venturer, co-partners, or any similar relationship, the existence of which is expressly denied by the parties.

13.5 No Waiver.

Neither party's failure to require the other party to comply with any provision of this Agreement or any Product Agreement will be deemed a waiver of the provision or any other provision of this Agreement or any Product Agreement, with the exception of Sections 6.1 and 8.2 of this Agreement.

13.6 Assignment and Subcontracting.

(a) Patheon may not assign this Agreement or any Product Agreement or any of its associated rights or obligations without the written consent of Client, this consent not to be unreasonably withheld. But Patheon may arrange for subcontractors to perform specific testing services arising under any Product Agreement with the consent of Client.

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Further it is specifically agreed, subject to the consent requirements of Section 2.1, that Patheon may subcontract any part of the Manufacturing Services under a Product Agreement to the Affiliate specified in the Product Agreement. Patheon will remain solely liable to Client for its obligations under this Agreement, and for the obligations of the applicable Affiliate of Patheon under the Quality Agreement, if the Manufacturing Services are subcontracted.

(b) Subject to Section 8.2(e), Client may assign this Agreement or any Product Agreement or any of its associated rights or obligations without approval from Patheon. But Client will give Patheon prior written notice of any assignment and any assignee will covenant in writing with Patheon to be bound by the terms of this Agreement or the Product Agreement.. Any partial assignment will be subject to Patheon's cost review of the assigned Products and Patheon may terminate this Agreement or any Product Agreement or any assigned part thereof, on […***…] months' prior written notice to Client and the assignee if good faith discussions do not lead to agreement on amended Manufacturing Service fees within a reasonable time. Despite the foregoing provisions of this Section 13.6, either party may assign this Agreement or any Product Agreement to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business, but the assignee must execute an agreement with the non-assigning party whereby it agrees to be bound hereunder.

13.7 Force Majeure.

Neither party will be liable for the failure to perform its obligations under this Agreement or any Product Agreement if the failure is caused by an event beyond that party's reasonable control, including, but not limited to, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, defective equipment, lack of or inability to obtain fuel, power or components, or compliance with any order or regulation of any government entity acting within colour of right (a "**Force Majeure Event**"). A party claiming a right to excused performance under this Section 13.7 will immediately notify the other party in writing of the extent of its inability to perform, which notice will specify the event beyond its reasonable control that prevents the performance. Neither party will be entitled to rely on a Force Majeure Event to relieve it from an obligation to pay money (including any interest for delayed payment) which would otherwise be due and payable under this Agreement or any Product Agreement.

13.8 Additional Product.

Additional Products may be added to, or existing Products deleted from, any Product Agreement by amendments to the Product Agreement including Schedules A, B, C and D as applicable.

13.9 Notices.

Unless otherwise agreed in a Product Agreement, any notice, approval, instruction or other written communication required or permitted hereunder will be sufficient if made or given to the other party by personal delivery or confirmed receipt email or by sending the same by first class mail, postage prepaid to the respective addresses or electronic mail addresses set forth below:

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If to Client:

Neurocrine Biosciences Inc.
12780 El Camino Real
San Diego 92130
California, USA

Attention: Darin Lippoldt, Chief Legal Officer
Email address: […***…]

If to Patheon:

Patheon UK Limited
Kingfisher Drive
Covingham
Swindon
SN3 6BZ
United Kingdom

Attention: Legal Director
Email address: […***…]

or to any other addresses or electronic mail addresses given to the other party in accordance with the terms of this Section 13.9. Notices or written communications made or given by personal delivery, or electronic mail will be deemed to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five days after being deposited in the United States, Canada, or European Union mail, postage prepaid or upon receipt, whichever is sooner.

13.10 **Severability**.

If any provision of this Agreement or any Product Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, that determination will not impair or affect the validity, legality, or enforceability of the remaining provisions, because each provision is separate, severable, and distinct.

13.11 **Entire Agreement**.

This Agreement, together with the applicable Product Agreement and the Quality Agreement, constitutes the full, complete, final and integrated agreement between the parties relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions, or understandings concerning the subject matter hereof. Any modification, amendment, or supplement to this Agreement or any Product Agreement must be in writing and signed by authorized representatives of both parties. In case of conflict, the prevailing order of documents will be this Agreement, the Product Agreement, and the Quality Agreement.

13.12 **Other Terms**.

No terms, provisions or conditions of any purchase order or other business form or written authorization used by Client or Patheon will have any effect on the rights, duties, or obligations of the parties under or otherwise modify this Agreement or any Product Agreement, regardless of any failure of Client or Patheon to object to the terms, provisions, or conditions unless the document specifically refers to this Agreement or the applicable Product Agreement and is signed by both parties.

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13.13 No Third Party Benefit or Right.

For greater certainty, nothing in this Agreement or any Product Agreement will confer or be construed as conferring on any third party any benefit or the right to enforce any express or implied term of this Agreement or any Product Agreement.

13.14 Execution in Counterparts.

This Agreement and any Product Agreement may be executed in two or more counterparts, by original, facsimile or "pdf" signature, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

13.15 Use of Client Name.

Patheon will not make any use of Client's name, trademarks or logo or any variations thereof, alone or with any other word or words, without the prior written consent of Client, which consent will not be unreasonably withheld. Despite this, Client agrees that Patheon may include Client's name and logo in customer lists or related marketing and promotional material for the purpose of identifying users of Patheon's Manufacturing Services.

13.16 Taxes.

(a) Client will bear all taxes, duties, levies and similar charges (and any related interest and penalties) ("**Tax**" or "**Taxes**"), however designated, imposed as a result of the provision by the Patheon of Services under this Agreement, except:

(i) any Tax based on net income or gross income that is imposed on Patheon by its jurisdiction of formation or incorporation ("**Resident Jurisdiction**");

(ii) any Tax based on net income or gross income that is imposed on Patheon by jurisdictions other than its Resident Jurisdiction if this tax is based on a permanent establishment of Patheon; and

(iii) any Tax that is recoverable by Patheon in the ordinary course of business for purchases made by Patheon in the course of providing its Services, such as Value Added Tax (as more fully defined in subparagraph (d) below), Goods & Services Tax ("**GST**") and similar taxes.

(b) If Client is required to bear a tax, duty, levy or similar charge under this Agreement by any state, federal, provincial or foreign government, including, but not limited to, Value Added Tax, Client will pay the tax, duty, levy or similar charge and any additional amounts to the appropriate taxing authority as are necessary to ensure that the net amounts received by Patheon hereunder after all such payments or withholdings equal the amounts to which Patheon is otherwise entitled under this Agreement as if the tax, duty, levy or similar charge did not exist.

(c) Patheon will not collect an otherwise applicable tax if Client's purchase is exempt from Patheon's collection of the tax and a valid tax exemption certificate is furnished by Client to Patheon.

(d) If Section 13.16 (a)(iii) does not apply, any payment due under this Agreement for the provision of Services to Client by Patheon is exclusive of value added taxes, turnover taxes, sales taxes or similar taxes, including any related interest and penalties (hereinafter all referred to as "**VAT**"). If any VAT is payable on a Service supplied by Patheon to Client under this Agreement, this VAT will be added to the invoice amount and will be for the account of (and reimbursable to Patheon by) Client. If VAT on

the supplies of Patheon is payable by Client under a reverse charge procedure (i.e., shifting of liability, accounting or payment requirement to recipient of supplies), Client will ensure that Patheon will not effectively be held liable for this VAT by the relevant taxing authorities or other parties. Where applicable, Patheon will use its reasonable commercial efforts to ensure that its invoices to Client are issued in such a way that these invoices meet the requirements for deduction of input VAT by Client, if Client is permitted by law to do so.

(e) Any Tax that Client pays, or is required to pay, but which Client believes should properly be paid by Patheon pursuant hereto may not be offset against sums due by Client to Patheon whether due pursuant to this Agreement or otherwise.

13.17 Governing Law.

This Agreement and any Product Agreement, unless otherwise agreed by the parties in the Product Agreement and then only for purposes of that Product Agreement, will be construed and enforced in accordance with the laws of England and subject to the exclusive jurisdiction of the courts thereof. The UN Convention on Contracts for the International Sale of Goods will not apply to this Agreement.

[Signature page to follow]

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Agreement as of the Effective Date.

PATHEON UK LIMITED

By: /s/ Andrew Robinson
Name: Andrew Robinson
Title: Director

Date: 12/22/2016

NEUROCRINE BIOSCIENCES INC.

By: /s/ Darin Lippoldt
Name: Darin Lippoldt
Title: Chief Legal Officer

Date: _____

APPENDIX 1

FORM OF PRODUCT AGREEMENT

(Includes Schedules A to D)

PRODUCT AGREEMENT

This Product Agreement (this "**Product Agreement**") is issued under the Master Manufacturing Services Agreement dated 28 November 2016 between Patheon UK Limited and Neurocrine Biosciences Inc. (the "**Master Agreement**"), and is entered into [ ] , 2016 (the "**Effective Date**"), between Patheon UK Limited, a corporation existing under the laws of England **[or applicable founding jurisdiction for Patheon Affiliate]**, having a principal place of business at Kingfisher Drive, Covingham, Swindon, SN3 5BZ, England ("**Patheon**") and Neurocrine Biosciences Inc, 12780 El Camino Real, San Diego 92130, California, USA ("**Client**").

The terms and conditions of the Master Agreement are incorporated herein except to the extent this Product Agreement expressly references the specific provision in the Master Agreement to be modified by this Product Agreement. All capitalized terms that are used but not defined in this Product Agreement will have the respective meanings given to them in the Master Agreement.

The Schedules to this Product Agreement are incorporated into and will be construed in accordance with the terms of this Product Agreement.

1. **Product List and Specifications** (See Schedule A attached hereto)
2. **Minimum Order Quantity, Annual Volume, and Price** (See Schedule B attached hereto)
3. **Annual Stability Testing and Validation Activities (if applicable)** (See Schedule C attached hereto)
4. **Active Materials, Active Materials Credit Value, and Maximum Credit Value** (See Schedule D attached hereto)
5. **Yearly Forecasted Volume:** (insert for sterile products if applicable under Section 4.2.1 of the Master Agreement)
6. **Territory**: (insert the description of the Territory here)
7. **Manufacturing Site**: (insert address of Patheon Manufacturing Site where the Manufacturing Services will be performed)
8. **Inflation Index:** pursuant to Section 4.2(a) of the Master Agreement, the inflation index is [actual index to be set out in the Product Agreement][for France, "Indices de salaires mensuels de base des salaries de l'industrie pharmaceutique", published by Les Entreprises du médicament (LEEM) (for illustration: http://www.leem.org/article/les-indices-des-salaires-de-lindustrie-pharmaceutique)].

9. **Initial Product Term:** (per Section 8.1 of the Master Agreement) from the Effective Date until December 31, 20

10. **Notices**: (if applicable under Section 13.9 of the Master Agreement)

11. **Other Modifications to the Master Agreement**: (if applicable under Section 1.2 of the Master Agreement)

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Product Agreement as of the Effective Date set forth above.

PATHEON UK LIMITED

By: _____
Name: _____
Title: _____

Date: _____

NEUROCRINE BIOSCIENCES INC.

By: _____
Name: _____
Title: _____

Date: _____

SCHEDULE A

PRODUCT LIST AND SPECIFICATIONS

Product List

[*Details to be set out in the applicable Product Agreement*]

Specifications

Prior to the start of commercial manufacturing of Product under this Agreement Client will give Patheon the originally executed copies of the Specifications as approved by the applicable Regulatory Authority. If the Specifications received are subsequently amended, then Client will give Patheon the revised and originally executed copies of the revised Specifications. Upon acceptance of the revised Specifications, Patheon will give Client a signed and dated receipt indicating Patheon's acceptance of the revised Specifications.

SCHEDULE B

MINIMUM ORDER QUANTITY, ANNUAL VOLUME, AND PRICE

[Insert Price Table]

Manufacturing Assumptions:

Packaging Assumptions:

Testing Assumptions:

[…*…]**

*** Confidential Treatment Requested for pages 43-44.

Omitted pages have been filed separately with the Commission.

SCHEDULE C

ANNUAL STABILITY TESTING [and VALIDATION ACTIVITIES (if applicable)]

Patheon and Client will agree in writing on any stability testing to be performed by Patheon on the Products. This agreement will specify the commercial and Product stability protocols applicable to the stability testing and the fees payable by Client for this testing including the Price for the Product withdrawn for the stability testing.

[NTD: Schedule C should clearly indicate when and/or under what conditions Patheon's responsibility to perform stability testing will end]

SCHEDULE D

ACTIVE MATERIALS

Active Materials	Supplier
[*Details to be set out in the applicable Product Agreement*]	• [*Details to be set out in the applicable Product Agreement*]

ACTIVE MATERIALS CREDIT VALUE

The Active Materials Credit Value will be as follows:

PRODUCT	ACTIVE MATERIALS	ACTIVE MATERIALS CREDIT VALUE
[*Details to be set out in the applicable Product Agreement*]	[*Details to be set out in the applicable Product Agreement*]	Client's actual cost for Active Materials not to exceed USD$ [*Details to be set out in the applicable Product Agreement*] per kilogram

MAXIMUM CREDIT VALUE

Patheon's liability for Active Materials calculated in accordance with Section 2.3 of the Master Agreement **[for any Product]** in a Year will not exceed, in the aggregate, the maximum credit value set forth below:

PRODUCT	MAXIMUM CREDIT VALUE
[*Details to be set out in the applicable Product Agreement*]	[…***…]% of revenues (being payments of the Price) per Year received by Patheon under this Product Agreement.

[End of Product Agreement]

EXHIBIT A

TECHNICAL DISPUTE RESOLUTION

Technical Disputes which cannot be resolved by negotiation as provided in Section 12.2 will be resolved in the following manner:

1. **Appointment of Expert**. Within […***…] Business Days after a party requests under Section 12.2 that an expert be appointed to resolve a Technical Dispute, the parties will jointly appoint a mutually acceptable expert with experience and expertise in the subject matter of the dispute. If the parties are unable to so agree within the […***…] Business Day period, or if there is a disclosure of a conflict by an expert under Paragraph 2 hereof which results in the parties not confirming the appointment of the expert, then an expert (willing to act in that capacity hereunder) will be appointed by an experienced arbitrator on the roster of the American Arbitration Association.

2. **Conflicts of Interest**. Any person appointed as an expert will be entitled to act and continue to act as an expert even if at the time of his appointment or at any time before he gives his determination, he has or may have some interest or duty which conflicts or may conflict with his appointment if before accepting the appointment (or as soon as practicable after he becomes aware of the conflict or potential conflict) he fully discloses the interest or duty and the parties will, after the disclosure, have confirmed his appointment.

3. **Not Arbitrator**. No expert will be deemed to be an arbitrator and the provisions of the American Arbitration Act or of any other applicable statute (foreign or domestic) and the law relating to arbitration will not apply to the expert or the expert's determination or the procedure by which the expert reaches his determination under this Exhibit A.

4. **Procedure**. Where an expert is appointed:

(a) Timing. The expert will be so appointed on condition that (i) he promptly fixes a reasonable time and place for receiving representations, submissions or information from the parties and that he issues the authorizations to the parties and any relevant third party for the proper conduct of his determination and any hearing and (ii) he renders his decision (with full reasons) within […***…] Business Days (or another date as the parties and the expert may agree) after receipt of all information requested by him under Paragraph 4(b) hereof.

(b) Disclosure of Evidence. The parties undertake one to the other to give to any expert all the evidence and information within their respective possession or control as the expert may reasonably consider necessary for determining the matter before him which they will disclose promptly and in any event within […***…] Business Days of a written request from the relevant expert to do so.

(c) Advisors. Each party may appoint any counsel, consultants and advisors as it feels appropriate to assist the expert in his determination and so as to present their respective cases so that at all times the parties will co-operate and seek to narrow and limit the issues to be determined.

(d) Appointment of New Expert. If within the time specified in Paragraph 4(a) above the expert will not have rendered a decision in accordance with his appointment, a new expert may (at the request of either party) be appointed and the appointment of the existing expert will thereupon cease for the purposes of determining the matter at issue between the parties except if the existing expert renders his decision with full reasons

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prior to the appointment of the new expert, then this decision will have effect and the proposed appointment of the new expert will be withdrawn.

(e) Final and Binding. The determination of the expert will, except for fraud or manifest error, be final and binding upon the parties.

(f) Costs. Each party will bear its own costs for any matter referred to an expert hereunder and, in the absence of express provision in the Agreement to the contrary, the costs and expenses of the expert will be shared equally by the parties.

For greater certainty, the release of the Products for sale or distribution under the applicable marketing approval for the Products will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including this Exhibit A) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.

EXHIBIT B

QUARTERLY ACTIVE MATERIALS AND CLIENT SUPPLIED COMPONENTS INVENTORY REPORT

TO: **NEUROCRINE BIOSCIENCES, INC.**
FROM: PATHEON UK LIMITED [or applicable Patheon Affiliate]

RE: Active Materials/Client-Supplied Components quarterly inventory report under Section 2.3(a) of the Master Manufacturing Services Agreement dated ● (the "**Agreement**")

Reporting quarter:	_____		
Active Materials			
Active Materials on hand at beginning of quarter:	_____	kg	(A)
Active Materials on hand at end of quarter:	_____	kg	(B)
Quantity Received during quarter:	_____	kg	(C)
Quantity Dispensed[1] during quarter: (A + C – B)	_____	kg	
Quantity Converted during quarter: (total Active Materials in Products produced and not rejected, recalled or returned or in work-in-process)	_____	kg	
Client-Supplied Components			
Client-Supplied Components on hand at beginning of quarter:	_____	kg	(A)
Client-Supplied Components on hand at end of quarter:	_____	kg	(B)
Quantity Received during quarter:	_____	kg	(C)
Quantity Dispensed[2] during quarter:	_____	kg	

1 Excludes any (i) Active Materials that must be retained by Patheon as samples, (ii) Active Materials contained in Product that must be retained as samples, (iii) Active Materials used in testing (if applicable), and (iv) Active Materials received or consumed in technical transfer activities or development activities, including, without limitation, any regulatory, stability, validation, or test batches manufactured during the quarter.

2 Excludes any (i) Client-Supplied Components that must be retained by Patheon as samples, (ii) Client-Supplied Components contained in Product that must be retained as samples, (iii) Client-Supplied Components used in testing (if applicable), and (iv) Client-Supplied Components received or consumed in technical transfer activities or development activities, including, without limitation, any regulatory, stability, validation, or test batches manufactured during the quarter.

(A + C – B)

Quantity Converted during quarter: _____ kg
(total Client-Supplied Components in Products produced
and not rejected, recalled or returned or in work-in-process)

Capitalized terms used in this report have the meanings given to the terms in the Agreement.

PATHEON UK LIMITED
[or applicable Patheon Affiliate]

DATE: _____

Per: _____
Name:
Title:

EXHIBIT C

REPORT OF ANNUAL ACTIVE MATERIALS INVENTORY RECONCILIATION AND CALCULATION OF ACTUAL ANNUAL YIELD

TO: **NEUROCRINE BIOSCIENCES, INC.**
FROM: PATHEON UK LIMITED [or applicable Patheon Affiliate]

RE: Active Materials annual inventory reconciliation report and calculation of Actual Annual Yield under Section 2.3(a) of the Master Manufacturing Services Agreement dated ● (the "**Agreement**")

Reporting Year ending:	_____	
Active Materials on hand at beginning of Year:	_____ kg	(A)
Active Materials on hand at end of Year:	_____ kg	(B)
Quantity Received during Year:	_____ kg	(C)
Quantity Dispensed[3] during Year: (A + C - B)	_____ kg	(D)
Quantity Converted during Year: (total Active Materials in Products produced and not rejected, recalled or returned or in work-in-process)	_____ kg	(E)
Active Materials Credit Value:	EUR _____ / kg	(F)
Target Yield:	_____ %	(G)
Actual Annual Yield: ((E / D) * 100)	_____ %	(H)

[3] Excludes any (i) Active Materials that must be retained by Patheon as samples, (ii) Active Materials contained in Product that must be retained as samples, (iii) Active Materials used in testing (if applicable), and (iv) Active Materials received or consumed in technical transfer activities or development activities, including, without limitation, any regulatory, stability, validation, or test batches manufactured during the Year.

Shortfall Credit: ((G – 5) - H) / 100) * F * D	EUR _____ (if a negative number, insert zero)	(I)

Based on the foregoing reimbursement calculation Patheon will reimburse Client the amount of EUR _____.

Surplus Credit: (H – G / 100) * F * D	EUR _____	(J)

Based on the foregoing reimbursement calculation Patheon may carry forward one Year a Surplus Credit in the amount of EUR _____.

Capitalized terms used in this report have the meanings given to the terms in the Agreement.

DATE: _____

PATHEON UK LIMITED
[or applicable Patheon Affiliate]

Per: _____

_____

Name:
Title:

EXHIBIT D

TECHNOLOGY TRANSFER AND SCALE-UP SERVICES

[…***…]

*** Confidential Treatment Requested for pages 53-91.

Omitted pages have been filed separately with the Commission.

*****Text Omitted and Filed Separately with the Securities and Exchange Commission. Confidential Treatment Requested Under 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2.**

PRODUCT AGREEMENT

(INGREZZA™ (valbenazine))

This Product Agreement (this "**Product Agreement**") is issued under the Master Manufacturing Services Agreement dated 28 November 2016 between Patheon UK Limited and Neurocrine Biosciences Inc. (the "**Master Agreement**"), and is entered into 28 November 2016 (the "**Effective Date**"), between Patheon UK Limited, a corporation existing under the laws of England, having a principal place of business at Kingfisher Drive, Covingham, Swindon, SN3 5BZ, England ("**Patheon**") and Neurocrine Biosciences Inc, 12780 El Camino Real, San Diego 92130, California, USA ("**Client**").

The terms and conditions of the Master Agreement are incorporated herein except to the extent this Product Agreement expressly references the specific provision in the Master Agreement to be modified by this Product Agreement. All capitalized terms that are used but not defined in this Product Agreement will have the respective meanings given to them in the Master Agreement.

The Schedules to this Product Agreement are incorporated into and will be construed in accordance with the terms of this Product Agreement.

1. **Product List and Specifications** (See Schedule A attached hereto)
2. **Minimum Order Quantity, Annual Volume, and Price** (See Schedule B attached hereto)
3. **Annual Stability Testing and Validation Activities (if applicable)** (See Schedule C attached hereto)
4. **Active Materials, Active Materials Credit Value, and Maximum Credit Value** (See Schedule D attached hereto)
5. **Yearly Forecasted Volume:**

   […***…]
6. **Minimum Annual Revenue**. as set out under Section 4.2.2 of the Master Agreement, Client shall be obliged to order and purchase an annual binding minimum amount of Product equal to USD$[…***…] (based on small scale commercial manufacturing) or USD$[…***…] (based on full scale commercial manufacturing) as applicable. If in any Year the amount of Product purchased by Client is less than USD$[…***…] or USD$[…***…] as applicable (i.e. payments of the Price received by Patheon) ("Actual Annual Purchase Amount") then Client shall pay Patheon the shortfall between USD$[…***…] or USD$[…***…] as applicable and the Actual Annual Purchase Amount. Patheon shall be entitled to invoice Client for any shortfall following 31 December of each Year.
7. **Territory**: USA
8. **Manufacturing Site**: the facility owned and operated by […***…].

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9. **Inflation Index:** pursuant to Section 4.2(a) of the Master Agreement, the inflation index is for France, "Indices de salaires mensuels de base des salaries de l'industrie pharmaceutique", published by Les Entreprises du médicament (LEEM) (for illustration: http://www.leem.org/article/les-indices-des-salaires-de-lindustrie-pharmaceutique) .

10. **Initial Product Term:** from the Effective Date until December 31, 2021.

11. **Notices**: as set out under Section 13.9 of the Master Agreement

12. **Other Modifications to the Master Agreement**: Not applicable

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Product Agreement as of the Effective Date set forth above.

PATHEON UK LIMITED

By: /s/ Andrew Robinson
Name: Andrew Robinson
Title: Finance Director

Date: 22 December 2016

NEUROCRINE BIOSCIENCES INC.

By: /s/ Tim Coughlin
Name: Tim Coughlin
Title: CFO

Date: 12/22/16

SCHEDULE A

PRODUCT LIST AND SPECIFICATIONS

Product List

[…***…]

*** Confidential Treatment Requested

SCHEDULE B

MINIMUM ORDER QUANTITY, ANNUAL VOLUME, AND PRICE

[…***…]

*** Confidential Treatment Requested for pages 4-7.

Omitted pages have been filed separately with the Commission.

SCHEDULE C

ANNUAL STABILITY TESTING

[…***…]

*** Confidential Treatment Requested for pages 8-9.

Omitted pages have been filed separately with the Commission.

SCHEDULE D

ACTIVE MATERIALS

[…***…]

*** Confidential Treatment Requested

Exhibit 99.3

*****Text Omitted and Filed Separately with the Securities and Exchange Commission. Confidential Treatment Requested Under 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2.**

COMMERCIAL PACKAGING AGREEMENT

This Commercial Packaging Agreement ("**Agreement**") is made as of this 12th day of December, 2016 ("**Effective Date**"), by and among Neurocrine Biosciences Inc., a corporation organized under the laws of Delaware, with offices at 12780 El Camino Real, San Diego, California, 92130, USA ("Client") and AndersonBrecon Inc., an Illinois corporation, doing business as PCI of Illinois , with a place of business at 4545 Assembly Drive, Rockford, IL 61109 ("**PCI**").

RECITALS

A. Client is a pharmaceutical company that develops, markets and sells pharmaceutical products;

B. PCI specializes in packaging for the pharmaceutical industry and has certain technical and commercial information and know-how relating to, among other things, performing packaging and labeling of pharmaceutical and other products, into various sized primary and secondary containers; and

C. Client desires to engage PCI to provide certain commercial packaging services to Client, and PCI desires to provide such services, all pursuant to the terms and conditions set forth in this Agreement.

THEREFORE, in consideration of the mutual covenants, terms and conditions set forth below, the parties agree as follows:

ARTICLE 1
DEFINITIONS

The following terms have the following meanings in this Agreement:

1.1 "**Affiliate(s)**" means, with respect to PCI, Client or any third party, any corporation, firm, partnership or other entity that controls, is controlled by or is under common control with such entity. For the purposes of this definition, "**control**" shall mean the ownership of at least 50% of the voting share capital of an entity or any other comparable equity or ownership interest.

1.2 "**Applicable Laws**" means (i) all laws, ordinances, rules and regulations, as amended from time to time, of the United States applicable to the Packaging or any aspect thereof and the obligations of PCI or Client, as the context requires, under this Agreement, including cGMP, and (ii) to the extent mutually agreed upon the parties in writing, any applicable laws, rules and regulations of one or more foreign jurisdictions relating directly to PCI's obligations under this Agreement.

1.3 "**Authorization to Package**" means a document, signed by a Client representative or designee and provided to PCI prior to the commencement of Packaging of such product, indicating the Bulk Product has been authorized to be Packaged.

1.4 "**Authorization to Transfer**" means a document, signed by a Client representative or designee and provided to PCI, authorizing PCI to transfer the Packaged Product from the Facility.

1.5 "**Batch**" means a defined quantity of Bulk Product that has been or is being Packaged in accordance with the Specifications.

1.6 "**Bulk Product**" means bulk and work in process product of Client to be Packaged that is specified in Attachment A.

1.7 "**Business Day**" means any day other than a Saturday, Sunday or a national holiday in the United States.

1.8 "**Certificate of Analysis**" means a certificate indicating the Bulk Product's conformance to the applicable Specifications, signed by a Client representative or designee and provided to PCI prior to the commencement of Packaging of such Bulk Product.

1.9 "**Certificate of Conformance**" means, with respect to a Client-supplied Material other than Bulk Product, a certificate indicating such Client-supplied Material's conformance with all required testing and other applicable Specifications, signed by a representative of the supplier of such material and provided to PCI prior to the commencement of Packaging using such material.

1.10 "**Certificate of Release**" means a certificate indicating that the Packaging conforms with the Specifications, signed by a PCI representative and provided to Client following the completion of Packaging in accordance with the Quality Agreement.

1.11 "**cGMP**" means all applicable laws, regulations and standards of the United States of America relating to the Packaging including but not limited to, the FDA current Good Manufacturing Practices, as set forth in the Title 21 of the United States Code of Federal Regulations as such regulations and guidelines may be revised from time to time and equivalent non-U.S. regulations solely to the extent such non-U.S. jurisdictions are otherwise included in the definition of "Applicable Laws."

1.12 "**Client**" has the meaning set forth in the introductory paragraph, or any successor or permitted assign.

1.13 "**Client Indemnitees**" has the meaning set forth in Section 13.1.

1.14 "**Client Intellectual Property**" means all Intellectual Property and embodiments thereof owned by or licensed to Client as of the date hereof or after by Client.

1.15 "**Client Material Loss**" has the meaning set forth in Section 3.1(h).

1.16 "**Client-supplied Materials**" means any materials to be supplied by or on behalf of Client to PCI for Packaging, as provided in Attachment A, including Bulk Product, artwork and labeling.

1.17 "**Confidential Information**" has the meaning set forth in Section 10.2.

1.18 "**Contract Year**" means each consecutive twelve (12) month period beginning on the Effective Date or anniversary thereof, as applicable.

1.19 "**Defective Packaging**" has the meaning set forth in Section 5.1.

1.20 **"Delivery Date"** has the meaning set forth in Section 4.2(b).

1.21 "**Effective Date**" has the meaning set forth in the introductory paragraph.

1.22 "**Exception Notice**" has the meaning set forth in Section 5.1.

1.23 **"Excess Loss"** has the meaning set forth in Section 3.1(i).

1.24 "**Facility**" means PCI's facility located in Rockford, Illinois, or such other facility as agreed by the parties.

1.25 **"FDA"** means the United States Food and Drug Administration or any successor Regulatory Authority having substantially the same function.

1.26 **"FD&C Act"** means the U.S. Federal Food, Drug and Cosmetic Act, as amended or supplemented from time to time.

1.27 "**Firm Commitment**" has the meaning set forth in Section 4.1.

1.28 "**Intellectual Property**" means all intellectual property (whether or not patented), including without limitation, brands, patents, patent applications, formulae, know-how, trade secrets, copyrights, trademarks, trademark applications, trade names, trade dress, trade secrets, industrial designs, designs, concepts, technical information, manuals, standard operating procedures, instructions, specifications, inventions, processes, data, improvements and developments.

1.29 "**Loss Allowance**" has the meaning set forth in Section 3.1(g).

1.30 "**Losses**" has the meaning set forth in Section 13.1.

1.31 "**Package**" or "**Packaging**" or "**Packaged**" means the packaging of Bulk Product and labeling the packages which contain the Bulk Product in accordance with the Specifications.

1.32 "**Packaged Product**" means the finished Packaging produced by PCI under this Agreement.

1.33 "**PCI**" has the meaning set forth in the introductory paragraph, or any successor or permitted assign.

1.34 "**PCI Fault**" has the meaning set forth in Section 5.2.

1.35 "**PCI Indemnitees**" has the meaning set forth in Section 13.2.

1.36 "**PCI Intellectual Property**" means all Intellectual Property and embodiments thereof owned by or licensed to PCI as of the date hereof or after by PCI.

1.37 "**Pick-Up Date**" shall have the meaning set forth in Section 6.1.

1.38 "**Pricing**" has the meaning set forth in Section 7.1(a).

1.39 "**Purchase Order**" has the meaning set forth in Section 4.2(a).

1.40 "**Quality Agreement**" has the meaning set forth in Section 9.8.

1.41 "**Raw Materials**" means all raw materials, supplies, components and packaging, as provided in Attachment A, but excluding Client-supplied Materials, necessary to Package and ship Packaged Product according to the Specifications.

1.42 "**Recall**" has the meaning set forth in Section 9.6.

1.43 "**Regulatory Approval**" means any approvals, permits, product and/or establishment licenses, registrations or authorizations, including approvals pursuant to U.S. Investigational New Drug applications, New Drug Applications and Abbreviated New Drug Applications (or equivalent non-U.S. filings, such as European marketing authorization applications), as applicable, of any Regulatory Authorities that are necessary or advisable in connection with the development, manufacture, testing, use, storage, exportation, importation, transport, promotion, marketing, distribution or sale of Packaged Product.

1.44 "**Regulatory Authority**" means any federal, state or local governmental or regulatory bodies, agencies, departments, bureaus, courts or other entities in the United States (including the FDA) responsible for (A) the regulation (including pricing) of any aspect of pharmaceutical or medicinal products intended for human use or (B) health, safety or environmental matters generally, and any equivalent non-U.S. governmental or regulatory bodies solely to the extent such non-U.S. jurisdictions are otherwise included in the definition of "Applicable Laws."

1.45 "**Review Period**" has the meaning set forth in Section 5.1.

1.46 "**Rolling Forecast**" has the meaning set forth in Section 4.1.

1.47 "**Specifications**" means the procedures, requirements, standards, quality control testing and other data and the scope of services as set forth in Attachment A, along with any valid amendments or modifications thereto, in accordance with Article 8.

1.48 "**Supplier**" has the meaning set forth in Section 3.3(a).

1.49 "**Term**" has the meaning set forth in Section 16.1.

ARTICLE 2
PROCESSING & RELATED SERVICES

2.1 Supply and Purchase of Packaging. PCI shall Package Bulk Product in accordance with the Specifications, Applicable Laws and the terms and conditions of this Agreement and the Quality Agreement for the consideration provided herein. Client shall be responsible for the manufacturing and testing of Bulk Products at the manufacturer. As agreed in

writing by the Parties, including as required by the Specifications and the Quality Agreement, PCI shall be responsible for incoming testing of Bulk Products and testing of Packaged Products. Client shall be responsible for the transportation, sale and distribution of the Packaged Product.

2.2 Other Related Services. PCI shall provide such related services (including tooling purchases and repair; analytical work; stability; auditing of Suppliers; and retain storage) other than Packaging, as agreed to in writing by the parties from time to time. Such writing shall include the scope and fees for any such services and be appended to this Agreement. The terms and conditions of this Agreement shall govern and apply to such services.

ARTICLE 3
MATERIALS

3.1 Client-Supplied Materials.

(a) Supply. Client or a Supplier on Client's behalf shall supply to PCI for Packaging, at Client's sole cost and risk, Client-supplied Materials, including Bulk Product, in quantities sufficient to meet Client's requirements for Packaging, as set forth in Article 4. Client shall deliver or cause to be delivered such items, together with associated Certificates of Analysis, Certificates of Conformance, lot numbers, expiration dates and Authorizations to Package to the Facility no later than […***…] days before, but not earlier than […***…] days before, the Delivery Date for the Packaged Product in which such items will be used by PCI. If PCI fails to receive the foregoing on a timely basis, PCI shall have the right to delay delivery of the related Packaged Product within the Firm Commitment and store such items, at Client's expense. The preceding supply schedule for Client-supplied Materials may be adjusted upon mutual agreement of the parties if Client is launching a new product. PCI shall use such items solely and exclusively for Packaging hereunder. Prior to first delivery of any such items, Client shall provide to PCI a copy of all associated material safety data sheets, safe handling instructions and health and environmental information, and shall promptly provide any updates, or revisions thereto.

(b) Conformity. Within […***…] days of receipt of Client-supplied Materials by PCI, PCI shall confirm that the labels on such items conform to their accompanying packing slip. Unless otherwise expressly required by the Specifications, PCI shall have no obligation to test such items to confirm that they meet the associated Specifications, Certificate of Analysis or Certificate of Conformance or otherwise; but in the event that PCI detects a nonconformity with Specifications, PCI shall give Client prompt notice of such nonconformity. PCI shall not be liable for any defects in Client-supplied Materials, or in Packaging or Packaged Product as a result of defective Client-supplied Materials, unless PCI failed to properly perform the foregoing obligations. PCI shall follow Client's reasonable written instructions in respect of return or disposal of defective Client-supplied Materials, at Client's sole cost and risk.

(c) Customs. Client shall be solely responsible for the proper release and clearance of Client-supplied Materials to be provided by Client or a Supplier for U.S. and foreign customs purposes, including any return thereof required by any Regulatory Authority following improper or unauthorized release, and Client acknowledges that it is the owner of such items for customs purposes. Client shall reimburse PCI for any and all costs, charges and expenses incurred by PCI in connection with customs clearance and release of any such Client-supplied

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Materials. Notwithstanding anything to the contrary herein, if any delay in customs clearance or release of any Client-supplied Materials occurs such that PCI cannot supply the quantity of Packaged Product to Client by the Delivery Dates specified in accepted Purchase Orders, then PCI shall not be obligated to supply Packaged Product to Client hereunder until full and proper customs clearance or release is obtained by Client.

(d) Title and Risk of Loss for Client-supplied Materials. Title and risk of loss to Client-supplied Materials shall remain with Client while such items are in the possession of PCI and for the duration of the services for each relevant Product. PCI's liability for any loss to such Client-supplied Materials shall be solely as set forth in Section 3.1(h). Client shall obtain and maintain insurance for Client-supplied Materials in accordance with Section 15.1.

(e) Artwork and Packaging. Client shall provide or approve, prior to the procurement of applicable components, all artwork, advertising and packaging information necessary for Packaging. Such artwork, advertising and packaging information is and shall remain the exclusive property of Client, and Client shall be solely responsible for the content thereof. Such artwork, advertising and packaging information or any reproduction thereof may not be used by PCI in any manner other than performing its obligations hereunder. PCI requires no less than […***…] calendar days' notice of changes in artwork, advertising and packaging information; provided, however, that PCI will work with Client in good faith to expedite copy changes on a quicker basis. If Client provides PCI with less notice of changes in artwork, advertising and packaging information, PCI shall not be responsible for any delay in the delivery of Packaged Products to which such changes apply.

(f) Expired Client-Supplied Materials. Client will be required to dispose of any Client-supplied Materials that have expired within […***…] calendar days of such expiration. PCI will manage destruction of such expired Client-supplied Materials if requested by Client and will invoice Client for the costs thereof. Notwithstanding anything to the contrary herein, PCI reserves the right to refuse to accept deliveries of new Client-supplied Materials pursuant to Section 3.1(a) until Client or its authorized agent has removed, or has authorized PCI to dispose of, all expired Client-supplied Material in PCI's possession.

(g) Loss Allowance. For each type of Packaged Product, the parties will mutually agree by […***…] on […***…] allowance for the […***…] for Bulk Product and other Client-supplied Materials that are not converted to Packaged Product ("**Loss Allowance**"). The initial Loss Allowance for each product shall be established after the first […***…] packaging lots following the validation campaign, instructed by data from such packaging lots. If the parties do not agree, PCI will propose a commercially reasonable Loss Allowance. If Client does not agree with such proposal, the Loss Allowance will be determined in accordance with the provisions of Section 18.10 below. The Loss Allowance shall be adjusted in the event of any changes to the Specifications, including without limitation any changes to the Bulk Product.

(h) Liability for Loss. PCI's liability to Client for any loss or damage, other than as a result of PCI's willful misconduct, to Client-supplied Materials is limited to: (i) process scrap arising from the Packaging operations, (ii) Client-supplied Materials that are not reasonably recoverable from Defective Packaging attributable to PCI Fault or (iii) Client-supplied Materials lost or damaged due to PCI's negligence or gross negligence in its handling or

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storing the Client-supplied Materials (collectively, "**Client Material Loss**"), but only to the extent that such Client Material Loss exceeds the Loss Allowance. When calculating the amount of Client Material Loss, the following shall not be counted as issued to the line for Packaging: (i) Client-supplied Materials used for samples and testing, (ii) Packaged Product that must be retained by PCI as samples, pursuant to this Agreement, the Quality Agreement or Applicable Laws, and (iii) Client-supplied Materials that are non-conforming to Specifications. Notwithstanding any other provision of this Agreement, PCI shall be liable to Client for all loss or damage to Client-supplied materials that results from PCI's willful misconduct.

(i) Annual Reconciliation of Excess Loss; Reimbursement. Within […***…] days following the end of each Contract Year, PCI will perform a reconciliation for each type of Packaged Product for the prior Contract Year and will calculate for applicable Client-supplied Materials (i) the Client Material Loss and (ii) the amount, if any, by which the Client Material Loss exceeds the Loss Allowance (such excess referred to as the "**Excess Loss**"). PCI will reimburse Client for Excess Loss, if any, at Client's cost to produce or acquire the Client-supplied Materials subject to the limitation set forth in Section 14.1. For purposes of this Section 3.1(i), "cost" shall mean (i) for Client-supplied Materials produced by Client or its Affiliate, material, fully-burdened labor and overhead costs to manufacture the Client-supplied Materials and (ii) for Client-supplied Materials purchased from unaffiliated third parties, the actual out of pocket costs paid to the third parties related to the acquisition of the Client-supplied Materials.

3.2 Raw Materials.

(a) Procurement. PCI shall be responsible for procuring, inspecting and releasing adequate Raw Materials as necessary to meet the Firm Commitment, unless otherwise agreed to by the parties in writing. PCI shall rely on the Firm Commitment for purchasing Raw Materials for use in the Packaged Products forecasted. To the extent practicable, PCI will procure Raw Materials on a quarterly basis based on projected quarterly requirements in an effort to reduce costs of such components and materials. Notwithstanding anything to the contrary herein, if the lead time necessary to acquire Raw Materials is greater than […***…] days, PCI shall submit orders for such Raw Materials based on the Rolling Forecast in a timely manner, and Client shall be liable for such costs incurred by PCI in the event that Client fails to purchase sufficient quantities of Packaged Products as provided in the Rolling Forecast on which PCI relied. In the event that the quantity of Packaged Products in any Rolling Forecast provided by Client pursuant to Article 4 decreases or increases significantly from one Rolling Forecast to the next, PCI reserves the right (i) to purchase the Raw Materials required for such Packaged Products on a periodic basis as needed to meet such fluctuating requirements and (ii) in accordance with Section 7.2, to adjust the Pricing for such Packaged Products to reflect the costs of such fluctuating purchases.

(b) Title and Risk of Loss for Raw Materials. Title and risk of loss with respect to the Raw Materials used for the Packaged Products will remain with PCI until PCI delivers Packaged Products to a common carrier for shipment to Client.

(c) Reimbursement for Raw Materials. In the event of (i) a Specification change for any reason, (ii) obsolescence of any Raw Material or (iii) further to Article 16, termination or expiration of this Agreement, Client shall bear the cost of any unused Raw Materials plus […***…]%, so long as PCI purchased such Raw Materials in quantities consistent with

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Client's most recent Firm Commitment, the Supplier's minimum purchase obligations and Section 3.2(a). Payment will be due within […***…] days of Client's receipt of PCI's invoice.

(d) Storage. […***…] days after receipt at PCI, Raw Materials or Client-supplied Materials, including Bulk Product, held in inventory will be subject to the storage and carrying costs as set forth on Attachment B, but only if no purchase orders have been submitted for Packaged Product to be delivered in the following month sufficient to utilize the Raw Materials or Client-supplied Materials. In the event that the storage and carrying costs are not included on Attachment B, such charge shall be $[…***…] per month per pallet.

3.3 Mandated Supplier.

(a) Use of Supplier. In certain instances, Client may require a specific supplier, manufacturer or vendor ("**Supplier**") to be used for Raw Materials or to furnish Client-supplied Materials. In such an event, (i) such Supplier will be identified in the Specifications or otherwise in writing, (ii) Client shall be responsible for the timeliness, quantity and quality of supply of Raw Materials or Client-supplied Materials from such Supplier, (iii) PCI shall not be liable for any defects in Raw Materials or Client-supplied Materials from such Supplier, or in Packaging or Packaged Product as a result of such defective Raw Materials or Client-supplied Materials, unless PCI failed to properly perform any testing required by the Specifications, and (iv) Raw Materials from such Supplier shall be deemed, for all purposes hereunder including required supply schedule and liability, Client-supplied Materials. If a Supplier fails to deliver the appropriate quantity and quality of Raw Materials or Client-supplied Materials on the required supply schedule and PCI is unable to resolve the issue with Supplier, PCI shall so notify Client of such supply issue and Client shall, to the extent practicable, have a discussion with the Supplier in an effort to resolve such failure. Client shall have no obligation to continue such discussion with the Supplier following the initial discussion or after such offer of an initial discussion, if the Supplier refuses such discussion. If a Supplier refuses such discussion or fails to supply PCI with Raw Materials or Client-supplied Materials such that PCI cannot supply Packaged Product to Client, then, to the extent of such failure, PCI shall not be obligated to supply Packaged Product to Client hereunder until such failure to supply is remedied, either with the Supplier or with an alternate supplier.

(b) Costs. If the cost of the Raw Material from any such Supplier is greater than PCI's costs for the same raw material of equal quality from other suppliers, PCI shall add the difference between PCI's cost of the Raw Material and the Supplier's cost of the Raw Material to the Pricing. Client will be responsible for all costs associated with qualification of any such Supplier that has not been previously qualified (as described in Section 3.3(c)) by PCI.

(c) Qualification. Client acknowledges and agrees that any Supplier mandated by Client (i) must meet PCI's requirements for credit approval and (ii) prior to the delivery of any Raw Materials or Client-supplied Materials by such Supplier to the Facility, must pass either (A) the quality audit conducted by PCI or, (B) if Client acknowledges in writing to PCI no later than […***…] days after selection of the Supplier that Client shall be solely responsible for conducting all quality audits of such Supplier, the quality audit conducted by Client. Notwithstanding anything to the contrary herein, Client further acknowledges and agrees that PCI shall not be required to utilize or contract with any Supplier that fails to meet the foregoing credit and audit requirements.

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ARTICLE 4
PURCHASE ORDERS & FORECASTS

4.1 Forecast. On or before the […***…] day of each […***…], beginning at least […***…] days prior to the first expected delivery of a Packaged Product, Client shall furnish to PCI a written […***…]-month rolling forecast of the quantities of Bulk Product that Client intends to have PCI Package during such period ("**Rolling Forecast**"). The Rolling Forecast shall be submitted in […***…] buckets and in Excel spreadsheet format and shall include […***…] quantity requirements by Client Packaged Product SKU and the proposed delivery date(s). The first […***…] of such Rolling Forecast shall constitute a binding order for the quantities of Product specified therein ("**Firm Commitment**") and the following […***…] of the Rolling Forecast shall be non-binding, good faith estimates. Notwithstanding anything to the contrary herein, if the lead time necessary to schedule production is greater than […***…] days, PCI shall schedule production based on the Rolling Forecast in a timely manner. In the event PCI believes it may not be able to meet the requirements of any Rolling Forecast, it shall notify Client within […***…] days of receipt of such Rolling Forecast, and the parties shall agree in good faith appropriate modifications to the Rolling Forecast.

4.2 Purchase Orders.

(a) From time to time as provided in this Section 4.2(a), Client shall submit to PCI a binding, non-cancelable purchase order for Packaging specifying the number of Batches, in whole Batch increments, to be Packaged, the Batch size (to the extent the Specifications permit Batches of different sizes), the proposed delivery date(s) for each Batch, and the lot numbers to be applied to such Batches ("**Purchase Order**"). Concurrently with the submission of each Rolling Forecast, Client shall submit a Purchase Order for the portion of the Firm Commitment which is not already subject to Purchase Order. Purchase Orders for Packaging quantities of Bulk Product in excess of the Firm Commitment shall be submitted by Client at least […***…] days in advance of the delivery date(s) requested in the Purchase Order.

(b) Provided that a Purchase Order is consistent with the Firm Commitment and other terms and conditions of this Agreement, within […***…] days following receipt of a Purchase Order, PCI may issue a written acknowledgement to Client that it accepts such Purchase Order with the proposed delivery date(s) or reasonable alternative delivery date(s), in which event the parties shall promptly reach mutual agreement on acceptable delivery date(s). The term "**Delivery Date(s)**" refers to the firm date(s), as agreed upon by the parties pursuant to this Section 4.2(b), upon which PCI must deliver to Client or authorized agent of Client the Packaged Products.

(c) PCI reserves the right to reject the portion of any Purchase Orders in excess of […***…]% of the Firm Commitment or otherwise not given in accordance with this Agreement.

(d) Notwithstanding Section 4.2(c), PCI shall use commercially reasonable efforts to Package Bulk Product in excess of the quantities specified in the Firm Commitment, subject to PCI's other supply commitments and packaging and equipment capacity; *provided*,

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that PCI's failure to Package Bulk Product quantities in excess of […***…]% of the quantities specified in the Firm Commitment shall not constitute a breach of this Agreement by PCI. Within […***…] days of receipt of a Purchase Order for quantities of Packaged Product in excess of the applicable Rolling Forecast, PCI will notify Client of PCI's capacity to supply such excess quantity.

(e) Notwithstanding any amounts due to PCI under Section 7.1, if Client fails to place Purchase Orders sufficient to satisfy the Firm Commitment, Client shall, within […***…] days of receipt of invoice, pay to PCI the Pricing for all Bulk Product that would have been Packaged if Client had placed Purchase Orders sufficient to satisfy the Firm Commitment.

4.3 PCI's Cancellation of Purchase Orders. Notwithstanding Section 4.4, PCI reserves the right to cancel all, or any part of, a Purchase Order upon […***…] days' written notice to Client, and PCI shall have no further obligations or liability with respect to such Purchase Order, if Client refuses or fails to timely supply conforming Client-supplied Materials in accordance with Section 3.1, including artwork or related information and such failure by Client to supply such Client-supplied Materials is the primary reason PCI is unable to fulfill all or part of such Purchase Order. Any such cancellation of Purchase Orders shall not constitute a breach of this Agreement by PCI nor shall it absolve Client of its obligation in respect of the Firm Commitment.

4.4 Client's Modification or Cancellation of Purchase Orders. Client may modify the Delivery Date or quantity of Bulk Product to be packaged in a Purchase Order only by submitting a written change order to PCI at least […***…] days in advance of the original Delivery Date covered by such change order. Such change order shall be effective and binding against PCI only upon the written approval of PCI, and notwithstanding the foregoing, Client shall remain responsible for the Firm Commitment. In no event shall PCI be required to incur any costs or suffer any losses in connection with such change order or its efforts to accommodate such a change. Any such costs or losses incurred by PCI shall be paid for by Client.

4.5 Unplanned Delay or Elimination of Packaging. PCI shall use commercially reasonable efforts to meet the Purchase Orders, subject to the terms and conditions of this Agreement. PCI shall provide Client with as much advance notice as possible (and will use commercially reasonable efforts to provide at least […***…] days' advance notice where possible) if PCI determines that any Packaging will be delayed or cancelled for any reason.

4.6 Observation of Packaging. In addition to Client's audit right pursuant to Section 9.5, Client may send a reasonable number of representatives to the Facility to observe Packaging, upon reasonable advance written request to PCI. Such representatives shall abide by all PCI safety rules and other applicable employee policies and procedures, and Client shall be responsible for such compliance and must have the appropriate insurance in place to cover such responsibilities. Client shall indemnify and hold harmless PCI for any Losses resulting from an action, omission or other activity of such representatives while on PCI's premises. PCI reserves the right to require such representatives to enter into separate confidentiality agreements directly with PCI in such persons' individual capacities on terms substantially similar to those set forth in Article 10.

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ARTICLE 5
TESTING; SAMPLES; RELEASE

5.1 Releasing; Rejection. PCI shall provide Client or its designee with a completed Batch Record according to Section 9.1. Upon review and acceptance of such batch record including resolution of any deviations, PCI will then provide Client with a Certificate of Release for each Batch consistent with the requirements in the Quality Agreement. Client shall notify PCI in writing that it agrees with this release according to terms of the Quality Agreement. Client is subsequently responsible for final release of Packaged Product to the market. Unless within […***…] days after Client's physical receipt of a Batch, including batch records ("**Review Period**"), Client or its designee notifies PCI in writing (an "**Exception Notice**") that the Packaging of such Batch does not meet the warranty set forth in Section 12.1 ("**Defective Packaging**"), and provides a sample of the alleged Defective Packaging, the Packaging shall be deemed accepted by Client and Client shall have no right to reject such Batch. Such acceptance will not apply in the case of any Defective Packaging not reasonably susceptible to discovery upon receipt of the Packaged Product, such defect to be defined as a "Latent Defect". Client will use commercially reasonable efforts to report Latent Defects as soon as possible but in any event not later than […***…] days after discovery by Client, but not after the expiration date of the Product.

5.2 Upon timely receipt of an Exception Notice from Client, PCI shall conduct an appropriate investigation in its discretion to determine whether or not it agrees with Client that the Packaging is Defective Packaging and to determine the cause of any nonconformity. If PCI agrees that Packaging is Defective Packaging and determines that the cause of nonconformity is attributable solely to PCI's negligence, willful misconduct, or failure to meet the warranty set forth in Section 12.1 ("**PCI Fault**"), then Section 5.4 shall apply. For avoidance of doubt, where the cause of nonconformity cannot be determined or assigned as above, it shall not be deemed PCI Fault.

5.3 Discrepant Results. In the event of a disagreement between the parties regarding whether Packaging is Defective Packaging and/or whether the cause of the nonconformity is PCI Fault, which disagreement cannot be resolved by the parties within […***…] days of the date of the completion of PCI's investigation, the parties shall cause a mutually agreeable independent third party to review records, test data and to perform comparative tests and/or analyses on samples of the alleged Defective Packaging and its components, including Client-supplied Materials. The independent party's determination as to whether or not Packaging is Defective Packaging and the cause of any nonconformity shall be final and binding. Unless otherwise agreed to by the parties in writing, the costs associated with such testing and review shall be borne by PCI if Packaging is Defective Packaging attributable to PCI Fault, and by Client in all other circumstances.

5.4 Defective Packaging. PCI will, at the sole option of Client after good faith consultation with PCI, either re-Package at its cost any Batch of Defective Packaging attributable to PCI Fault (and Client shall be liable to pay for either the rejected Batch(es) or the replacement Batch(es), but not both), or credit any payments made by Client for such Batch. THE FOREGOING OBLIGATION OF PCI TO RE-PACKAGE (REGARDLESS OF COST) OR CREDIT PAYMENTS MADE BY CLIENT AND REIMBURSE FOR CLIENT MATERIALS IN THE EVENT OF EXCESS LOSS UNDER SECTION 3.1(i) SHALL BE CLIENT'S SOLE AND EXCLUSIVE REMEDY UNDER THIS AGREEMENT FOR DEFECTIVE PACKAGING AND IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED.

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5.5 Supply of Material for Defective Packaging. In the event PCI re-Packages pursuant to Section 5.4, Client shall supply PCI with sufficient quantities of Client-supplied Materials in order for PCI to complete such re-Packaging and any Client-supplied Materials in the Defective Packaging that are destroyed or that cannot be re-packaged shall be included in the Excess Loss calculations under Section 3.1(i). Any such re-packaging shall be done on an expedited basis including to the extent that PCI determines in good faith to be necessary to provide on an expedited basis, use of overtime, such overtime costs to be the responsibility of PCI.

ARTICLE 6
DELIVERY

6.1 Delivery. PCI shall deliver Packaged Product Ex Works (Incoterms 2010) the Facility promptly following PCI's receipt of the Authorization to Transfer, which shall be provided by Client no more than […***…] days after PCI's issuance of a Certificate of Release, *provided*, that Client's failure to provide the Authorization to Transfer in such timeframe shall be deemed as authorizing PCI to tender the Packaged Product for delivery. Notwithstanding the prior sentence, the parties agree that PCI shall be responsible for the loading of the Packaged Product on the carrier's trucks and shall bear the costs of such loading. Client shall qualify at least […***…] to deliver Packaged Product. Client will schedule carrier for Packaged Product pick-up no later than […***…] days after Client's release of the Packaged Product according to terms in the Quality Agreement ("**Pick-Up Date**"). If the Packaged Product is to be exported out of the United States, Client shall be solely responsible for obtaining all required export or import licenses available to the Packaged Product prior to such export or import and shall reimburse PCI for any and all costs, charges, expenses and import and export duties for delivery and transportation of Packaged Product from the Facility. PCI should not be listed as the exporter (U.S. Principle Party in Interest) on any documentation relating to the export.

6.2 Failure to Take Delivery; Storage. Upon written agreement of the parties, or if Client fails to take delivery of any Packaged Product according to Section 6.1 , PCI shall store such Packaged Product according to Specifications and cGMP requirements as Client's agent. If Client or its authorized agent fails to take delivery within […***…] calendar days of the Delivery Date, Client shall be billed $[…***…] per pallet of unshipped Packaged Product at such time and thereafter on the […***…] day of each month until Client or its authorized agent releases and takes delivery of such Packaged Product. For each such Batch of stored Packaged Product, Client agrees that: (A) Client has made a fixed commitment to purchase the Packaging of such Packaged Product, (B) Client has title and risk of loss for such Packaged Product, (C) such Packaging for Packaged Product shall be on a bill and hold basis for legitimate business purposes, and (D) if no rescheduled Delivery Date is determined at the time of billing, PCI shall have the right to ship such Packaged Product to Client within […***…] after billing. Within […***…] Business Days following a written request from PCI, Client shall provide PCI with a letter confirming items (A) through (D) of this Section 6.2 for each Batch of stored Packaged Product.

ARTICLE 7
PAYMENTS

7.1 Fees. In consideration for PCI performing services hereunder:

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(a) Client shall pay PCI the pricing for Packaging set forth on Attachment B ("**Pricing**"). Such fees shall be paid within […***…] days following date of invoice, which invoice shall be submitted to Client by PCI upon delivery of Packaged Product as provided in Section 6.1 or the entry of the Packaged Products into storage as provided in Section 6.2.

(b) Other Fees. Client shall pay PCI for all other fees and expenses of PCI owing in accordance with the terms of this Agreement, including pursuant to Sections 2.2, 6.2 and 16.3. Such fees and expenses shall be paid within […***…] days following date of invoice, which invoice shall be submitted to Client by PCI as and when appropriate.

7.2 Pricing Adjustment. The Pricing shall be adjusted following advance written notice from PCI to Client and shall be effective on […***…] of each year of the Term as follows: (i) labor costs shall be subject to annual increase to reflect any increase in the Producer Price Index, commodity code 06-38 for Pharmaceutical Preparations, issued by the Bureau of Labor Statistics, United States Department of Labor over the prior calendar year (based on the publication by the U.S. Department of Labor of the PPI on or about October 15th of the prior calendar year); (ii) cost in Raw Materials shall be subject to annual increase to reflect any increase in PCI's costs over the prior calendar year, including any increases imposed by a Supplier; and (iii) production costs shall be subject to annual increase to reflect any reduction in purchase volume level below anticipated purchase volume over the prior calendar year. In addition, the parties acknowledge and agree that the Pricing is based on PCI performing order runs of consistent size and frequency and that the Pricing shall be subject to review and adjustment promptly following the occurrence of any unanticipated fluctuation in order run sizes or frequency or fluctuations in forecasted quantities as described in Sections 4.1 and 4.2. For example, such adjustment may include an increase in the Pricing due to reduced order run sizes. In addition, the parties shall negotiate in good faith changes to the Pricing resulting from changes to Applicable Laws that are reasonably likely to materially increase the cost of providing the services.

7.3 Payment Terms. Client shall make payment in U.S. dollars, and otherwise as directed in the applicable invoice. In the event payment is not received by PCI on or before the due date, then PCI may, in addition to any other remedies available at equity or in law, at its option, elect to do any one or more of the following: (A) charge interest on the outstanding sum from the due date (both before and after any judgment) at […***…]%) per month until paid in full (or, if less, the maximum amount permitted by Applicable Laws); (B) suspend any further performance hereunder until such invoice is paid in full; and/or (C) terminate this Agreement pursuant to Section 16.2(b).

7.4 Taxes. PCI shall bear and pay all federal, state and local taxes based upon or measured by its net income, and all franchise taxes based upon its corporation existence, or its general corporate right to transact business. Any other tax, however denominated and measured, imposed upon the Products, the Packaged Products or Packaging or upon their storage, inventory, sales, transportation, delivery, use or consumption shall be paid directly by Client, or if prepaid by PCI, shall be invoiced to Client, at cost, as a separate item and paid by Client to PCI.

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ARTICLE 8
CHANGES TO SPECIFICATIONS

All Specifications and any changes thereto agreed to by the parties from time to time shall be in writing, dated and signed by the parties. Any change to the Packaging process shall be deemed a Specification change. No change in the Specifications shall be implemented by PCI, whether requested by Client, requested by PCI or requested or required by any Regulatory Authority, until the parties have agreed in writing to such change, the implementation date of such change, and any increase or decrease in costs, expenses or fees associated with such change (including any change to Pricing). PCI shall respond promptly to any request made by Client for a change in the Specifications, and both parties shall use commercially reasonable, good faith efforts to agree to the terms of such change in a timely manner. As soon as possible after a request is made for any change in Specifications, PCI shall notify Client of the costs associated with such change and shall provide such supporting documentation as Client may reasonably require. Client shall pay all costs associated with such agreed upon changes. If there is a conflict between the terms of this Agreement and the terms of the Specifications, this Agreement shall control. PCI reserves the right to postpone effecting changes to the Specifications, or in the case of changes requested or required by any Regulatory Authority postpone Packaging under this Agreement, until such time as the parties agree to and execute the required written amendment.

ARTICLE 9
RECORDS; REGULATORY MATTERS

9.1 Batch Records and Data. Within […***…] days following the completion of Packaging of each Batch, PCI shall provide Client with properly completed copies of Batch records prepared in accordance with the Specifications; except in the event an unplanned deviation in the Packaging process occurs, PCI promptly notify Client according to terms in the Quality Agreement. PCI shall then provide such Batch records within […***…] days following resolution of the unplanned deviation. The "Review Period" begins upon receipt of the batch records.

9.2 Recordkeeping. PCI shall maintain materially complete and accurate books, records, reports and all other information relating to Packaging, including all information required to be maintained by Applicable Laws, in accordance with PCI standard operating procedures. Such information shall be maintained for a period of at least […***…] from the relevant Packaged Product expiration date or longer if required under Applicable Laws.

9.3 Regulatory Compliance. Client shall be solely responsible for and will obtain all Regulatory Approvals associated specifically with the Packaged Products, including any applications and amendments in connection therewith. Client shall use its best efforts to expedite and obtain all Regulatory Approvals necessary for PCI to commence Packaging at the Facility. PCI will be responsible to maintain all permits and licenses required by any Regulatory Authority with respect to the Facility generally.

9.4 Governmental Inspections and Requests. PCI shall promptly, but not later than […***…], advise Client if an authorized agent of any Regulatory Authority visits the Facility concerning the Packaging. PCI shall allow up to two Client representatives to be present at any scheduled regulatory inspection directly affecting the Packaged Product. PCI shall

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furnish to Client a copy of the relevant portions of any report by such Regulatory Authority within […***…] days of PCI's receipt of such report. Further, upon receipt of a Regulatory Authority request to inspect the Facility or audit PCI's books and records with respect to Packaging, PCI shall promptly notify Client, and shall provide Client with a copy of the relevant portions of any written document received from such Regulatory Authority.

9.5 Client Inspections and Audits.

(a) During the Term, up to […***…] duly-authorized employees, agents and representatives of Client shall be granted access for a maximum of up to […***…] days (unless otherwise agreed to by PCI in writing) upon reasonable prior written notice and at reasonable times during regular business hours to (i) the portion of the Facility where PCI performs Packaging, (ii) relevant personnel involved in Packaging and (iii) Packaging records described in Section 9.2, in each case solely for the purpose of inspecting and verifying that PCI is Packaging in accordance with cGMPs and the Specifications.

(b) Client will arrange audit visits with PCI Quality Management at least […***…] days in advance of such visit. Inspections shall be designed to minimize disruption of operations at the Facility. Client may not conduct an inspection under this Section 9.5 more than […***…] during any […***…] period; *provided*, that additional inspections may be conducted upon reasonable advance written notice in the event there is a material quality or compliance issue concerning Packaging. PCI will allow such an additional inspection within […***…] of the discovery of any material quality or compliance issue subject to the terms of the Quality Agreement.

(c) During the Term, up to […***…] duly-authorized employees, agents and representatives of Client shall be granted access for a maximum of up to […***…] days (unless otherwise agreed to by PCI in writing) upon reasonable prior written notice and at reasonable times during regular business hours solely for the purpose of conducting an audit of Packaged Product, Client-supplied Materials, or other inventory of Client that is required to be audited for the purpose of preparing Client's financial statements.

(d) Employees, agents and representatives of Client performing an audit or inspection shall abide by all PCI safety rules and other applicable employee policies and procedures, and Client shall be responsible for such compliance and must have the appropriate insurance in place to cover such responsibilities. Client shall indemnify and hold harmless PCI for Losses resulting from any action, omission or other activity of such representatives while on PCI's premises. PCI reserves the right to require such representatives to enter into separate confidentiality agreements directly with PCI in such persons' individual capacities on terms substantially similar to those set forth in Article 10.

9.6 Recall. If a Regulatory Authority orders or requires the recall of any Packaged Product supplied hereunder or if Client or PCI believes a recall, field alert, Packaged Product withdrawal or field correction ("**Recall**") may be necessary with respect to any Packaged Product supplied under this Agreement, the party receiving the notice from the Regulatory Authority or that holds such belief shall promptly notify the other party in writing. With respect to any Recall, PCI shall provide all necessary cooperation and assistance to Client. Client shall provide PCI with an advance copy, when possible, of any proposed submission to a Regulatory

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Authority in respect of any Recall, and shall consider in good faith any comments from PCI. Client is responsible for initiating a recall or Field letter. The cost of any Recall shall be borne by Client, and Client shall reimburse PCI for expenses incurred in connection with any Recall, in each case unless such Recall is caused solely by PCI's gross negligence, willful misconduct, or breach of this Agreement, in which case PCI's liability for such Recall costs and expenses is limited to a maximum of the lesser of (i) $[…***…] or (ii) the Pricing charged for the recalled Packaged Product, plus reimbursement for any Product that cannot be recovered from such recalled Packaged Product in accordance with the limitation set forth in Section 3.1(i). For purposes of clarification, Recall costs and expenses shall include, without limitation, notification to customers, Product retrieval, Product destruction, shipping and taxes. In the event that a Product is Recalled or Client is required to disseminate information relating to Packaged Product covered by this Agreement, Client shall so notify PCI within a reasonable time so as to enable PCI to provide Client with such assistance in connection with such Recall as may reasonably be requested by Client. PCI will comply with all such reasonable requests from Client. Client shall handle exclusively the organization and implementation of all Recalls of Products and Packaged Products. Any such Recall shall be implemented and administered in a manner which is appropriate and reasonable under the circumstances and in conformity with any requests or orders of the applicable Regulatory Authority, as well as to the extent not inconsistent with requests or orders of the applicable Regulatory Authority, accepted trade practices.

9.7 Duty to Inform. Client shall inform PCI promptly of any important information relating to the activity, side effects, toxicity and/or safety of the Products or Packaged Products that becomes known to Client during the term of this Agreement and that is relevant to the performance of the services by PCI.

9.8 Quality Agreement. Prior to the first Packaging hereunder, the parties shall negotiate in good faith and enter into a Quality Agreement substantially in the form attached hereto as Attachment C (the "**Quality Agreement**"). The Quality Agreement shall in no way determine liability or financial responsibility of the parties for the responsibilities set forth therein. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to quality-related activities, including compliance with cGMP, the provisions of the Quality Agreement shall govern. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to any commercial matters, including allocation of risk, liability and financial responsibility, the provisions of this Agreement shall govern.

ARTICLE 10
CONFIDENTIALITY AND NON-USE

10.1 Mutual Obligation. PCI and Client each agrees that it will not use the other party's Confidential Information except in connection with the performance of its obligations hereunder and will not disclose the other party's Confidential Information to any third party without the prior written consent of the other party, except as required by law, regulation or court or administrative order; *provided*, that prior to making any such legally required disclosure, the party making such disclosure shall give the other party as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances. Notwithstanding the foregoing, each party may disclose the other party's Confidential Information to any of its Affiliates that (A) need to know such Confidential Information for the purpose of performing

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under this Agreement, (B) are advised of the contents of this Article 10 and (C) agree to be bound by the terms of this Article 10. Without prejudice to the rights and remedies otherwise available to a party at law or in equity, the parties agree that a non-breaching party shall be entitled to seek equitable relief by way of specific performance and injunction or otherwise if the other party breaches or threatens to breach any of the provisions of this Article 10.

10.2 Definition. As used in this Agreement, the term "**Confidential Information**" includes all such information furnished by PCI or Client, or any of their respective representatives or Affiliates, to the other party or its representatives or Affiliates, whether furnished before, on or after the Effective Date and furnished in any form, including written, verbal, visual, electronic or in any other media or manner. Confidential Information includes all proprietary technologies, know-how, trade secrets, discoveries, inventions and any other Intellectual Property (whether or not patented), analyses, compilations, business or technical information and other materials prepared by either party, or any of their respective representatives or Affiliates, containing or based in whole or in part on any such information furnished by the other party or its representatives or Affiliates. Confidential Information also includes the existence of this Agreement and its terms.

10.3 Exclusions. Notwithstanding Section 10.2, Confidential Information does not include information that (A) is or becomes generally available to the public or within the industry to which such information relates other than as a result of a breach of this Agreement, (B) is already known by the receiving party at the time of disclosure as evidenced by the receiving party's written records, (C) becomes available to the receiving party on a non-confidential basis from a source that the receiving party reasonably believes is entitled to disclose it on a non-confidential basis or (D) was or is independently developed by or for the receiving party without reference to the Confidential Information of the other party as evidenced by the receiving party's written records.

10.4 No Implied License. Except as expressly set forth in Section 11.1, the receiving party will obtain no right of any kind or license under any Confidential Information of the disclosing party, including any patent application or patent, by reason of this Agreement. All Confidential Information will remain the sole property of the party disclosing such information or data, subject to Article 11.

10.5 Return of Confidential Information. Upon expiration or termination of this Agreement, the party receiving Confidential Information will cease its use and, upon request, within […***…] days either return or destroy (and certify as to such destruction) all Confidential Information of the other party, including any copies thereof, except for a single copy thereof which may be retained for the sole purpose of determining the scope of the obligations incurred under this Agreement. Notwithstanding the generality of the foregoing, nothing contained herein shall be construed as requiring the destruction of system wide back-up materials which may incidentally contain or have reference to Confidential Information.

10.6 Survival. The obligations of this Article will terminate […***…] years from the expiration or termination of this Agreement, except with respect to trade secrets, for which the obligations of this Article will continue for […***…].

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ARTICLE 11
***INTELLECTUAL PROPERTY

11.1 Ownership of Client Intellectual Property; License. All Client Intellectual Property, including any improvements thereto (except as such improvement may relate to packaging which shall be deemed PCI Intellectual Property), shall be the sole and exclusive property of Client. Client grants to PCI a non-exclusive, non-transferable, royalty-free license to use Client Intellectual Property solely to the extent necessary for PCI to perform its obligations under this Agreement. No other license to Client Intellectual Property is hereby granted.

11.2 Ownership of PCI Intellectual Property. All PCI Intellectual Property, including but not limited to any improvements to packaging processes, shall be the sole and exclusive property of PCI. No license or other right to PCI Intellectual Property is granted to Client.

11.3 Ownership of Deliverables. Except as set forth in Section 11.2, all data and information resulting from the conduct of Packaging and required to be delivered to Client hereunder shall be the sole property of Client and shall be subject to Client's exclusive use, commercial or otherwise.

ARTICLE 12
REPRESENTATIONS AND WARRANTIES

12.1 PCI. PCI represents, warrants and undertakes to Client that Packaging shall have been performed in accordance with , cGMP, Applicable Laws and in conformance with the Specifications; *provided*, that PCI shall not be liable for defects attributable to Client-supplied Materials (including artwork and labeling).

12.2 Client. Client represents, warrants and undertakes to PCI that:

(a) the Client-supplied Materials (including artwork and labeling) shall have been produced in accordance with and not violate Applicable Laws and shall comply with all applicable specifications;

(b) no Client-supplied Materials shall, at the time of delivery, be (i) adulterated or misbranded within the meaning of the FD&C Act, or any similar law of any other jurisdiction, or (ii) an article which may not, under the provisions of the FD&C Act, or any similar law of any other jurisdiction, be introduced into interstate commerce;

(c) no specific safe handling instructions, health and environmental information or material safety data sheets are applicable to any other Client-supplied Materials, except as provided to PCI in writing by Client in sufficient time for review and training by PCI;

(d) all Packaged Product delivered to Client by PCI will be held, used and disposed of by or on behalf of the Client in accordance with all Applicable Laws, and Client will otherwise comply with all laws, rules, regulations and guidelines applicable to Client's performance under this Agreement and its use of Packaged Product provided by PCI under this Agreement;

(e) Client will not release any Batch of Packaged Product if Client knows or can reasonably determine that Packaging does not comply with the Specifications;

(f) Client has all necessary authority to use and to permit PCI to use pursuant to this Agreement all Intellectual Property related to Client-supplied Materials (including artwork and labeling), and the Packaging, including any copyrights, trademarks, trade dress, trade secrets, patents, inventions and developments; and

(g) the work to be performed by PCI under this Agreement will not violate or infringe upon any trademark, trade name, copyright, patent, trade secret, trade dress or other Intellectual Property or other right held by any person or entity.

12.3 Limitations. THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS ARTICLE 12 ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES MADE BY EACH PARTY TO THE OTHER PARTY, AND NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS, WARRANTIES OR GUARANTEES OF ANY KIND WHATSOEVER, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 13
INDEMNIFICATION

13.1 Indemnification by PCI. PCI shall indemnify, defend and hold harmless Client, its Affiliates, and their respective directors, officers, employees, representatives, and agents ("**Client Indemnitees**") from and against any and all suits, claims, losses, demands, liabilities, damages, costs and expenses (including reasonable attorneys' fees and reasonable investigative costs) in connection with any suit, demand or action by any third party ("**Losses**") arising out of or resulting from (A) any breach of its representations, warranties or obligations set forth in this Agreement or (B) any negligence or willful misconduct by PCI; in each case except to the extent that any of the foregoing arises out of or results from any Client Indemnitee's negligence, willful misconduct or breach of this Agreement.

13.2 Indemnification by Client. Client shall indemnify, defend and hold harmless PCI, its Affiliates, and their respective directors, officers, employees, representatives, and agents ("**PCI Indemnitees**") from and against any and all Losses arising out of or resulting from (A) any breach of its representations, warranties or obligations set forth in this Agreement, (B) any manufacture, labeling, packaging, sale, promotion, distribution or use of or exposure to Client-supplied Materials or Packaged Product, including product liability or strict liability, (C) Client's exercise of control over the Packaging, to the extent that Client's instructions or directions violate Applicable Laws, (D) use of a Supplier, (E) any actual or alleged infringement or violation of any third party Intellectual Property by Client's Intellectual Property, products or components of Client, including Client-supplied Materials, information provided by Client or otherwise caused by Client, or (F) any negligence or willful misconduct by Client; in each case except to the extent that any of the foregoing arises out of or results from any PCI Indemnitee's negligence, willful misconduct or breach of this Agreement.

13.3 Indemnification Procedures. All indemnification obligations in this Agreement are conditioned upon the party seeking indemnification promptly notifying the indemnifying party of any claim or liability of which the party seeking indemnification becomes aware (including a copy of any related complaint, summons, notice or other instrument); *provided*, that failure to provide such notice within a reasonable period of time shall not relieve the indemnifying party of any of its obligations hereunder except to the extent the indemnifying party is materially prejudiced by such failure. The indemnifying party will assume and conduct the legal defense of the indemnified party in any suit that could result in claims under this Article 13. The indemnifying party will not settle any case without with prior written consent of the indemnified party and such consent shall not be unreasonably withheld or delayed. The indemnified party shall cooperate with the indemnifying party in the defense of any such claim or liability and any related settlement negotiations at the indemnifying party's expense.

ARTICLE 14
LIMITATIONS OF LIABILITY

14.1 WITH RESPECT TO EACH TYPE OF BULK PRODUCT PACKAGED UNDER THIS AGREEMENT, PCI'S LIABILITY TO CLIENT UNDER THIS AGREEMENT WITH RESPECT TO ANY 12-MONTH PERIOD SHALL IN NO EVENT EXCEED THE NET FEES (EXCLUDING PASS THROUGH COSTS) PAID BY CLIENT OR PAYABLE BY CLIENT TO PCI UNDER THIS AGREEMENT DURING SUCH 12 MONTH PERIOD. FOR CLARITY, AS AN EXAMPLE BASED UPON INITIAL PACKAGING REQUIREMENTS, THE PRECEDING SENTENCE WOULD BE CALCULATED BASED UPON THE NET FEES (EXCLUDING PASS THROUGH COSTS) PAID BY CLIENT OR PAYABLE BY CLIENT TO PCI UNDER THIS AGREEMENT DURING SUCH 12 MONTH PERIOD FOR ALL PACKAGING OF VALBENAZINE DITOSYLATE 40MG & 80MG CAPSULES. EXCEPT IN THE CASE OF PCI'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, IN NO 12 MONTH PERIOD SHALL PCI'S LIABILITY UNDER THIS AGREEMENT EXCEED $[…***…].

14.2 NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR LOSS OF REVENUES, PROFITS OR DATA ARISING OUT OF PERFORMANCE UNDER THIS AGREEMENT, WHETHER IN CONTRACT OR IN TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

ARTICLE 15
INSURANCE

15.1 By Client. Client shall maintain (i) property insurance against the perils of physical loss, including those generally associated with "all risk" property insurance, flood, earth movement and theft, in amounts sufficient to protect all Client-supplied Materials at PCI's facility or while in transit, and (ii) a commercial general liability insurance policy covering product liability and personal injury damages with limits of $[…***…] dollars) per occurrence. Client agrees to designate PCI as an "additional insured" under such general liability insurance policy. Client shall also carry and maintain in force at all times relevant hereto all other insurance required by law or statute.

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15.2 By PCI. PCI shall maintain (i) employer's liability insurance with a limit of not less than […***…] dollars ($[…***…]), (ii) commercial general liability insurance with limits of […***…] dollars ($[…***…]) per occurrence and a general aggregate limit of […***…] dollars ($[…***…]), (iii) umbrella liability insurance, in excess of the above coverage, with a limit per occurrence of […***…] dollars ($[…***…]) and an aggregate limit of […***…] dollars ($[…***…]), and (iv) products liability insurance exclusive of the above coverage for general liability, with a per claim limit of […***…] dollars ($[…***…]) and an aggregate limit of […***…] dollars ($[…***…]).

15.3 General. The policies required in this Article 15 shall remain in effect throughout the term of this Agreement and shall not be canceled or subject to reduction or any other material modification without […***…] days' prior written notice to the other party. Each party may self-insure all or any portion of the required insurance as long as, together with its Affiliates, its US GAAP net worth is greater than $[…***…] or its annual EBITDA (earnings before interest, taxes, depreciation and amortization) is greater than $[…***…]. Each required insurance policy, other than self-insurance, shall be obtained from an insurance carrier with an A.M. Best rating of at least A-. If any of the required policies of insurance are written on a claims made basis, such policies shall be maintained throughout the Term and for a period of at least three years thereafter. Upon the other party's written request from time to time, each party shall promptly furnish to the other party a certificate of insurance or other evidence of the required insurance.

ARTICLE 16
TERM AND TERMINATION

16.1 Term. This Agreement shall commence on the Effective Date and shall continue until September 30, 2019, unless earlier terminated in accordance with Section 16.2 (as may be extended in accordance with this Section, the "**Term**"). The Term shall automatically be extended for successive two-year periods unless and until one party gives the other party at least one year prior written notice of its desire to terminate as of the end of the then-current Term.

16.2 Termination. This Agreement may be terminated immediately without further action:

(a) by either party if the other party files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver, administrative receiver, trustee or administrator, or makes an assignment for the benefit of creditors, or suffers or permits the entry of any order adjudicating it to be bankrupt or insolvent and such order is not discharged within 30 days, or takes any equivalent or similar action in consequence of debt in any jurisdiction;

(b) by either party if the other party materially breaches any of the provisions of this Agreement and such breach is not cured within 60 days after the giving of written notice requiring the breach to be remedied; *provided*, that in the case of a failure of Client to make payments in accordance with the terms of this Agreement, PCI may terminate this Agreement if such payment breach is not cured within 20 days of receipt of notice of non-payment from PCI; or

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(c) by either party for any reason or no reason upon 24 months' prior written notice to the other party; or

(d) any required license, permit or certificate required of the other party to perform its obligations under this Agreement is not approved and/or issued, or is revoked, by any applicable Regulatory Authority.

16.3 Effect of Termination. Expiration or termination of this Agreement shall be without prejudice to any rights or obligations that accrued to the benefit of either party prior to such expiration or termination. In the event of a termination of this Agreement:

(a) PCI shall promptly return to Client, at Client's expense and at Client's direction, any remaining inventory of Client-supplied Materials; *provided*, that PCI shall have no obligation to so return such items until all outstanding invoices sent by PCI to Client have been paid in full.

(b) In accordance with the provisions regarding payment under this Agreement, Client shall pay PCI all invoiced amounts outstanding hereunder, plus, upon receipt of invoice therefore, for any (i) Packaging of Packaged Product that has been shipped pursuant to Purchase Orders but not yet invoiced, (ii) Packaging performed pursuant to Purchase Orders that has been completed but Packaged Product has not yet shipped, (iii) in-process Packaging pursuant to Purchase Orders (or, alternatively, Client may instruct PCI to complete such Packaging in process, and the resulting completed Packaged Product shall be governed by clause (ii)) and (iv) in addition to Client's obligations under Section 3.2(c), all costs and expenses incurred, and all noncancellable commitments (including all Product specific tooling that has been, or remains to be, amortized) made, in connection with PCI's performance of this Agreement, so long as such costs, expenses or commitments were made by PCI consistent with Client's most recent Firm Commitment. To the extent that Client has previously paid for all or a portion of Product specific tooling through incremental increases in Pricing or otherwise, such amounts shall not be charged under this Section 16.3.

16.4 Survival. The rights and obligations of the parties shall continue under Article 11 (Intellectual Property), Article 13 (Indemnification), Article 14 (Limitations of Liability), Article 17 (Notice), Article 18 (Miscellaneous); under Article 10 (Confidentiality and Non-Use) and Article 15 (Insurance), in each case to the extent expressly stated therein; and under Sections 3.1(h) (Liability for Loss), 3.1(i) (Annual Reconciliation of Excess Loss; Reimbursement), 5.4 (Defective Packaging), 7.3 (Payment Terms), 7.4 (Taxes), 9.2 (Recordkeeping), 9.6 (Recall), 12.3 (Limitations on Warranties), 16.3 (Effect of Termination) and 16.4 (Survival), in each case in accordance with their respective terms if applicable, notwithstanding expiration or termination of this Agreement.

ARTICLE 17
NOTICE

All notices and other communications hereunder shall be in writing and shall be deemed given: (A) when delivered personally; (B) when delivered by facsimile transmission (receipt verified); (C) when received or refused, if mailed by registered or certified mail (return receipt requested), postage prepaid; or (D) when delivered if sent by express courier service, to the

parties at the following addresses (or at such other address for a party as shall be specified by like notice; *provided*, that notices of a change of address shall be effective only upon receipt thereof):

To Client:	Neurocrine Biosciences, Inc. 12780 El Camino Real San Diego, California 92130 Attn: T. Ramesh, Vice President Commercial Manufacturing Facsimile: (858) 777-3488 With a copy to: Darin Lippoldt, Chief Legal Officer, at the same address and facsimile
To PCI:	AndersonBrecon Inc. 3001 Red Lion Road Philadelphia, PA 19114 Attn: Bill Mitchell, CEO Facsimile: +1 (215) 613-3127

ARTICLE 18
MISCELLANEOUS

18.1 Entire Agreement; Amendments. This Agreement, together with all Attachments and the Quality Agreement, constitutes the entire understanding between the parties, and supersedes any contracts, agreements or understandings (oral or written) of the parties (except for confidentiality agreements), with respect to the subject matter hereof including any prior quotations executed. No modification or amendment to this Agreement shall be effected by or result from the receipt, acceptance, signing or acknowledgment of any Party's purchase orders, order acknowledgements, quotations, invoices, shipping documents or other business forms containing terms or conditions in addition to or different from the terms and conditions set forth in this Agreement, and the terms of this Agreement shall supersede any provision in any purchase order or other document that is in addition to or inconsistent with the terms of this Agreement. No term of this Agreement may be amended except upon written agreement of the parties, unless otherwise expressly provided in this Agreement.

18.2 Captions; Certain Conventions. The captions in this Agreement are for convenience only and are not to be interpreted or construed as a substantive part of this Agreement. Unless otherwise expressly provided herein or the context of this Agreement otherwise requires, (A) words of any gender include each other gender, (B) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (C) words using the singular shall include the plural, and vice versa, (D) the words "include(s)" and "including" shall be deemed to be followed by the phrase "but not limited to", "without limitation" or words of similar import, (E) the word "or" shall be deemed to include the word "and" (e.g., "and/or") and (F) references to "Article," "Section," "subsection," "clause" or other subdivision, or to an Attachment or other

appendix, without reference to a document are to the specified provision or Attachment of this Agreement. This Agreement shall be construed as if it were drafted jointly by the parties.

18.3 Further Assurances. The parties agree to execute, acknowledge and deliver such further instruments and to take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

18.4 No Waiver. Failure by either party to insist upon strict compliance with any term of this Agreement in any one or more instances will not be deemed to be a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.

18.5 Severability. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement will continue in full force and effect.

18.6 Independent Contractors. The relationship of PCI and Client is that of independent contractors, and neither will incur any debts or make any commitments for the other except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or will be construed as creating between the parties the relationship of joint ventures, co-partners, employer/employee or principal and agent. Neither PCI nor Client shall have any responsibility for the hiring, termination or compensation of the other's employees or contractors or for any employee benefits of any such employee or contractor.

18.7 Successors and Assigns. This Agreement will be binding upon and inure to the benefit of the parties, their successors and permitted assigns. Neither party may assign this Agreement, in whole or in part, without the prior written consent of the other party, except that either party may, without the other party's consent, assign this Agreement in its entirety to an Affiliate or to a successor to substantially all of the business or assets of the assigning party or the assigning party's business unit responsible for performance under this Agreement.

18.8 No Third Party Beneficiaries. This Agreement shall not confer any rights or remedies upon any person or entity other than the parties named herein and their respective successors and permitted assigns.

18.9 Governing Law. This Agreement shall be governed by and construed under the laws of the state of Delaware, excluding its conflicts of law provisions. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

18.10 Alternative Dispute Resolution. If any dispute arises between the parties in connection with this Agreement, such dispute shall be presented to the respective presidents or senior executives of PCI and Client for their consideration and resolution. If such parties cannot reach a resolution of the dispute, then such dispute shall be resolved by binding alternative dispute resolution in accordance with the then existing commercial arbitration rules of CPR Institute for Dispute Resolution, 575 Lexington Avenue, New York, NY 10022 (or then current address in New York City). Arbitration shall be conducted in the jurisdiction of the defendant party, in the English language.

18.11 Prevailing Party. In any dispute resolution proceeding between the parties in connection with this Agreement, the prevailing party will be entitled to recover its reasonable attorney's fees and costs in such proceeding from the other party.

18.12 Publicity. Neither party will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other party's express prior written consent, except as required under Applicable Laws, by any governmental agency or by the rules of any stock exchange on which the securities of the disclosing party are listed, in which case the party required to make the press release or public disclosure shall use commercially reasonable efforts to obtain the approval of the other party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.

18.13 Setoff. Without limiting either party's rights under law or in equity, each of PCI and Client, and their respective Affiliates, parent or related entities, collectively or individually, may exercise a right of set-off against any and all amounts due to the other party. For purposes of this Section, PCI, its Affiliates, parent or related entities shall be deemed to be a single creditor.

18.14 Force Majeure. Except as to payments required under this Agreement, a party shall be liable in damages for, nor shall this Agreement be terminable or cancelable by reason of, any delay or default in such party's performance hereunder if such default or delay is caused by events beyond such party's reasonable control, including acts of God, law or regulation or other action or failure to act of any government or agency thereof, strikes, lockouts, slowdowns, delay of subcontractors or vendors, war (declared or undeclared) or insurrection, civil commotion, terrorism, destruction of production facilities or materials by earthquake, fire, flood or weather, labor disturbances, epidemic or failure of suppliers, public utilities or common carriers; *provided*, that the party seeking relief under this Section shall immediately notify the other party of such cause(s) beyond such party's reasonable control. The party that may invoke this Section 18.14 shall use commercially reasonable efforts to reinstate its ongoing obligations to the other party as soon as practicable. If the cause(s) shall continue unabated for […***…] days, then both parties shall meet to discuss and negotiate in good faith what modifications to this Agreement should result from such cause(s).

18.15 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. Any photocopy, facsimile or electronic reproduction of the executed Agreement shall constitute an original.

[Signature page follows]

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IN WITNESS WHEREOF, the parties have caused their respective duly authorized representatives to execute this Agreement effective as of the Effective Date.

ANDERSONBRECON INC.

By: /s/ Philip DiGiacomo
Name: Philip DiGiacomo
Its: EVP of Sales

NEUROCRINE BIOSCIENCES INC.

By: /s/ Darin Lippoldt
Name: Darin Lippoldt
Its: Chief Legal Officer

ATTACHMENT A

BULK PRODUCT, MATERIALS, and PACKAGING SPECIFICATIONS

[…***…]

*** Confidential Treatment Requested for pages 27-28.

Omitted pages have been filed separately with the Commission.

ATTACHMENT B

UNIT PRICING AND FEES

[…***…]

*** Confidential Treatment Requested for pages 29-31.

Omitted pages have been filed separately with the Commission.

ATTACHMENT C

FORM OF QUALITY AGREEMENT

See attached.

Exhibit 99.4

*****Text Omitted and Filed Separately**
with the Securities and Exchange Commission.
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Under 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2.

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "**Agreement**") is made and entered into as of February 9, 2017 (the "**Effective Date**")

by and between

BIAL – PORTELA & CA, S.A., a Portuguese corporation having a principal place of business at À Avenida da Siderurgia Nacional, 4745-457 Coronado (S. Romão e S. Mamede), Portugal (hereinafter referred to as "**BIAL**")

and

NEUROCRINE BIOSCIENCES, INC., a Delaware corporation having a principal place of business at 12780 El Camino Real, San Diego, CA 92130, USA (hereinafter referred to as "**NBIX**").

Each of NBIX and BIAL may be referred to herein as a "**Party**" or collectively as the "**Parties**".

WITNESSETH

WHEREAS, BIAL Controls (as defined below) the BIAL Patents and BIAL Know-How (each as defined below), which relate to the compound BIA 9-1067 (as defined below) and its use in the treatment of human diseases and conditions, including Parkinson's disease; and

WHEREAS, NBIX wishes to acquire licenses under the BIAL Patents, BIAL Know-How and Trademarks (as defined below) for the purpose of using, developing, marketing, distributing, importing, commercializing, offering for sale and selling the Licensed Products (as defined below) under the Trademark within the Field and Territory (each as defined below); and

WHEREAS, BIAL is willing to grant such licenses to NBIX under the terms and conditions of this Agreement; and

WHEREAS, BIAL is willing to manufacture and supply Licensed Products to NBIX for using, developing, marketing, distributing, importing, commercializing, offering for sale and selling the Licensed Products under the Trademark within the Field and Territory under the terms and conditions of this Agreement and a Supply Agreement (as defined below) to be entered into between the Parties; and

NOW, THEREFORE, in reliance on the foregoing recitals and in consideration of the mutual covenants and promises set forth herein, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

As used in this Agreement, the following terms have the following meanings:

1.1. "**Affiliate**" means any person or entity that, as of the Effective Date or at any time during the Term, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with a Party. For purposes of this definition, "control" means **(i)** the ownership of at least fifty percent (50%) of the voting securities of the entity or such lesser percentage which is the maximum allowed by applicable law; or **(ii)** the ability to otherwise direct the management and operations of the entity.

1.2. "**Agency**" means the FDA (as defined below), Health Canada or any other governmental entity(ies), and its or their successor bodies, whose authorization is required to market and sell any pharmaceutical product in Territory.

1.3. "**Agency Interactions**" has the meaning set forth in Section 7.2(e).

1.4. "**Agreed Sales Forecast**" has the meaning set forth in Section 8.3(d).

1.5. "**Alleged Infringement**" has the meaning set forth in Section 12.2(a).

1.6. "**Alleged Manufacturing Infringement**" has the meaning set forth in Section 12.2(b).

1.7. "**Alleged Manufacturing Infringement Costs**" has the meaning set forth in Section 12.2(d).

1.8. "**Alliance Manager**" has the meaning set forth in Section 5.8(a).

1.9. **"Alternative Trademarks"** has the meaning set forth in Section 2.3(d).

1.10. "**Annual Commercialization Plan**" has the meaning set forth in Section 8.2(a).

1.11. "**Approval**" means the marketing authorization issued by an Agency for the commercialization of a Licensed Product within the Field and Territory.

1.12. "**Assumptions**" has the meaning set forth in Section 8.3(e).

1.13. "**BIA 9-1067**" means […***…].

1.14. "**BIA 9-1067 API**" means the active pharmaceutical ingredient of BIA 9-1067.

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1.15. "BIA 9-1067 IND" means the IND No.[…***…].

1.16. "**BIAL Indemnitees**" has the meaning set forth in Section 16.2.

1.17. "BIAL Know-How" means any and all research and development information, unpatented inventions, trade secrets, proprietary materials, or any other type of proprietary or confidential technical data or information, including without limitation, products, methods, techniques, processes, specifications, recipes, formulae, designs, plans, drawings, data, protocols, or non-clinical and clinical data (including, without limitation, Data), which are Controlled by BIAL or its Affiliates as of the Effective Date or during the Term and are either **(i)** reasonably necessary for the use, development marketing, distribution, importation, commercialization, manufacture (other than the Manufacturing Know-How), offer for sale or sale of the Licensed Products, or **(ii)** useful for the use, development marketing, distribution, importation, commercialization, manufacture (other than the Manufacturing Know-How), offer for sale or sale of the Licensed Products, and in such case (i) or (ii) to the extent that BIAL or its Affiliates have developed or used such know-how in connection with the Licensed Products. The term "BIAL Know-How" includes, without limitation, all proprietary and confidential information included in INDs/NDAs and any other regulatory filings and correspondence related to any Licensed Product and all Data and information to be submitted in support of such filings or correspondence, and information relating to marketing and commercialization, to the extent Controlled by BIAL or its Affiliates during the Term and related to Licensed Products, and BIAL's interest in Development Intellectual Property jointly owned by the Parties; provided however that in the event that any Third Party becomes a BIAL Affiliate by merger with or by acquisition of BIAL or any of its Affiliates, any know-how of such Third Party in existence as of the effective date of such merger or acquisition shall not be included in BIAL Know-How so long as it is not used and was not generated in connection with the development, manufacture or commercialization of any Licensed Product. For greater certainty, the term "BIAL Know-How" does not include the Manufacturing Know-How.

1.18. "**BIAL Logo**" means the logo included in **Exhibit 2.4**, which BIAL may, at its own discretion, update from time to time.

1.19. "**BIAL Patents**" means **(i)** all US and Canadian Patents Controlled by BIAL or its Affiliates as of the Effective Date or during the Term, claiming or covering or which would be practiced by the use, development, marketing, distribution, import, commercialization, offer for sale and sale of the Licensed Products, including, without limitation, the BIAL Patents listed in **Exhibit 2.1**; **(ii)** any US and Canadian provisional, divisional, substitution, continuation or continuation-in-part applications based on, directly or indirectly, relying for priority on, or having identical disclosure as, any of the US or Canadian Patents in (i); **(iii)** any US and Canadian Patent issuing from any of the Patents in (i) or (ii); and **(iv)** any extensions, patent term adjustments, reissues, supplemental examinations or reexaminations of any of the Patents in (i), (ii) and/or (iii). BIAL Patents also include any Patents covering any Development Intellectual Property owned solely by BIAL or one of its Affiliates or jointly by BIAL and its Affiliates. BIAL agrees to update Exhibit 2.1 from time to time with additional BIAL Patents;

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provided however that in the event that any Third Party becomes a BIAL Affiliate by merger with or by acquisition of BIAL or any of its Affiliates, any Patent of such Third Party in existence as of the effective date of such merger or acquisition shall not be included in BIAL Patents, so long as it does not cover any subject matter that is directly used or directly generated in connection with the development or commercialization of any Licensed Product.

1.20. "BIAL Representatives" has the meaning set forth in Section 2.10(iii).

1.21. "BIAL Representatives Costs" has the meaning set forth in Section 2.10(iii).

1.22. "BIAL Studies" means the studies set out in **Exhibit 6.4**.

1.23. "**Blocking BIAL IP**" means any Patent or other Intellectual Property outside the Territory that is Controlled by BIAL (by ownership, license or otherwise) and which would be infringed by the use, manufacture, development, marketing, distribution, importation, commercialization, offer for sale or sale of any product or process that is claimed, covered or would be practiced by such Patent or Intellectual Property.

1.24. "**Business Day**" means any of the days Monday through Friday less **(i)** public holidays in Porto, Portugal, **(ii)** public holidays in San Diego, California, United States of America, **(iii)** first two (2) weeks of August of each Calendar Year, and **(iv)** the period between 24th December of a Calendar Year and 1st January of the subsequent Calendar Year.

1.25. "Calendar Quarter" means each period of three (3) months ending on 31st March, 30th June, 30th September and 31st December.

1.26. "**Calendar Year**" means each twelve (12) months period starting on 1st January and ending on 31st December.

1.27. "Change of Control" means, with respect to NBIX, any of the following events: **(i)** a Third Party (or group of Third Parties acting in concert) directly or indirectly, acquires more than fifty percent (50%) of the then outstanding capital stock entitled to vote for the election of NBIX's directors; or **(ii)** a consolidation, reorganization or merger involving NBIX in which more than fifty percent (50%) of the then outstanding capital stock of the surviving entity entitled to vote for the election of directors is not held by the parties holding at least fifty percent (50%) of the outstanding shares of NBIX preceding such consolidation or merger; or **(iii)** NBIX conveys, transfers or sells all or substantially all of its assets relating to Licensed Products.

1.28. "**Change of Control Entity**" has the meaning set forth in Section 15.2(d)(i).

1.29. "**Change of Control Notice**" has the meaning set forth in Section 2.11.

1.30. "**Claim**" has the meaning set forth in Section 16.1.

1.31. "**Clinical Trials**" means Phase I Clinical Trials, Phase II Clinical Trials and/or Phase III Clinical Trials.

1.32. "**Co-Promotion Agreement**" has the meaning set forth in Section 2.10(c).

1.33. "**Co-Promotion Option**" has the meaning set forth in Section 2.10(a).

1.34. "**Co-Promotion Plan**" has the meaning set forth in Section 2.10(b).

1.35. "**Co-Promotion Steering Committee**" has the meaning set forth in Section 2.10(c)(vii).

1.36. "**Combination Product**" means […***…].

1.37. "**Commercial Year**" has the meaning set forth in Section 8.3(d).

1.38. **"Commercially Reasonable Efforts"** means, with respect to a Party's obligations under this Agreement, with respect to each Licensed Product, the level of efforts required to carry out a task in a diligent and sustained manner without undue interruption, pause or delay, which level is at least commensurate with the level of efforts that a similarly situated biopharmaceutical company, of similar size and resources, would devote to a product of similar commercial and market potential and at a similar stage of development or commercialization and having similar commercial and scientific advantages and disadvantages resulting from such company's own research efforts (*i.e*. explicitly ignoring the upfront, milestone, and royalty payments, but including payments for product supply and other payments related to the Co-Promotion Agreement due to BIAL under this Agreement), taking into account all relevant factors, including (without limitation) Patent coverage, safety, efficacy, product profile, competitiveness of the marketplace, proprietary position and profitability. Commercially Reasonable Efforts requires (without limitation) that NBIX **(i)** promptly assigns responsibility for its obligations to specific employee(s) who are held accountable for progress and monitor such progress on an ongoing basis, **(ii)** continues to seek to achieve specific and meaningful objectives for carrying out such obligations and **(iii)** makes and/or implements decisions and allocates resources designed to make progress with respect to such objectives.

1.39. "**Competing Product**" means […***…].

1.40. "**COMT**" means catechol-O-methyl transferase.

1.41. "**Confidential Information**" has the meaning set forth in Section 13.1(a).

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1.42. "**Confidentiality Agreement**" has the meaning set forth in Section 13.1(a).

1.43. "**Controlled**" means, with respect to any Intellectual Property (as defined below), the possession by a Party of the right, whether directly or indirectly, whether by ownership, license or otherwise, to grant a license, sublicense or other right to or under such Intellectual Property, as provided for in this Agreement, without violating the terms of any agreement, contract or any other arrangement with any Third Party. For the avoidance of doubt, Third Party Intellectual Property shall only be considered "Controlled" by a Party, if the Party has right to assign or grant a license, sublicense or otherwise grant rights to the other Party as provided for in this Agreement, at no additional cost (unless the other Party agrees to assume such cost) and without prior Third Party approval. The term "**Control**" or "**Controls**" used in this context will also have a correlative meaning.

1.44. "**Data**" means any and all scientific, technical or test data pertaining to Licensed Product(s) (provided, that if any such scientific, technical and/or test data pertains to Licensed Product(s) and something other than Licensed Product(s), then only such scientific, technical and test data that pertains to Licensed Product(s) and not to something else) that is generated by or under the authority of NBIX or its Affiliates and contractors, or by or under the authority of BIAL or BIAL's Affiliates and contractors (provided however that in the event that any Third Party becomes a BIAL Affiliate by merger with or by acquisition of BIAL or any of its Affiliates, any data of such Third Party in existence as of the effective date of such merger or acquisition shall not be included as Data) or by or under the authority of any Third Party licensee in respect of BIA 9-1067 and/or Licensed Products of BIAL outside the Territory, including, without limitation, research data, non-clinical data, clinical data and/or all submissions made in association with an IND or application for a Marketing Authorization filed in or outside the Territory with respect to such Licensed Product(s), in each case to the extent such data either **(a)** is Controlled by BIAL or its Affiliates on the Effective Date or **(b)** comes within a Party's or its Affiliates' Control during the Term (provided however that in the event that any Third Party becomes a BIAL Affiliate by merger with or by acquisition of BIAL or any of its Affiliates, any data of such Third Party in existence as of the effective date of such merger or acquisition shall not be included as Data unless BIAL Controls such Data prior to the effective date of such merger or acquisition or BIAL subsequently includes such data in regulatory filings in connection with the Licensed Product outside the Territory). Data shall not include any Manufacturing Know-How.

1.45. **"Data Update Filings"** has the meaning set forth in Section 7.2(f).

1.46. "**Detail**" means, with respect to a Licensed Product in the Territory, a face-to-face contact between a sales representative of NBIX (or of BIAL or its Affiliate or its contractor in the case the Parties have executed a Co-Promotion Agreement and are co-promoting) and a physician or other medical professional licensed to prescribe drugs, during which promotional, scientific and/or medical information about the Licensed Products is discussed at length with such person in either a first position detail (as defined in the Annual Commercialization Plan) or a second position detail (as defined in the Annual Commercialization Plan), in each case as measured by each Party's internal recording of such

activity; *provided* that such meeting is consistent with and in accordance with the requirements of applicable law and this Agreement and the Co-Promotion Agreement. A Detail shall not include discussions at medical congress or meetings or any other form of communication that is not face to face and shall not include a reminder call in which the Licensed Products are not discussed at length or a Licensed Product sample drop if the sole purpose of the face to face contact was a sample drop. "Detailing" shall be construed accordingly. When used as a verb, "**Detail**" means to engage in a Detail.

1.47. "**Development and Regulatory Plan**" has the meaning set forth in Section 6.2(a).

1.48. "**Development Intellectual Property**" means any inventions or discoveries (whether or not patentable) made solely by or on behalf of one Party or its Affiliates or jointly by or on behalf of both Parties or their respective Affiliates in the performance of this Agreement, but only to the extent related to BIA 9-1067 or any Licensed Product. Development Intellectual Property does not include any Manufacturing Know-How or Patents to the extent that they claim or cover the manufacture of BIA 9-1067 API.

1.49. "**Development License**" has the meaning set forth in Section 2.2.

1.50. "**Development Studies**" means any Nonclinical Studies, Clinical Trials, Post-Approval Commitment (PAC) (or post-marketing requirement) Studies and Phase IV Studies in respect of BIA 9-1067 or Licensed Products carried out by or on behalf of NBIX in accordance with this Agreement.

1.51. "**Difference**" has the meaning set forth in Section 8.3(g).

1.52. "**Dispute**" has the meaning set forth in Section 17.1(a).

1.53. "**Divestiture**" has the meaning set forth in Section 2.8(b).

1.54. "**EMA**" means the European Medicines Agency and its successor bodies.

1.55. **"Excluded Claim"** has the meaning set forth in Section 17.1(k).

1.56. "**Exclusivity Rights**" means a marketing or data exclusivity right conferred by any Agency, including rights conferred in the United States under the Hatch-Waxman Act or the FDA Modernization Act of 1997 (including pediatric exclusivity), or rights similar thereto in Canada.

1.57. "**Executive Officer**" means (a) with respect to NBIX, […***…] and (b) with respect to BIAL, an individual **(i)** […***…] or **(ii)** […***…].

1.58. "**Existing Licensees**" has the meaning set forth in Section 9.2(c).

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1.59. "**Extension Party**" has the meaning set forth in Section 11.4(e).

1.60. **"FDA"** means the United States of America Food and Drug Administration.

1.61. "**Field**" means […***…]. For certainty, Field includes the Initial Indication and any Subsequent Indications (both as defined below).

1.62. "**First Development and Regulatory Plan**" has the meaning set forth in Section 6.3(a).

1.63. **"First Tentative Supply Price"** has the meaning set forth in Paragraph 1.1(b)(ii) of Exhibit 4.

1.64. "**For Cause Audit**" has the meaning set forth in Sections 7.6(b) and 7.6(d).

1.65. "**Force Majeure**" has the meaning set forth in Section 17.3.

1.66. "**Fully Burdened Manufacturing Cost**" means […***…]. Such costs shall be calculated in accordance with International Financial Reporting Standards and using BIAL's or its Affiliates normal cost accounting and allocation methods and procedures, consistently applied historically and across all of BIAL's and its Affiliates' investigational medicinal products and commercial products.

1.67. "**GAAP**" means US generally accepted accounting principles.

1.68. "**GCPs**" or "**Good Clinical Practices**" means a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and the rights, integrity, and confidentiality of the trial subjects are protected, as defined in ICH E6: Good Clinical Practice, April 1996, as amended.

1.69. "**Generic Product**" means a Third Party pharmaceutical product that […***…].

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1.70. "**Global Brand Identity**" means the designs and colors of Licensed Products' trademark(s) and logos used by BIAL or its Affiliates or licensees outside the Territory and related guidance for their use and placement in promotional materials with respect to the Licensed Products.

1.71. "**GLPs**" or "**Good Laboratory Practices**" means a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported., as defined in the Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice, as amended.

1.72. "**GMPs**" or "**Good Manufacturing Practices**" means the then current Good Manufacturing Practices pursuant to the EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines, containing guidance documents for the interpretation of the principles and guidelines of good manufacturing practices for medicinal products for human use laid down in Commission Directive 2003/94/EC, as may be amended from time to time. "GMP" also includes adherence to the then-current requirements of the European Pharmacopoeia and the relevant current ICH Quality Guidelines.

1.73. "**GVPs**" or "**Good Pharmacovigilance Practices**" means a set of guidelines for the conduct of pharmacovigilance in the EU, drawn up based on Article 108a of Directive 2001/83/EC, by the European Medicines Agency in cooperation with competent authorities in Member States and interested parties, and applying to marketing authorization holders in the EU or the Territory.

1.74. "**ICH**" means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.75. "**IMP**" or "**Investigational Medicinal Product**" means […***…].

1.76. "**IND**" or "**Investigational New Drug Application**" means an investigational new drug application, clinical study application, clinical trial exemption, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

1.77. "**IND Filings**" has the meaning set forth in Section 7.2(c).

1.78. "**Indemnification Claim Notice**" has the meaning set forth in Section 16.3.

1.79. "**Indemnified Party**" has the meaning set forth in Section 16.3.

1.80. "**Indemnifying Party**" has the meaning set forth in Section 16.3.

1.81. "**Indemnitees**" has the meaning set forth in Section 16.3.

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1.82. "**Initial BIAL Patent**" means the US patent […***…] and any patent term extension thereof.

1.83. "**Initial Indication**" means […***…], as filed by BIAL with the European Medicines Agency, or any indication substantially similar thereto as recommended, required or approved by an Agency.

1.84. "**Initial Product**" means a capsule formulation in fully finished and final packaged consumer form ready for sale and administration, […***…]. The definition of Initial Product may also include a capsule formulation in fully finished and final packaged consumer form ready for sale and administration, containing […***…] and in fully finished and final packaged consumer form, provided that […***…].

1.85. "**Intellectual Property**" means any Patents (including, without limitation, the BIAL Patents and NBIX Patents), Development Intellectual Property, copyrights, designs, database rights, trademarks (including, without limitation, the Trademarks), know-how (including, without limitation, the BIAL Know-How and the NBIX Know-How), trade secrets, proprietary information or data (including, without limitation, any regulatory filings and related data), or any application for any of the foregoing, or any other forms of comparable property rights protected by applicable law.

1.86. "**Interaction Agenda**" has the meaning set forth in Section 7.2(e).

1.87. "**Joint Patent**" means a Patent covering Development Intellectual Property jointly owned by the Parties.

1.88. "**JSC**" has the meaning set forth in Section 5.2.

1.89. "**Kick-Off Meeting**" has the meaning set forth in Section 2.6(a).

1.90. "**Knowledge of BIAL**" means BIAL's and its Affiliates' actual understanding and knowledge in good faith as possessed by its Executive Officers.

1.91. "**Label Related Documents & Materials**" has the meaning set forth in Section 7.2(a).

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1.92. "**LCIA**" means the London Court of International Arbitration.

1.93. "**Licensed Products**" means the Initial Product, any Subsequent Products and any Investigational Medicinal Product.

1.94. "**Losses**" has the meaning set forth in Section 16.1.

1.95. "**Manufacturing Know-How**" means manufacturing information, unpatented inventions, trade secrets, proprietary materials, or any other type of proprietary or confidential technical data or information, including, without limitation, methods, techniques, processes, specifications, recipes, formulae, designs, plans, drawings, data, or protocols, which are Controlled by BIAL or its Affiliates as of the Effective Date or during the Term and are either **(i)** reasonably necessary for the manufacture of the BIA 9-1067 API, or **(ii)** reasonably useful for the manufacture of BIA 9-1067 API to the extent that BIAL or its Affiliates have developed or used such know-how in connection with the BIA 9-067 API as of the Effective Date or during the Term; provided however that in the event that any Third Party becomes a BIAL Affiliate by merger with or by acquisition of BIAL or any of its Affiliates, any manufacturing know-how of such Third Party in existence as of the effective date of such merger or acquisition shall not be included in Manufacturing Know-How, unless such manufacturing know-how was Controlled by BIAL or its Affiliates prior to the effective date of such merger or acquisition, or it is used thereafter and Controlled by BIAL or its Affiliates in connection with the manufacture of the BIA 9-1067 API. For greater certainty, the Manufacturing Know-How is not included in the BIAL Know-How.

1.96. "**Marketing Authorization**" means all approvals from the relevant Regulatory Authority necessary to import, market and sell a pharmaceutical product (including, without limitation, as and when applicable, all drug pricing and governmental reimbursement approvals, and Approval).

1.97. "**Milestone Event**" has the meaning set forth in Section 3.1(b).

1.98. "**Milestone Payments**" has the meaning set forth in Section 3.1(b).

1.99. "**Minimum Detail Effort**" has the meaning set forth in Section 2.10(c)(i).

1.100. "**Minimum Sales**" has the meaning set forth in Section 8.3(f).

1.101. "**Minimum Supply Price**" has the meaning set forth in Paragraph 1.1(a) of Exhibit 4.

1.102. "**NBIX Indemnitees**" has the meaning set forth in Section 16.1.

1.103. "**NBIX Know-How**" means **(a)** research and development or commercialization information, unpatented inventions, trade secrets, proprietary materials, or any other proprietary or confidential technical data or information, Development Intellectual Property, including without limitation, products, methods, techniques, processes, specifications, recipes, formulae, designs, plans,

drawings, data, protocols or non-clinical and clinical studies (including, without limitation Data), which are generated by or under the authority of NBIX or its Affiliates and contractors or otherwise Controlled by NBIX during the Term (including without limitation any of the foregoing arising from any Development Studies), and are either **(i)** reasonably necessary for the manufacture, use, development, marketing, distribution, importation, commercialization, offer for sale or sale of BIA 9-1067 or any Licensed Product, or **(ii)** useful for the manufacture, development, marketing, distribution, importation, commercialization, offer for sale or sale of any Licensed Products to the extent that NBIX has developed or otherwise uses such know-how in connection with BIA 9-1067 or any Licensed Products. The term "NBIX Know-How" includes all information included in INDs/NDAs and any other regulatory filings and correspondence related to BIA 9-1067 or any Licensed Product and all Data and information submitted in support of such filings or correspondence, and information relating to marketing and commercialization, to the extent Controlled by NBIX during the Term and which relate to BIA 9-1067, the Initial Product or any other Licensed Products, and NBIX's interest in Development Intellectual Property jointly owned by the Parties; provided however that in the event that any Third Party becomes an Affiliate of NBIX by merger with or by acquisition of NBIX or any of its Affiliates, any know-how of such Third Party in existence as of the effective date of such merger or acquisition shall not be included in NBIX Know-How so long as it is not used and was not generated in connection with the development, manufacture or commercialization of any Licensed Product.

1.104. "**NBIX License**" has the meaning in Section 2.7(b).

1.105. "**NBIX Patents**" means any and all Patents which are Controlled by NBIX and which: **(i)** claim or cover or would be practiced by using, manufacturing, developing, marketing, distributing, importing, commercializing, offering for sale or selling BIA-9-1067 or the Licensed Products; or **(ii)** claim or cover Development Intellectual Property Controlled by NBIX.

1.106. "**NDA**" means a New Drug Application or similar application or submission for Approval of a pharmaceutical product filed with Regulatory Authority to obtain marketing approval for such product.

1.107. "**Net Sales**" means the gross amounts invoiced by NBIX or its Affiliates (the "**Selling Party**") on account of sales of the Licensed Products to the first Third Party in the distribution chain in the Territory, less the following deductions to the extent actually allowed and specifically allocated to the Licensed Products by the Selling Party in accordance with GAAP:

[…***…]

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[…***…].

In no event shall any particular amount, identified above, be deducted more than once in calculating Net Sales (i.e., no "double counting" of reductions). Sales of the Licensed Products between the Selling Party and its Affiliates shall be excluded from the computation of Net Sales, but the subsequent resale of such the Licensed Products to the first Third Party in distribution chain shall be included within the computation of Net Sales. Any amounts hereunder shall be determined from the books and records of the Selling Party maintained in accordance with GAAP, consistently applied to all products of the Selling Party.

Notwithstanding the foregoing, "Net Sales" shall not include any amounts invoiced for sales of Licensed Products supplied for use in clinical trials conducted by or on behalf of NBIX (including investigator initiated studies where NBIX does not charge for Licensed Product), or under any early access, named patient, indigent access, patient assistance or other programs whereby patients received free Licensed Product, or as samples or donations.

In the event that the Parties agree that NBIX commercializes a Combination Product, the Parties will, in connection with the negotiation under Section 2.9, determine a reasonable allocation of Net Sales to BIA 9-1067 and the other active pharmaceutical ingredient(s) therein.

1.108. "**Net Sales Estimation**" has the meaning set forth in Section 8.3(e).

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1.109. "**Net Sales Volume**" means, for each applicable period, […***…].

1.110. "**Net Selling Price**" means, for each applicable period, […***…].

1.111. "**Nonclinical Study**" means any study of a product or active pharmaceutical ingredient which is not conducted in humans and which may be conducted in animals (*in vivo*) or in a test tube (*in vitro*).

1.112. "**Non-Extension Party**" has the meaning set forth in Section 11.4(e).

1.113. "**Opposition Contest**" has the meaning set forth in Section 11.2.

1.114. "**Outside Territory KOL**" means healthcare providers outside of the Territory that have administered a Licensed Product in clinical trials, have published academic articles relating to a Product, or are otherwise regarded by BIAL, its Affiliates and licensees or NBIX, as the case may be, as a key opinion leader ("**KOL**") for a Licensed Product or products in the same therapeutic class outside of the Territory.

1.115. "**Patent**" means any and all patents, patent applications and patents issued from such patent applications, including, without limitation, divisions, continuations, continuations-in-part, reissues, renewals, extensions, supplementary protection certificates, and the like of any such patents and patent applications and foreign equivalents thereof.

1.116. "**Phase I Clinical Trial**" means a clinical trial in humans the principal purpose of which is determining safety and/or metabolism, and/or pharmacokinetic properties and/or clinical pharmacology of such product, as described in 21 C.F.R. § 312.21(a), as amended from time to time.

1.117. "**Phase II Clinical Trial**" means a clinical trial in humans of a product for an indication, the principal purpose of which is a determination of safety and efficacy for such indication in the target patient population over a range of doses and/or to obtain sufficient information about such product's efficacy to permit the design of further clinical trials, as described in 21 C.F.R. § 312.21(b), as amended from time to time.

1.118. "Phase III Clinical Trial" means a clinical trial in humans of a product for an indication on a sufficient number of subjects that is prospectively designed to statistically demonstrate that the product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with the product in the dosage range to be prescribed, and to support regulatory approval of the product for such indication or label expansion of the product, as described in 21 C.F.R. § 312.21(c), as amended from time to time.

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1.119. "**Phase IV Studies**" means both post-marketing and pharmacoeconomic studies that are initiated by NBIX after Approval and are not requested, mandated or required by an Agency to support or maintain an Approval. Phase IV Studies does not include investigator initiated studies or Post-Approval Commitment Studies in the Territory.

1.120. "**Post-Approval Commitment Studies**" means any study or data collection effort in respect of the Licensed Products which is requested, mandated or required by an Agency following an Approval for the Licensed Products in the Territory.

1.121. **"Process Modification Costs"** has the meaning set forth in Section 12.2(d).

1.122. "**Product Specifications**" means the specifications for the Initial Product, as such specifications shall be defined in the Quality Agreement , as may be amended or modified by BIAL from time to time in accordance with the terms of the Quality Agreement.

1.123. "**Publishing Party**" has the meaning set forth in Section 9.3(b).

1.124. "**Quality Agreement**" means a quality agreement between the Parties relating to the IMP and/or the Licensed Products.

1.125. "**Recall Costs**" has the meaning set forth in Section 7.8(b).

1.126. **"Reconciliation Payment"** has the meaning set forth in paragraph 1.2(a) of Exhibit 4.

1.127. "**Regulatory Authority**" means any governmental and/or regulatory authority involved in granting approvals for the marketing, reimbursement and/or pricing of a pharmaceutical product including, without limitation, as and when applicable, the EMA in the European Union, and an Agency in the Territory.

1.128. "**Representatives**" has the meaning set forth in Section 13.3(a).

1.129. **"Re-Manufacturing"** has the meaning set forth in Section 7.9.

1.130. "**Right to Object**", with respect to a Development and Regulatory Plan, has the meaning set forth in Section 6.3(h), and with respect to any Label Related Documents & Materials, has the meaning set forth in Section 7.2(b).

1.131. "**SDEA**" or "**Safety Data Exchange Agreement**" has the meaning set forth in Section 7.5(a).

1.132. "**Subsequent Indication**" means any indication within the Field other than the Initial Indication.

1.133. "**Subsequent Product**" means: **(a)** […***…]; and **(b)** any Combination Product.

1.134. "**Subsequent Product Development**" has the meaning set forth in Section 2.9(a).

1.135. **"Subsequent Tentative Supply Price"** has the meaning set forth in paragraph 1.1(b)(ii) of Exhibit 4.

1.136. "**Supply Agreement**" has the meaning set forth in Section 4.1(b).

1.137. "**Supply Price**" means the supply price for the Initial Product as set forth in Paragraph 1.1(a) of Exhibit 4.

1.138. **"Supply Price Report"** has the meaning set forth in paragraph 1.2(a) of Exhibit 4.

1.139. **"Supply Related Filings"** has the meaning set forth in Section 7.2(f).

1.140. **"Tentative Supply Price"** has the meaning set forth in paragraph 1.1(b)(ii) of Exhibit 4.

1.141. "**Term**" has the meaning set forth in Section 15.1(a).

1.142. "**Termination Event**" has the meaning set forth in Section 15.2.

1.143. "**Territory**" means the United States of America ("US") and Canada.

1.144. "**Territory KOL**" means healthcare providers in the Territory that have administered a Licensed Product in clinical trials, have published academic articles relating to a Licensed Product, or are otherwise regarded by BIAL, its Affiliates and licensees or NBIX, as the case may be, as a key opinion leader for a Licensed Product or products in the same therapeutic class in the Territory.

1.145. "**Third Party**" means any person or entity who or which is neither a Party nor an Affiliate of a Party.

1.146. "**Third Party License**" has the meaning set forth in Section 12.2(c).

1.147. "**Trademark**" means the US and Canadian trademarks or trademark applications Controlled by BIAL and listed in **Exhibit 2.3**, for use in conjunction with the Licensed Products within the Field and Territory, or any trademark that is selected by the Parties pursuant to the terms of Section 2.3(c). For the avoidance of doubt, the term "Trademarks" does not encompass the INN Opicapone, the BIAL Logo or any marks, brand names and/or other indicators of source not specifically listed in Exhibit 2.3.

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1.148. "**Transfer Plan**" has the meaning set forth in Section 2.6(b).

1.149. "**Unit**" means each single tablet, capsule or other pharmaceutical finished form of the Licensed Products as specifically applied to each dosage strength.

1.150. "**US**" means the United States of America, including its territories and possessions.

1.151. **Interpretation.** In this Agreement (except where the context otherwise requires):

(a) any reference to a Recital, Section or Exhibit is a reference to the relevant recital, section or exhibit of or to this Agreement, and the Exhibits and Recitals form part of this Agreement;

(b) the table of contents and section headings are included for convenience only and shall not affect the interpretation of this Agreement;

(c) use of the singular includes the plural and vice versa;

(d) use of any gender includes the other genders;

(e) any reference to "persons" includes natural persons, firms, partnerships, companies, corporations, associations, organizations, governments, governmental agencies and departments, states, foundations and trusts (in each case whether or not having separate legal personality);

(f) any reference to an English legal term for any action, remedy, method of judicial proceeding, legal document, legal status, court, official or any legal concept or thing shall, in respect of any jurisdiction other than England, be deemed to include a reference to what most nearly approximates in that jurisdiction to the English legal term;

(g) the words "include", "includes", "including" and "such as" and "in particular" are to be construed as if they were immediately followed by the words "without limitation"; and

(h) references to any statute or statutory provision shall include (i) any subordinate legislation made under it, (ii) any provision which it has modified or re-enacted (whether with or without modification) and (iii) any provision which subsequently supersedes it or re-enacts it (whether with or without modification).

ARTICLE 2
GRANT OF RIGHTS

2.1 **Sole Commercialization License**: BIAL grants to NBIX during the Term a sole and non-sublicensable license under the BIAL Patents and BIAL Know-How and BIAL's interest in the jointly owned Development Intellectual Property and Joint Patents to use, market, distribute, import, commercialize, offer for sale and sell the Licensed Products under the Trademark within the Field and

Territory. The “sole” license means that, save that BIAL retains the right to co-promote as set forth in Section 2.10 below and subject to Section 2.1(g)(ii), NBIX has the exclusive (even as to BIAL) license under the BIAL Patents and BIAL Know-How and BIAL’s interest in the jointly owned Development Intellectual Property and Joint Patents to use, market, distribute, import, commercialize, offer for sale and sell the Licensed Products under the Trademark within the Field and Territory.

(a) BIAL reserves to itself all rights not expressly granted to NBIX under this Agreement, including all rights under the BIAL Know-How and BIAL’s interest in Development Intellectual Property and in Joint Patents for all uses outside of the Territory.

(b) NBIX agrees not to directly or indirectly export, develop, manufacture, use, quality control, package, register, market (except as expressly set forth in Exhibit 2.1(g)(i)), distribute, commercialize, offer for sale or sell BIA 9-1067 in any form or formulation and/or any Licensed Products and/or use the Trademarks outside the Territory. NBIX shall promptly notify BIAL if it has reason to believe that any Licensed Product has been or will be exported from the Territory. Other than in accordance with this Agreement and the Supply Agreement, BIAL agrees not to directly or indirectly license any Third Party licensees or distributors to export, develop, manufacture, use, quality control, package, register, market, distribute, commercialize, offer for sale or sell BIA 9-1067 in any form or formulation and/or any Licensed Products and/or use the Trademarks in the Territory. BIAL shall promptly notify NBIX if it has reason to believe that any Licensed Product (other than Licensed Product supplied to NBIX) has been or will be exported into the Territory. Upon either Party notification to the other pursuant to this Section 2.1(b), the Parties shall in good faith discuss any possible actions to be undertaken by any or both Parties, provided that neither Party shall be under an obligation to agree on any such actions.

(c) NBIX shall not have any right or license under the BIAL Patents, BIAL Know-How, BIAL’s interest in any Development Intellectual Property and in Joint Patents, Trademarks or Manufacturing Know-How to manufacture or have manufactured Licensed Products, except as separately agreed by the Parties in writing.

(d) NBIX shall not have any right to develop or have developed Subsequent Products unless separately agreed by the Parties in writing.

(e) Subject to Sections 2.3 and 2.4, the primary and secondary packaging of the Licensed Product shall bear the Trademark and BIAL’s trade dress and logo and, to the extent permitted by applicable laws and regulations in the Territory, shall contain with legible letters of reasonable size the words “under license from [BIAL Logo]” unless BIAL determines in its sole discretion that such reference shall be “under license from BIAL”.

(f) Subject to Section 2.4, the promotional materials and documents that are used by NBIX in connection with the development, marketing, distribution, importation, commercialization, offer for

sale and sale of the Licensed Products shall, to the extent allowed under the laws and regulations in the Territory, contain with legible letters of reasonable size the words "under license from [BIAL Logo]" or, as determined by BIAL in its sole discretion, "under license from BIAL".

(g) The Parties agree that **(i)** NBIX shall have certain rights to engage in marketing-related activities with respect to Licensed Products in cooperation with BIAL outside the Territory, for the purpose of promotion of Licensed Products by NBIX and its Affiliates in the Field in the Territory, and **(ii)** BIAL shall have certain rights to engage in marketing-related activities with respect to Licensed Products in cooperation with NBIX in the Territory, for the purpose of promotion of Licensed Products by BIAL and its Affiliates and licensees outside the Territory and to prepare a Co-Promotion Plan in accordance with Section 2.10(b), in each case, strictly in accordance with **Exhibit 2.1(g)**. For clarification, nothing herein or in Exhibit 2.1(g) shall give NBIX any license or other right to develop, use, sell, offer for sale, and import Licensed Products outside the Territory.

(h) For greater certainty, NBIX shall not have any right, license or authorization, during or after the Term, to practice or otherwise use (directly or via any Affiliates or Third Parties) any BIAL Know-How, BIAL Patents, Joint Patents, BIAL Development Intellectual Property or Trademark outside of the Territory until the end of the term of the confidentiality obligation hereunder and further provided that NBIX can obtain such BIAL Know-How and BIAL Development Intellectual Property from a Third Party publicly available source.

2.2 Non-Exclusive Development License: BIAL grants to NBIX during the Term a non-exclusive and non-sublicensable license under the BIAL Patents, BIAL Know-How and BIAL's interest in jointly owned Development Intellectual Property and Joint Patents to develop Licensed Products within the Field and Territory (the "**Development License**").

(a) The development of Licensed Products under the Development License includes all activities necessary or useful for regulatory and commercialization purposes within the Field and Territory. All development of Licensed Products under the Development License shall in all cases be subject to the prior approval of the JSC in accordance with Article 5 and all development of Subsequent Products shall be subject to the prior written approval of BIAL in accordance with Section 2.9.

(b) BIAL retains the right, in accordance with this Section 2.2(b), to, directly or via its Affiliates or Third Party contractors, carry out any development activities with respect to Licensed Products and/or the BIA 9-1067 API in the Territory. BIAL shall provide not less than […***…] days advance notification to NBIX before seeking to commence any Clinical Trial of any Licensed Product in the Territory and shall consult with NBIX as to the scope (*i.e.* intended number of patients to be recruited), Clinical Trial design, and location of such Clinical Trial and shall consider NBIX's comments and suggestions in good faith. BIAL shall not conduct any Clinical Trial with respect to any Licensed Product in the Territory in the event that NBIX objects to such Clinical Trial and it is able to

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reasonably demonstrate in writing that conducting such Clinical Trial could adversely affect NBIX's development and/or commercialization of any Licensed Product in the Territory.

2.3 **Trademark License**: BIAL grants NBIX during the Term a sole, non-sublicensable, royalty-free license to use the Trademark solely in connection with the promotion, marketing, distribution and sale of the Licensed Products in the Field in the Territory. The "sole" license means that, save that BIAL retains the right to co-promote as set forth in Section 2.10 and subject to Section 2.1(g), NBIX has the exclusive rights even as to BIAL.

(a) BIAL or its Affiliate shall own all right, title and interest in the Trademark and the goodwill associated therewith. BIAL shall be solely responsible for registering and maintaining such Trademark and shall not abandon such Trademark or license others to use such Trademark in the Territory without the prior written consent of NBIX. If reasonably requested by BIAL, NBIX shall assist and cooperate with BIAL in the selection, registration and maintenance of the Trademark in the Territory, at BIAL's expense.

(b) Any marketing, promotion, sale or distribution of Licensed Products by or on behalf of NBIX under the license set forth in Section 2.1, shall take place exclusively under the Trademark.

(c) The Trademark shall be the same selected by BIAL and approved by the EMA (*i.e.* Ongentys®); provided that **(i)** in the event that such Trademark is not accepted by the relevant Agency in the Territory or **(ii)** NBIX can demonstrate to BIAL in writing via properly documented market research that such Trademark is not appropriate for the Licensed Products in the Territory, the Parties shall discuss and mutually select other trademark or trademarks from those listed Exhibit 2.3.

(d) In the event that **(i)** such other Trademark or Trademarks listed Exhibit 2.3 is/are not accepted by the Agency or **(ii)** NBIX can demonstrate to BIAL in writing via properly documented market research that such Trademark or Trademarks is/are not appropriate for the Licensed Products in the Territory, the Parties shall discuss and mutually agree upon trademarks **("Alternative Trademarks")** other than the Trademarks. In the event that any of the Alternative Trademarks are not already registered or applied for by BIAL, then NBIX shall, with the prior written consent of BIAL, apply for such trademarks (if not already registered or applied for by NBIX), and NBIX shall propose one or more of the Alternative Trademarks to the FDA for approval and in the event that the FDA approves an Alternative Trademark, NBIX shall within […***…] days after such FDA approval, assign the approved Alternative Trademark or Alternative Trademark application and all right, title and interest in and to, including the goodwill associated thereto, such Alternative Trademark to BIAL or its Affiliate at no cost to BIAL and thereafter such Alternative Trademark shall be deemed a Trademark such that it shall be automatically added to Exhibit 2.3, pursuant to this Section 2.3(c), and all other Trademarks or Trademark applications listed in Exhibit 2.3 will be considered automatically excluded from Exhibit 2.3 and from the Trademark license granted hereunder.

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(e) NBIX shall not file or obtain any trademark application or registration, or Internet domain name registration, comprised of, containing or confusingly similar with, any Trademarks, Alternative Trademarks, trademarks used for the Licensed Products outside the Territory, or the INN Opicapone, or any variations thereof, without BIAL's express written permission.

(f) BIAL reserves to itself all rights in and to the Trademarks outside of the Territory; provided, however, NBIX shall have the right to use the Trademark as expressly provided in Section 2.1(g).

2.4 BIAL Logo License:

(a) BIAL grants NBIX a non-exclusive license during the Term to use the BIAL Logo on all packaging materials, promotional materials and documents that are used by NBIX either directly on its own and/or through its contractors in connection with the marketing, distribution, importation, commercialization, offer for sale and sale of the Licensed Products. NBIX shall use the BIAL Logo on all such materials on which it also uses the NBIX logo to the extent permitted by the relevant Agency.

(b) If BIAL modifies or otherwise changes the BIAL Logo then:

(i) BIAL shall pay for all official fees associated with varying or amending any Approvals in respect of such change of the BIAL Logo;

(ii) NBIX shall have the right to continue to use its stocks of packaging materials, promotional materials and documents with the previous BIAL Logo that existed at the time of such change or are on order at that date until such stocks are exhausted, unless BIAL pays NBIX for the costs of replacement materials bearing the new BIAL Logo.

2.5 Contracting:

NBIX shall have the right to contract with Third Parties in the Territory to perform its development and commercialization (i.e. marketing services, such as market research, development of marketing materials, or pricing research, but not services such as Detailing) responsibilities under this Agreement in accordance with the terms of this Agreement; provided: **(i)** that NBIX markets, imports, distributes, commercializes, offers for sale and sells the Licensed Products at all times in its own name, **(ii)** that NBIX enters into a written agreement with such Third Parties, which imposes obligations on such Third Parties substantially similar to those imposed on NBIX under this Agreement (as appropriate to the particular arrangements with the Third Party), **(iii)** that, unless otherwise requested by BIAL pursuant to Section 15.5(i)*(A)* or agreed between the Parties or required by applicable law, an institutional review board or a drug safety monitoring board, or a clinical trial site, despite the use of Commercially Reasonable Efforts by NBIX, all contracts relating to Licensed Products shall terminate automatically on early termination of this Agreement, **(iv)** that any such contracts contain confidentiality provisions consistent with this Agreement, **(v)** that NBIX obtains an assignment from such Third Parties

of any Development Intellectual Property made by such Third Parties under such agreement and **(vi)** that NBIX remains, at all times, solely responsible and liable to BIAL for all of such Third Parties' activities and for any failure by such Third Parties to comply with the terms of this Agreement.

2.6 Delivery of BIAL Know-How:

(a) Kick-Off Meeting: Promptly following the Effective Date but in no event later than […***…] Business Days following the Effective Date, the Parties shall hold a face to face meeting at BIAL's head-office, at a mutually agreed appropriate time ("**Kick-Off Meeting**"), in order to discuss and agree the transfer of the existing BIAL Know-How necessary for the development, promotion, marketing and sale of the Licensed Products in the Territory, including the transfer to NBIX in accordance with Section 2.6(b). The Alliance Managers shall be responsible for co-ordinating and setting up the meeting. The agenda for the meeting shall be mutually agreed by both Parties.

(b) Technology Transfer: Promptly following the Effective Date, BIAL shall commence the transfer to NBIX of all BIAL Know-How pursuant to the technology transfer plan set forth in Exhibit 2.6(b) (the "**Transfer Plan**"). BIAL shall complete the transfer described in the Transfer Plan within […***…] days after the Kick-Off Meeting. If such transfer is not completed by the end of such […***…]-day period, then all development and commercialization timelines set forth in this Agreement will be extended by the number of days by which the completion of the technology transfer is delayed. Each Party shall bear its own expenses in conducting such technology transfer.

(c) IND Ownership of BIA 9-1067 IND: Within […***…] Business Days after the Effective Date, BIAL shall submit to the FDA the application requesting the transfer of the BIA 9-1067 IND to NBIX. BIAL shall transfer all right, title and interest in the BIA 9-1067 IND to NBIX, subject to the reservation set forth in Section 2.6(c)(ii), for the Term of this Agreement. NBIX shall promptly notify the FDA in writing that the BIA 9-1067 IND has been transferred to NBIX and that NBIX accepts all rights and responsibilities thereunder.

(i) Subject to the exclusive licenses granted to NBIX herein, BIAL retains all right, title and interest in all BIAL Know-How submitted in support of the BIA 9-1067 IND, including but not limited to, all safety and effectiveness data, provided that NBIX has the right to rely upon and utilize such BIAL Know-How during the Term to support any future regulatory applications or submissions to the FDA, Health Canada, or any other relevant regulatory bodies in the Territory related to the Licensed Products and to the extent consistent with the terms of this Agreement.

(ii) BIAL reserves the right to use and refer to the BIA 9-1067 IND and BIAL Know-How submitted in support of the BIA 9-1067 IND, including but not limited to, all safety and effectiveness data for ***(A)*** any purpose outside the Territory, including without limitation for any development and regulatory activities, and ***(B)*** in accordance with the provisions of Section

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2.2(b) and Article 6, for the sole purpose of conducting permitted development activities within the Territory.

(iii) Upon the expiration or termination of this Agreement, all right, title, and interest in the BIA 9-1067 IND shall be assigned back to BIAL in accordance with Section 15.5(c).

(d) **BIAL Know-How and BIAL Development Intellectual Property during the Term**: BIAL shall, as soon as reasonably practicable, and in any event on a Calendar Year basis or as reasonably requested by NBIX, provide NBIX, in the form agreed upon by the Parties, with any BIAL Know-How (including without limitation, BIAL Development Intellectual Property) that comes under BIAL's Control after the Effective Date and during the Term.

(e) All BIAL Know-How (including without limitation BIAL Development Intellectual Property) disclosed to NBIX under Sections 2.6(a), 2.6(b) and 2.6(c) above, is subject to the terms and conditions of this Agreement, including without limitation, the confidentiality provisions of Article 13 and Section 9.4(a).

2.7 **NBIX License to BIAL under NBIX Patents, NBIX Development Intellectual Property, Joint Patents and NBIX Know-How**:

(a) NBIX shall, as soon as reasonably practicable, and in any event on a Calendar Year basis or as reasonably requested by BIAL, provide BIAL, in the form agreed upon by the Parties, with any NBIX Know-How and any NBIX Development Intellectual Property created during the Term.

(b) NBIX grants to BIAL a royalty-free, irrevocable, perpetual, non-exclusive license, with the right to grant sublicenses to BIAL's Affiliates and Third Party licensees through multiple tiers of sublicensees, in any country outside the Territory, under NBIX Patents, NBIX's interest in Joint Patents, NBIX's Development Intellectual Property and NBIX Know-How (including Data) to develop, use, manufacture, package, make, have made, import, register, distribute, market, offer for sale, commercialize and sell products that contain or comprise BIA 9-1067, alone or in combination with other active pharmaceutical ingredient(s), in any form or formulation, and/or use processes to manufacture such products, in each case outside the Territory ("**NBIX License**"); provided however that, under the NBIX License, BIAL shall also have a royalty-free, irrevocable, perpetual, non-exclusive license, with the right to grant sublicenses to BIAL's Affiliates and Third Party licensees through multiple tiers of sublicensees, in any country outside the Territory, under NBIX Patents, NBIX's interest in Joint Patents, NBIX's Development Intellectual Property and NBIX Know-How (including Data) to manufacture, have manufactured, package, have packaged, make, have made, import and/or have imported products that contain or comprise BIA 9-1067, alone or in combination with other active pharmaceutical ingredient(s), in any form or formulation, and/or use processes to manufacture such products in the Territory. For the avoidance of doubt, notwithstanding that the NBIX License under this Section 2.7(b) is non-exclusive, NBIX shall not, without the prior written consent of BIAL (which, for

the avoidance of doubt, BIAL may withhold at its discretion), have any license, right or any authorization to practice or otherwise use (directly or via any Affiliates or Third Parties) NBIX Patents, NBIX's interest in Joint Patents, NBIX Development Intellectual Property and NBIX Know-How (including Data) for any purpose whatsoever outside the Territory during the Term and thereafter for the period that BIAL Controls outside the Territory any Blocking BIAL IP.

(c) After the Term and thereafter the period that BIAL Controls outside the Territory any Blocking BIAL IP, the NBIX License under Section 2.7(b) shall continue as a royalty-free, irrevocable and non-exclusive license, provided, however, that in the event that BIAL is interested to negotiate an exclusive license under NBIX Patents, NBIX's interest in Joint Patents, NBIX Development Intellectual Property and NBIX Know-How (including Data), then the Parties shall negotiate in good faith the terms of a license, including consideration payable by BIAL for such exclusivity.

(d) NBIX shall use Commercially Reasonable Efforts to ensure that NBIX retains all right, title and interest in and to any of NBIX Know-How, NBIX Patents and NBIX Development Intellectual Property. If NBIX is unable to retain all right, title and interest in and to any NBIX Know-How, NBIX Patents and NBIX Development Intellectual Property, NBIX shall use Commercially Reasonable Efforts to obtain an exclusive, worldwide license under such NBIX Know-How, NBIX Patents and NBIX Development Intellectual Property, to import, develop, manufacture, quality control, package, use, market, distribute, commercialize, offer for sale and sell products that contain or comprise BIA 9-1067, alone or in combination with other active pharmaceutical ingredient(s), in any form or formulation, and/or use processes to manufacture such products, in each case outside the Territory, with the right to grant BIAL a sublicense consistent with the terms in Sections 2.7(b) and 2.7(c).

2.8 Non-Compete Undertaking:

(a) During the Term of this Agreement, NBIX and its Affiliates shall not directly or indirectly, use, develop, market, distribute, import, commercialize, promote, offer for sale or sell any Competing Product within the Field and Territory.

(b) In the event that a Third Party becomes an Affiliate of NBIX after the Effective Date through merger, acquisition, consolidation or other similar transaction (other than a Change of Control of NBIX), and such Third Party, as of the closing date of such transaction, is conducting any activities with respect to a Competing Product that would cause NBIX to breach Section 2.8(a), then NBIX and its new Affiliate or Affiliates shall have […***…] from the closing date of such transaction to complete the Divestiture of such Competing Product. The conduct of activities with respect to such Competing Product by NBIX and any applicable Affiliate during such […***…] period shall not deemed a breach of this Section 2.8, provided that such new Affiliate conduct such activities with respect to such Competing Product during such […***…] period independent from the activities under this Agreement and does not use any BIAL Confidential Information, BIAL Patents, Development Intellectual Property or any BIAL Know-How in the conduct of such activities.

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"**Divestiture**", as used in this Section 2.8(b), means the sale or transfer of rights to the Competing Product to a Third Party without retaining any decision-making related to or Control of such Competing Product.

2.9 Subsequent Product(s):

(a) If NBIX is interested in developing any Subsequent Product in the Territory by conducting Nonclinical Studies, Phase I or Phase II Clinical Studies (such research or development to be referred to as **"Subsequent Product Development")**, then, subject to NBIX **(i)** demonstrating to BIAL with written evidence that […***…], and **(ii)** providing BIAL with […***…], then the Parties may agree in their absolute discretion that such Subsequent Product may be developed. In such event, the Parties shall discuss whether any amendments to the SDEA, the Supply Agreement and the Quality Agreement are necessary.

(b) If, after reaching an agreement on the matters identified in Section 2.9(a) and completing Subsequent Product Development, NBIX is interested in developing and commercializing in the Territory any Subsequent Product by conducting Phase III Clinical Trial(s), then subject to NBIX **(i)** demonstrating to BIAL with written evidence that […***…], and **(ii)** providing BIAL with […***…], then the Parties may agree in their absolute discretion that such Subsequent Product may be developed. In such event:

(A) the Parties shall negotiate in good faith to determine whether NBIX or BIAL will supply such Subsequent Product and either ***(A)*** a supply price and minimum supply price for the supply, from BIAL or its Affiliate or designee to NBIX, of the Subsequent Product and/or IMP to be used for Development Studies; or ***(B)*** the amount to be paid to BIAL in respect of each Unit of Subsequent Product and/or the IMP to be used for Development Studies manufactured by or on behalf of NBIX and the mechanism for such payment; and

(B) the Parties shall enter into appropriate amendments to this Agreement, the SDEA, the Supply Agreement and the Quality Agreement.

(c) In the event that the Parties fail to reach an agreement with respect to the matters identified in Sections 2.9(a) and 2.9(b) and other terms and conditions thereof within the period of […***…]

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[…***…] after NBIX's notification to BIAL pursuant to Section 2.9(a), then NBIX shall not have any rights (including, without limitation, the right to develop, manufacture, register or commercialize) with respect to such Subsequent Product, and for clarity BIAL shall have no such rights in the Territory during the Term either.

2.10 Co-Promotion:

(a) Option. Starting the earlier of **(i)** […***…] to a period of […***…] thereafter after or **(ii)** during the period […***…], BIAL shall have the right to, directly or via an Affiliate or contractor (subject to the terms of 2.10(c) below), and in common and coordinated with NBIX, to initiate co-promotion of the Licensed Products in the US (the "**Co-Promotion Option**"). For purposes of this Section 2.10, "co-promote" or "co-promotion" means the Detailing of such Licensed Product by BIAL or its Affiliates or contractors under the then-current Approval and the Trademark, and shall not mean the sale or distribution of such Licensed Product by BIAL or its Affiliates or contractors other than in accordance with this Agreement. For the avoidance of doubt, NBIX shall continue to book all sales in the Territory.

(b) Notice. BIAL may exercise the Co-Promotion Option by providing NBIX with […***…] advance written notice and a plan (the **"Co-Promotion Plan"**) with respect to its intended promotional efforts, including but not limited to, the number of representatives and their geographical alignment, estimated number of Details (which shall not in any event exceed […***…]) of the Detailing effort then being made by NBIX), compensation structure and sales force hiring plans and a reasonable sales projection. Following delivery of such notice and Co-Promotion Plan, the Parties shall negotiate a Co-Promotion Agreement (as defined below) reasonably and in good faith and with such diligence as is required to execute and deliver the Co-Promotion Agreement by […***…]. If the Parties cannot agree the terms of the Co-Promotion Agreement within such […***…] period then the terms shall be determined in accordance with the Final Position Arbitration Procedure set out in **Exhibit 2.10**.

(c) Terms of Co-Promotion Agreement. The terms and conditions of a co-promotion arrangement shall be set forth in a co-promotion agreement (the "**Co-Promotion Agreement**") to be entered into between the Parties as set forth in this Section 2.10(c).

(i) Subject to the provisions of Sections 2.10(d) to 2.10(i), the Parties shall negotiate and agree *(A)* the minimum number of Details (not to exceed […***…]) and the prioritization of such Details to be provided by BIAL based on BIAL's, its Affiliates' or contract sales force capabilities, and *(B)* the minimum number of Details and the prioritization of such Details to be provided by

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NBIX taking into account the then-current commercial requirements for the Licensed Products ("**Minimum Detail Effort**") .

(ii) BIAL shall have the right to use a contract sales force (**"CSO"**) at the time it initiates its Co-Promotion Option, provided that BIAL provides NBIX, with a detailed written plan to convert the relevant CSO employees to BIAL employees within […***…].

(iii) Except as specifically provided in the Co-Promotion Agreement, BIAL shall have exclusive responsibility for all costs and expenses of its CSO and/or its employees (collectively, **"BIAL Representatives"**), including all training (other than internal NBIX training costs), compensation, salaries, benefits and expenses, which shall include but not be limited to, sales infrastructure and support costs (such costs referred to as "**BIAL Representatives Costs**").

(iv) For so long as Licensed Product(s) are the only product(s) being promoted by BIAL Representatives, the BIAL Representatives Costs shall be paid […***…]. In the event the BIAL Representatives are promoting products other than the Licensed Products, the foregoing reimbursement mechanism shall be adjusted commensurately using the following guidelines:

(A) If BIAL Representatives are promoting […***…], then the product in the first Detail position shall be responsible for […***…]) of the BIAL Representatives Costs and the product in the second Detail position shall be responsible for […***…]) of the BIAL Representatives Costs; and

(B) If BIAL Representatives are promoting […***…], then the product in the first Detail position shall be responsible for […***…]) of the BIAL Representatives Costs, the product in the second Detail position shall be responsible for […***…]) of the BIAL Representatives Costs, and the product in the third Detail Position shall be responsible for […***…]) of the BIAL Representatives Costs.

(v) The Co-Promotion Plan shall be reviewed and agreed on an annual basis as part of the Annual Commercialization Plan and the Parties shall agree the Minimum Detail Effort that each Party shall make to target prescribers during each Calendar Year. The Parties shall also agree the maximum number of Details that BIAL may perform in any given Calendar Year. Either Party shall have the right to terminate the Co-Promotion Agreement if […***…], or, in the event BIAL uses a CSO, if BIAL has not

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converted the CSO to BIAL employees after […***…] of initiating the Detailing the Licensed Products under the Co-Promotion Agreement.

(vi) The Co-Promotion Agreement shall include such provisions as are usual and customary in co-promotion agreements in the Territory, including provisions related to sales force training and qualifications, incentive compensation, sales reporting system and data access, sales territory alignment, compliance with applicable laws, Detail allocation and Minimum Detail Effort requirements.

(vii) The Parties shall establish a co-promotion steering committee (the **"Co-Promotion Steering Committee"**) with equal management representation from both Parties who shall be directly involved in the co-promotion. The Co-Promotion Steering Committee shall jointly oversee the strategy and tactics for the marketing and sale of the Licensed Products on an annual basis and provide an Annual Commercialization Plan to the JSC for review and approval. The Co-Promotion Steering Committee shall report to the JSC and any disputes shall be resolved at the JSC; provided however, that if the JSC is unable to resolve the dispute, then NBIX shall have final decision-making authority to the extent it does not cause BIAL to incur additional costs or liabilities.

(d) Upon entry into the Co-Promotion Agreement and subject to performing the agreed Minimum Detail Effort and implementing the agreed Annual Commercialization Plan and associated promotional budget, the obligations under Sections 8.3(f), 8.3(g) and 8.3(h) shall not apply.

2.11. Change of Control Notice: Within […***…] after a Change of Control of NBIX, NBIX shall forthwith give notice in writing (a "**Change of Control Notice**") to BIAL. A Change of Control Notice shall inform BIAL of the Change of Control and provide details of the person or entity which has obtained control of NBIX. A failure to provide such a Change of Control Notice shall be considered to be an uncurable material breach of this Agreement allowing BIAL to terminate this Agreement in accordance with Section 15.2(a).

ARTICLE 3
PAYMENTS

3.1 **License Fees and Milestone Payments**: NBIX shall make the following payments to BIAL:

(a) License Fee: Within […***…] Business Days after the Effective Date, NBIX shall pay to BIAL Thirty Million United States Dollars (US$30,000,000), as a licensing fee. This license fee is not refundable under any circumstances and is not creditable against any payments due by NBIX under this Agreement or any other agreements between the Parties.

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(b) Milestone Payments: NBIX shall make the following one-time milestone payments (the "**Milestone Payments**") to BIAL upon the first occurrence of each of the milestone events specified below (each, a "**Milestone Event**"):

	Milestone Event	Milestone Payment (in US Dollars)
(i)	Upon confirmation from the FDA that [...***...] is not required to be completed prior to [...***...] for the [...***...] in the [...***...]:	$[...***...]
(ii)	Upon acceptance by the FDA of the [...***...] for the [...***...] in the [...***...]:	
	(a) In the event that [...***...] is not required to be completed prior to [...***...] for the [...***...] in the [...***...]:	$[...***...]
	Or	
	(ß) In the event that [...***...] is required to be completed prior to [...***...] for the [...***...] in the [...***...]:	$[...***...]
(iii)	Grant of [...***...] by the FDA for the [...***...] in the [...***...]:	US$[...***...]
(iv)	Upon the first occurrence of Net Sales in the Territory equal to or greater than [...***...] US Dollars (US$[...***...]) in any Calendar Year:	US$[...***...]
(v)	Upon the first occurrence of Net Sales in the Territory equal to or greater than [...***...] US Dollars (US$[...***...]) in any Calendar Year:	US$[...***...]
(vi)	Upon the first occurrence of Net Sales in the Territory equal to or greater than [...***...]	US$[...***...]

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[...***...] US Dollars (US$[...***...]) in any Calendar Year:

(c) NBIX shall report in writing the occurrence of each of Milestone Events (i), (ii) and (iii) to BIAL within […***…] of the date on which the Milestone Event has occurred, and shall pay the corresponding Milestone Payment within […***…] after the occurrence of the applicable Milestone Event. NBIX shall report in writing the occurrence of each of Milestone Events (iv), (v) and (vi), and shall pay the corresponding Milestone Payment, within […***…] the Milestone Event occurs. If two or more of the milestones set forth in Sections 3.1(b) (iv), (v) or (vi) occur in the same Calendar Quarter, then all applicable milestones shall be payable following such Calendar Quarter. The Milestone Payments are not refundable under any circumstances and are not creditable against any payments due by NBIX under this Agreement or any other agreements between the Parties.

3.2 Tax Matters:

(a) The Parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding or similar obligations in respect of payments made by NBIX to BIAL under Section 3.1, namely in accordance with the treaty between Portugal and the US to avoid double taxation.

(b) BIAL will pay and otherwise be responsible for all value added taxes and transfer taxes and/or taxes of equivalent effect in connection with any payment made to BIAL pursuant to this Agreement or the Supply Agreement, for all applicable sales, goods and services. For the avoidance of doubt, customs and import duties and levies and/or taxes of equivalent effect arising out or in connection with the supply of the Licensed Products or IMP by or on behalf of BIAL to NBIX shall be borne and paid in full by NBIX.

(c) Except as set forth in Section 3.2(b) above, any income or other tax that one Party hereunder is required to withhold and pay on behalf of the other Party hereunder with respect to amounts payable under this Agreement shall be deducted from said amounts prior to payment to the other Party; provided, however, that in regard to any tax so deducted, the Party making the withholding shall give or cause to be given to the other Party all assistance reasonably necessary to enable that other Party to claim exemption therefrom or credit therefor, and in each case shall promptly furnish the Party on whose behalf amounts were withheld, proper evidence of the taxes paid on its behalf and execute and provide such Party with any documents reasonably necessary in connection therewith. Each Party shall comply with reasonable requests of the other Party to take any proper actions that may minimize any withholding obligation. BIAL shall provide to NBIX a properly completed and executed Form W8-BEN prior to any payment made to BIAL and annually thereafter.

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3.3 **Interest:** If NBIX fails to make payment within any of the above stated timeframe, BIAL is entitled, without prejudice to any other right or remedy available to BIAL, to charge NBIX interest (both before and after judgment) on the unpaid amount for every day that the amount remains unpaid at a rate of […***…])) annually until the payment is made; provided, however, that in no event shall such rate exceed the maximum legal annual interest rate.

3.4 Any and all sums payable under this Agreement and any costs and expenses incurred by NBIX in connection with this Agreement are not refundable under any circumstances.

ARTICLE 4
SUPPLY AND MANUFACTURE

4.1 **General**:

(a) During the Term, BIAL or its Affiliate shall supply or have supplied to NBIX, and NBIX shall purchase from BIAL or its Affiliate or its or their designee at the Supply Price stipulated in Paragraph 1.1(a) of Exhibit 4 all of NBIX's requirements of Initial Product and IMP.

(b) Promptly after the Effective Date and within a period of […***…] thereof (or as otherwise agreed in writing by the Parties), BIAL and its Affiliate and NBIX shall negotiate in good faith and enter into a supply agreement (the "**Supply Agreement**") for the clinical supply of IMP and commercial supply of Licensed Products to NBIX. The Supply Agreement shall include the terms set out in Exhibit 4 and other customary terms for an agreement of such nature.

ARTICLE 5
COLLABORATION MANAGEMENT

5.1 **Collaboration Management**: The Parties will manage the collaboration in good faith to **(i)** conduct the Transfer Plan as efficiently and effectively as possible in order for NBIX to submit an NDA for an Initial Product by the earliest date possible, for **(ii)** NBIX to develop the Initial Product for all indications in the Field for which it can be demonstrated there is a scientific and commercial justification (subject, in any event, to the provisions of Article 6) and **(iii)** to, subject to Section 7.2, support labelling designed to ensure the broadest commercial success for the Initial Product.

5.2 **Joint Steering Committee Formation**: The Parties shall within the period of […***…] after the Effective Date form a Joint Steering Committee (the "**JSC**"), with overall coordination and strategic oversight over the Parties' activities hereunder and to provide a forum for regular exchange of information (to the extent required under this Agreement) relating to the Licensed Products.

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5.3 Make-up of the JSC:

(a) The JSC shall consist of […***…] members, namely, […***…] members from each of BIAL or its Affiliates and NBIX, each of whom shall be an Executive Officer of such Party. Each of its JSC members shall have the knowledge, experience and seniority to take decisions within the JSC's purview.

(b) BIAL and NBIX may each replace any or all of its representatives on the JSC at any time upon written notice to the JSC members and Alliance Manager of the other Party, provided however that each Party shall use its reasonable endeavours to reduce replacements as much as reasonably possible.

(c) BIAL and NBIX each may, in its sole discretion, invite to attend in a non-voting capacity meetings or portions of such meetings JSC non-member representatives of such Party (including, without limitation, its employees or non-employee professional advisors), with a maximum of […***…] non-member representatives per meeting unless otherwise agreed by the Parties, who have a reasonable purpose for attending such JSC meeting or portion of such JSC meeting. The inviting Party shall ensure that each such representative is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

(d) The Parties acknowledge and agree that the development and commercialization of Licensed Products in and outside the Territory will benefit from the Parties' regular communications and interactions. From time to time, the JSC may establish subcommittees with appropriate technical, regulatory or commercial personnel as it deems appropriate, to oversee specific matters, activities and obligations of the Parties under this Agreement, the SDEA, the Supply Agreement and the Quality Agreement as set forth herein in order to facilitate the effective coordination between the Parties and to make progress with respect to such matters, activities and obligations. Such subcommittees are not empowered with decision making responsibility, except as expressly delegated by the JSC and recorded in writing between the Parties, and shall keep the JSC regularly updated of all progress. The Parties acknowledge and understand that the JSC and subcommittees shall have only the powers expressly assigned to it in this Article 5 and elsewhere in this Agreement, and shall not have any power to amend, modify or waive compliance with this Agreement.

(e) It is understood between the Parties that in no event shall the activities to be performed by, or under oversight of, the JSC (or any subcommittee) be intended or allowed to violate any applicable law (including, without limitation, any competition or antitrust law).

5.4 JSC Responsibilities: Responsibilities of the JSC shall be the following:

(i) Discussing and reviewing the development and regulatory strategies and activities for the Licensed Products in and outside the Territory and, to the extent reasonably possible, coordinating strategies in and outside the Territory;

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(ii) Discussing and reviewing the commercialization strategies and activities of the Licensed Products in and outside the Territory and, to the extent reasonably possible, coordinating strategies in and outside the Territory;

(iii) Discussing and reviewing the matters relating to supply that are not specifically addressed within the Supply Agreement of the Licensed Products by BIAL to NBIX for use hereunder;

(iv) Discussing, reviewing and approving the Development and Regulatory Plan and amendments thereto prior to adoption or implementation thereof;

(v) Discussing, reviewing and approving the Annual Commercialization Plan, and updates or amendments thereto prior to adoption or implementation thereof;

(vi) Reporting on the status of ongoing Development Studies and other development activities with respect to Licensed Products in the Field in and, to the extent BIAL has the right to disclose them, outside the Territory;

(vii) Reporting on the status of ongoing commercial activities with respect to Licensed Products in the Field in and, to the extent BIAL has the right to disclose them, outside the Territory;

(viii) Reviewing and agreeing the Agreed Sales Forecast;

(ix) Resolving disputes in respect of proposed publications in accordance with Section 9.3; and

(x) Performing such other responsibilities as may be assigned to the JSC pursuant to this Agreement or as may be mutually agreed upon in writing by the Parties from time to time.

5.5 Meetings:

(a) The JSC may meet, convene or be polled in person or by video or telephone conference (where all Parties can hear and be heard). In addition, the JSC may be polled through electronic mail or correspondence.

(b) The JSC shall meet on such dates, and at such places and times or in such manner, as the members of the JSC shall agree from time to time. The first JSC meeting shall be held in person immediately following the Kick-Off Meeting and, unless otherwise agreed upon by the Parties, the subsequent JSC meetings shall be held […***…] where one such meeting shall always be held in person.

(c) Meetings of the JSC that are held in person shall alternate between the offices of BIAL's facility in Portugal and NBIX's facility in San Diego, California, USA, or at such other place as the Parties may agree, with each Party bearing its own costs associated with attendance at such meetings.

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(d) The chairperson of the JSC shall alternate at each meeting between one of BIAL's JSC members designated by BIAL and one of NBIX's JSC members designated by NBIX.

(e) Acting on behalf of the chairperson, the Alliance Managers shall establish the timing (at a mutually agreed upon time with the other Party) and agenda for all JSC meetings and shall send notice of such meetings to all JSC members, including the agenda at least […***…] prior to the meeting; provided, however, that either Party may request an *ad-hoc* JSC meeting (which may be held by teleconference or videoconference) by providing at least […***…] advance notice to the other Party, if the Party requesting such *ad-hoc* meeting reasonably believes that a significant matter must be addressed prior to the next scheduled (in person) JSC meeting, and the *ad-hoc* meeting will be held as requested.

(f) The Alliance Managers shall be responsible for circulating all relevant materials to enable discussion and decision making at a JSC meeting at least […***…] prior to such meeting and shall jointly preside at the meeting to ensure the preparation of the meeting minutes. For the avoidance of doubt, the Alliance Managers shall not vote on any decisions of the JSC.

(g) The minutes shall be circulated to both Parties' JSC members promptly following the JSC meeting for review, comment and written approval; provided, however, that both Parties acknowledge that the Alliance Manager of the Party to which the chairperson belongs shall prepare a first draft of the minutes within […***…] after each meeting.

5.6 **Decision-making**: The JSC may make decisions with respect to any subject matter within the JSC's functions as described above. Except as expressly provided in this Agreement, all decisions which are to be made by the JSC shall be made by unanimous vote or written consent, with each Party having one vote in all decisions. The JSC shall use best efforts to resolve any disputes over the matters within its roles and functions or otherwise referred to it, and each Party's JSC representatives shall consider in good faith the views of the other Party's JSC representatives in making decisions.

5.7 **Right to Decide**:

(a) If, with respect to a decision that is to be made by the JSC pursuant to Section 5.6, the JSC cannot reach consensus within […***…] after it has met to discuss and reach consensus on such matter, the dispute in question shall be referred to the head of the relevant department ("Department Heads") of each of the Parties.

(b) If the Department Heads of the Parties cannot resolve the matter within […***…], then the matter shall be referred to the President/Chief Executive Officer (**"President/CEO"**) of BIAL and the President/CEO of NBIX for resolution. The President/CEOs shall use best efforts to resolve the matter referred to them.

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(c) If the Presidents/CEOs cannot resolve the matter within […***…], then (subject to Section 5.7(d)):

(i) if the dispute relates to […***…], the President/CEO of NBIX shall have the right to decide the matter, provided that NBIX shall not have the right to decide any matter:

(A) […***…],

or

(B) […***…]; and

(ii) if the dispute relates to […***…], the President/CEO of BIAL shall have the right to decide the matter, provided that BIAL shall not have the right to decide […***…];

and

(iii) If the dispute relates to […***…], then neither Party shall have the right to decide the matter […***…].

(d) For clarity, if the Parties cannot agree the Agreed Sales Forecast or revised Net Sales Estimation then […***…].

5.8 Alliance Managers:

(a) Each Party shall, within the period of […***…] after the Effective Date, appoint an individual having the appropriate experience, including a general understanding of pharmaceutical development and commercialization matters, to act as the alliance manager for such Party (the "**Alliance Manager**").

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(b) The Alliance Managers are not permitted to be a member of the JSC but shall attend meetings of the JSC to perform the functions of the Alliance Manager pursuant to Sections 5.5(e), 5.5(f) and 5.5(g). The Alliance Managers shall be the primary contact for the Parties regarding the activities contemplated by this Agreement and shall facilitate all such activities hereunder, including facilitating the flow of information and otherwise promoting communication, coordination and collaboration between the Parties.

(c) Each Party may replace its Alliance Manager with an alternative representative at any time with prior written notice to the other Party, but each Party shall use its reasonable endeavours to reduce replacements of its Alliance Manager as much as reasonably possible.

(d) The Alliance Managers shall not, in any manner, take over the role of the JSC and shall not have any rights, powers or discretion except as expressly granted to the Alliance Managers hereunder. In no event will the Alliance Managers have any power to modify or amend this Agreement or to waive any Party's rights under it.

ARTICLE 6
DEVELOPMENT OF THE LICENSED PRODUCTS IN THE FIELD AND TERRITORY

6.1 Responsibility:

All development activities under the Development License including any Development Studies shall be managed and funded fully and exclusively by NBIX.

6.2 Development Activity:

(a) NBIX shall use Commercially Reasonable Efforts to conduct and complete, at its own expense, each and all of the activities in respect of the development of the Initial Product (and Subsequent Products, if any) in accordance with the then current development and regulatory plan for the Initial Product (and Subsequent Products, if any) within the Field and Territory, including obtaining all possible Exclusivity Rights for the Licensed Products (the "**Development and Regulatory Plan**").

(b) NBIX shall use Commercially Reasonable Efforts to complete any Development Studies and all other activities in the Development and Regulatory Plan in accordance with the timelines set out therein.

(c) NBIX shall at all times, when carrying out any Development Studies, or any other development activities with respect to the Licensed Products, comply with all applicable laws and regulations, including, without limitation, as applicable, the GCPs and GLPs.

(d) NBIX shall not carry out any research or development in respect of any Subsequent Product except in accordance with Section 2.9.

6.3 Development and Regulatory Plans:

(a) The initial development and regulatory plan with an estimated development and regulatory schedule until the US NDA filing for the Initial Product for the Initial Indication within the Field and Territory agreed by the Parties as of the Effective Date (the "**First Development and Regulatory Plan**") is attached hereto as **Exhibit 6.3(a)**.

(b) The First Development and Regulatory Plan is **(i)** of the essence of this Agreement for BIAL and NBIX and **(ii)** subject to update in accordance with Section 6.3(c).

(c) NBIX shall submit to the JSC, for JSC's review and approval (further subject to Section 6.3(f) and to BIAL's rights under Section 6.3(h)), a revised Development and Regulatory Plan providing updates on a necessary basis but at least once per Calendar Year by […***…].

(d) Each Development and Regulatory Plan shall (to the extent appropriate to the stage of development reached by the relevant Licensed Product at the date of submission of such plan and/or the time on the market from first commercial sale of the relevant Licensed Product) include a detailed description of the following matters together with a detailed description of the overall budget and the resources to be expended:

(i) proposed Development Studies including their design, purpose, estimated timing of initiation and estimated timings for completion;

(ii) any major regulatory events such as timings for submission of updates to the BIA 9-1067 IND, consultation meetings with the FDA, US NDA filing and anticipated Approval;

(iii) proposals for any Subsequent Products or Subsequent Indications within the Field and Territory;

(iv) publication plans;

(v) market and key opinion leader development plans, including plans to support continuing medical education;

(vi) field based medical science liaison activity plans and strategies; and

(vii) any other development or regulatory information reasonably requested by BIAL.

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(e) It is understood that the format in which the information within a Development and Regulatory Plan shall be provided by NBIX to BIAL shall be determined in good faith by NBIX but shall contain, as applicable, a detailed description of the items in Section 6.3(d) and an update thereof.

(f) Subject to **(**a**)** NBIX's obligations to consider in good faith all BIAL's comments to each draft Development and Regulatory Plan, and **(**b**)** BIAL's right set forth in Section 6.3(h), NBIX shall have the right to make modifications to the then-current Development and Regulatory Plan only to the extent necessary to reflect substantial changes:

(i) […***…];

(ii) […***…];

(iii) […***…];

(iv) […***…].

(g) The JSC shall review and approve each Development and Regulatory Plan within […***…] of receipt thereof.

(h) BIAL (rather than the JSC) shall have the right to object to the relevant part of each Development and Regulatory Plan and/or to each Development Study ("**Right to Object**") within the period of […***…] mentioned in each of Sections 6.3(g), 6.3(i) and 6.3(j), as applicable, if and only to the extent that:

(i) the relevant part of such Development and Regulatory Plan does not comply with NBIX's obligations under Sections 6.3(f); or

(ii) BIAL reasonably believes in good faith and provides an explanation of such reasonable belief to NBIX that the relevant part of such Development and Regulatory Plan and/or Development Study […***…].

(i) NBIX shall submit any proposed amendments to the Development and Regulatory Plan for the JSC's review and comment within the period of […***…] after receipt thereof and subject to all other provisions under this Section 6.3.

(j) If not submitted as part of the Development and Regulatory Plan**,** NBIX shall submit any proposed Development Study for the Initial Product (and Subsequent Product, if any) in the Territory,

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including the final draft protocol thereof, for review and comment by the JSC within the period of […***…] after receipt thereof.

(k) NBIX shall regularly, through the JSC, keep BIAL fully informed of the status of any Development Study.

6.4 **BIAL Studies**: BIAL shall use Commercially Reasonable Efforts to carry out the BIAL Studies set out in **Exhibit 6.4**.

ARTICLE 7
REGULATORY

7.1 **General:**

(a) NBIX shall be responsible for the filing of and shall own any and all INDs (including the BIA 9-1067 IND), US NDA and other regulatory filings for the Licensed Products within the Field and Territory during the Term.

(b) NBIX shall, in coordination and agreement with BIAL, file all appropriate Orange Book listings in the US and equivalent listings in Canada, if applicable, to provide the maximum protection for Licensed Products that is available under such regulatory procedures.

(c) In addition to the provisions of Article 6 with respect to the Development and Regulatory Plan, the Parties shall discuss NBIX's regulatory strategy for the Licensed Products at the JSC meetings and, if applicable, subteam meetings and NBIX shall in good faith take into consideration BIAL's comments in relation thereto. The Parties acknowledge and agree that […***…], and each Party, while exercising its rights and fulfilling its responsibilities in Section 7.2, will […***…] (for the avoidance of doubt, the foregoing shall not be interpreted or construed as limiting BIAL's Right to Object under Section 7.2(b)).

(d) NBIX shall use Commercially Reasonable Efforts to obtain an Approval and all applicable Exclusivity Rights for the Licensed Products within the Field in the Territory.

(e) For so long as BIAL is supplying Licensed Product for the Territory, BIAL shall be responsible for the timely filing and maintenance of the DMF pursuant to Section 7.4 and providing NBIX will all other (i.e., not contained in the closed part of the DMF) chemistry, manufacturing and controls ("**CMC**") information necessary for Regulatory Filings in the Territory.

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7.2 Regulatory Filings and Interactions with an Agency:

(a) NBIX shall inform BIAL, through the Development and Regulatory Plan, regular JSC meetings and subcommittee meetings if applicable, of any regulatory filings or material interactions with an Agency. Within […***…], the heads of regulatory for each Party shall begin discussions on a draft label to be submitted to an Agency. In addition, NBIX shall, prior to submission or responding to an Agency, provide BIAL, for review and written approval for a period of […***…], with a draft of any label related documents and materials, including a summary of product characteristics, patient information leaflet and primary and secondary packaging (**"Label Related Documents & Materials"**). Notwithstanding the terms of the previous sentence, in the event that the Parties agree that NBIX should respond to the relevant Agency within a period shorter than […***…], the Parties shall also agree a time period for BIAL's review of the draft Label Related Documents & Materials. In the event that the Parties agree that NBIX should respond to the relevant Agency within a period shorter than […***…] but are unable to agree the time period for BIAL's review, NBIX shall, as a minimum, provide BIAL with a draft of the Label Related Documents & Materials to be submitted to the Agency for review by BIAL […***…], and BIAL shall have […***…] to review such materials.

(b) BIAL shall have the right to withhold its approval to the draft Label Related Documents & Materials (**"Right to Object")** prior to the first submission thereof to an Agency in the Territory if the Label Related Documents & Materials or part thereof would, in BIAL's reasonable opinion, […***…]; provided, however, in exercising its Right to Object, BIAL shall not object to […***…]. After the first submission of the Label Related Documents & Materials approved by BIAL, BIAL shall only have the Right to Object if the Label Related Documents & Materials or part thereof would, in BIAL's reasonable opinion, have the potential to materially adversely affect […***…]. Notwithstanding the foregoing, BIAL's Right to Object may not be exercised by BIAL in respect of any portion of the Label Related Documents & Materials that […***…]

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[…***…] despite NBIX having used Commercially Reasonable Efforts to clear or overcome it.

(c) NBIX shall inform BIAL of any proposed filings, including annual updates, in respect of the BIA 9-1067 IND (the "**IND Filings**") and provide BIAL, for review within the period of […***…], with a draft of any such IND Filings. BIAL shall have the right to comment on such IND Filings and NBIX shall take all comments of BIAL into account before such IND Filings are filed with an Agency. Notwithstanding the terms of the previous sentence, in the event that the Parties agree that NBIX should submit an IND Filing other than an annual update to the FDA within a period shorter than […***…], the Parties shall also agree a time period for BIAL's review of the draft. In the event that the Parties agree that NBIX should respond to the relevant Agency within a period shorter than […***…] but are unable to agree the time period for BIAL's review, NBIX shall, as a minimum, provide BIAL with a draft of such IND Filing by BIAL at the same time as such IND Filing is first circulated for review within NBIX, and BIAL shall have the same amount of time as NBIX personnel to review and comment on such IND Filing. NBIX shall provide BIAL with a copy of each IND Filing in respect of the BIA 9-1067 IND in the form that it has been filed with the relevant Agency.

(d) NBIX shall provide BIAL with a copy of each document filed with an Agency in connection with the Licensed Products. In addition, BIAL shall have the right to participate in any NBIX internal meetings related to Agency Interactions or regulatory filings for a Licensed Product in the Territory.

(e) BIAL shall have the right to participate in or attend any in-person or material telephonic meetings with the FDA or other Agencies in the Territory ("**Agency Interactions**") to the extent that Agency permits the participation or attendance of BIAL. Prior to any such Agency Interactions, NBIX shall provide BIAL with a draft (or electronic access thereto) of any communication, agenda and/or notice ("**Interaction Agenda**") of any planned interaction […***…] and shall consider in good faith any comments provided by BIAL within the period of […***…]. Notwithstanding the terms of the previous sentence, in the event that such Interaction Agenda is not available […***…], NBIX shall provide BIAL with a draft of such Interaction Agenda for review by BIAL […***…], and BIAL shall have […***…] to review such Interaction Agenda.

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(f) NBIX understands and acknowledges that BIAL, as the Marketing Authorization holder of Licensed Products containing the BIA 9-1067 API outside the Territory and/or as licensor and/or supplier of such Licensed Products within and outside the Territory, may be interested in, from time to time, submitting or having submitted certain variations, supplements, amendments, changes or updates to any IND (including the BIA 9-1067 IND), NDAs, Approvals or any other regulatory filings to an Agency in the Territory, in order to keep such regulatory filings up to date with other regulatory filings outside the Territory ("**Data Update Filings**") and/or to register other manufacturers (including packagers) and/or routes or processes of manufacture (including packaging) of BIA 9-1067 API or Licensed Products ("**Supply Related Filings**"). BIAL acknowledges and understands that NBIX, as the holder of the BIA 9-1067 IND and the eventual Marketing Authorization holder for Licensed Products in the Territory, is responsible for assuring that any such regulatory submissions meet regulatory standards. Accordingly, subject to Section 7.4, NBIX shall, within the period of […***…], review and provide comments regarding the documentation to BIAL, which BIAL shall reasonably consider in good faith. In the event NBIX and BIAL are unable to agree on the documentation, the issue will be submitted to the JSC for discussion and final decision to determine if any such comments by NBIX are necessary to assure such regulatory filings meet regulatory standards. NBIX shall be under the obligation to adopt the JSC's comments, recommendations, and proposed changes if any to such regulatory filings. Should the Parties be unable to reach a joint decision at the JSC within […***…] of the matter being referred to the JSC, then such matter shall be finally decided […***…]. If NBIX does not provide any comments, or after NBIX has received the revised documentation from BIAL following BIAL's receipt of NBIX's comments, or after BIAL has confirmed, following BIAL's receipt of NBIX's comments, that it has no modifications to the documentation, then within […***…], NBIX shall file at the appropriate Agency in the Territory any and all such variations, amendments, changes or updates to any IND (including the BIA 9-1067 IND), NDAs, Approvals or any other regulatory filings as requested in accordance with the terms of this Section 7.2(f) by BIAL.

7.3 NDA:

(a) Subject to Sections 7.3(d) and (e), NBIX shall use Commercially Reasonable Efforts to file an NDA in the US for the Initial Product for:

(i) the Initial Indication, by the later of ***(A)*** […***…] or ***(B)*** […***…] after the receipt of meeting minutes from the pre-NDA meeting with the FDA confirming that there is sufficient or adequate information to file an NDA submission in the US;

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And

(ii) each Subsequent Product and/or Subsequent Indication, by the date set forth in the then current and approved Development and Regulatory Plan.

(b) Subject to Sections 7.3(d) and 7.3(e), in the event that the FDA does not require any further Phase III Clinical Trial for the submission of an application for an Approval of the Initial Product for the Initial Indication, then if NBIX has not submitted an NDA in the US by […***…] (despite NBIX having used its Commercially Reasonable Efforts to do so), then BIAL shall have the right to terminate the Agreement under Section 15.2(c).

(c) Subject to Section 7.3(d), in the event that the FDA requires a further Phase III Clinical Trial for the submission of an application for an Approval of the Initial Product for the Initial Indication, then if NBIX has not submitted an NDA in the Territory by […***…] (despite NBIX having used its Commercially Reasonable Efforts to do so), then BIAL shall have the right to terminate the Agreement under Section 15.2(c).

(d) If **(i)** BIAL is in material breach of, or is materially delayed in performing, any of its obligations under this Agreement, including timely completion of the Transfer Plan under Section 2.6(b) and timely DMF submission under Section 7.4, or if **(ii)** NBIX's development of the Initial Product is delayed by reason of an unexpected significant safety issue not within the control of NBIX, and by reason of that material breach, material delay or significant safety issue, the filing of the NDA in the US is delayed, then in each case the deadlines in Sections 7.3(b) and 7.3(c) shall be extended by […***…].

(e) If:

(i) the FDA does not require any further Phase III Clinical Trial for submission of an application for an Approval of the Initial Product for the Initial Indication but does requires Clinical Trials which are not contemplated in the First Development and Regulatory Plan,

and

(ii) by reason of carrying out such Clinical Trials the filing of the NDA in the US is delayed,

then the deadline in Section 7.3(b) shall be extended by […***…]. For clarity, the delays set forth in this Section 7.3(e) and 7.3(d) are cumulative, if applicable.

(f) Without prejudice to the foregoing provisions of this Section 7.3, NBIX shall use Commercially Reasonable Efforts to, within […***…] from the Effective Date, request an FDA

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meeting seeking guidance from the FDA on the appropriateness of the data package for a potential NDA filing and whether the FDA will require an additional Phase III Clinical Trial to be completed prior to submission of the NDA for the first Licensed Product in the Initial Indication.

7.4 **Drug Master File**: BIAL, itself or through its Affiliate, shall be responsible for filing and maintaining, directly or through a Third Party appointed by BIAL, the Drug Master File relating to the manufacture of the BIA 9-1067 API ("**DMF**"). BIAL shall file and maintain such DMF in its own name and/or in the name of its relevant suppliers and shall permit NBIX to cross-reference such DMF in its regulatory filings for Licensed Products in the Territory. BIAL, itself or through a Third Party appointed by BIAL, shall be responsible for providing to NBIX all information requested by NBIX related to the manufacture of Licensed Products by dates set forth in the applicable Regulatory and Development Plan.

7.5 **Pharmacovigilance**

(a) Promptly following the Effective Date, but in no event later than […***…] thereafter, BIAL or its Affiliate and NBIX shall develop and agree upon safety data exchange procedures in a separate and detailed Safety Data Exchange Agreement ("**SDEA**"). The SDEA shall, *inter alia*, describe the collection, investigation, analysis, reporting and exchange of information concerning adverse events and product safety relating to the Licensed Products, sufficient to permit each Party to comply with its legal or regulatory obligations, including to the extent applicable, those obligations contained in ICH guidelines.

(b) NBIX shall be responsible for pharmacovigilance activities in the Territory, including maintenance of a local safety database of the Licensed Products for the Territory, and shall provide BIAL with the data in such safety database.

(c) BIAL or its Affiliates shall be responsible for pharmacovigilance activities outside the Territory, including the maintenance of worldwide database for the Initial Product and, subject to Section 7.5(d), Subsequent Products, which will include the data in the local safety database of the Licensed Product for the Territory provided by NBIX.

(d) In the event that any Combination Product is agreed to be developed and/or commercialized by NBIX, the Parties shall also discuss and agree appropriate pharmacovigilance provisions with respect to such Combination Product.

7.6 **Audits**:

(a) During the Term, NBIX shall allow (and cause its contractors to allow) BIAL or a Third Party appointed by BIAL to access, examine or audit, in accordance with the Quality Agreement and the SDEA, **(i)** the conduct and results of any Development Studies and **(ii)** all the safety and pharmacovigilance activities related to the development or commercialization of the Licensed Products

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in the Territory, including in each case (i) and (ii) the facilities and equipment at or with which the activities are or were conducted, and personnel, procedures, programming, and any documents, data and records related to such activities, with reasonably advanced written notice (except in the event of For Cause Audits pursuant to Section 7.6(b)) during regular business hours to determine whether such activities are being or have been conducted in accordance with this Agreement, the SDEA, the Supply Agreement and the Quality Agreement and with all applicable laws and regulations, including without limitation, and as applicable, Good Clinical Practices, Good Laboratory Practices, Good Manufacturing Practices, and Good Pharmacovigilance Practices. NBIX shall also cooperate (and cause its contractors to cooperate) with BIAL by providing, in a timely manner, all the information and resources necessary for the preparation, conduct and report of the audit. After the audit and upon receipt of the audit findings in the form of a report, NBIX agrees to (and cause its contractors to) define and implement corrective and/or preventive actions in a timely manner.

(b) In the event that an audit pursuant to Section 7.6(a) reveals material non-compliance issues with NBIX's obligations under this Agreement, the SDEA, the Supply Agreement and the Quality Agreement, BIAL or its Affiliates shall have the right to subsequently audit NBIX and/or its contractors by providing reasonable advance written notice but in any event such advance written notice may be made within […***…] of completion of the audit conducted pursuant to Section 7.6(a) ("**For Cause Audit**").

(c) During the Term, BIAL shall allow (and use Commercially Reasonable Efforts to cause its contractors to allow) NBIX or a Third Party appointed by NBIX to access, examine or audit, in accordance with the Quality Agreement, the Supply Agreement, and the SDEA, **(i)** the conduct and results of any Development Studies, **(ii)** all the safety and pharmacovigilance activities related to the development or commercialization of the Licensed Products in the Territory, and **(iii)** the manufacture of Licensed Product, including in each case (i), (ii) and (iii) the facilities and equipment at or with which the activities are or were conducted, and personnel, procedures, programming, and any documents, data and records related to such activities, with reasonably advanced written notice (except in the event of For Cause Audits pursuant to Section 7.6(d)) during regular business hours to determine whether such activities are being or have been conducted in accordance with this Agreement, the SDEA, the Supply Agreement and the Quality Agreement and with all applicable laws and regulations, including without limitation, and as applicable, Good Clinical Practices, Good Laboratory Practices, Good Manufacturing Practices, and Good Pharmacovigilance Practices. BIAL shall also cooperate (and use reasonable efforts to cause its contractors to cooperate) with NBIX by providing, in a timely manner, all the information and resources necessary for the preparation, conduct and report of the audit. After the audit and upon receipt of the audit findings in the form of a report, BIAL agrees to (and use reasonable efforts to cause its contractors to) define and implement corrective and/or preventive actions in a timely manner.

(d) In the event that an audit pursuant to Section 7.6(c) reveals material non-compliance issues with BIAL's obligations under this Agreement, the SDEA, the Supply Agreement and the Quality Agreement, NBIX or its Affiliates shall have the right to subsequently audit BIAL and/or its contractors

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by providing reasonable advance written notice but in any event such advance written notice may be made within […***…] of completion of the audit conducted pursuant to Section 7.6(c) ("**For Cause Audit**").

7.7 Medical inquiries:

(a) NBIX shall be responsible for handling all medical questions or inquiries for the Field in the Territory with regard to the Licensed Products (including setting up a call center or other centralized response center in connection therewith), but shall consider in good faith input from BIAL or its Affiliate in connection therewith.

(b) NBIX shall promptly forward any and all medical questions or inquiries which it receives in relation to the Licensed Product in the Field outside the Territory to BIAL in accordance with all applicable laws.

(c) BIAL or its Affiliate shall be responsible for handling all medical questions or inquiries for the Field with regard to the Licensed Products outside the Territory, but shall consider in good faith input from NBIX or its Affiliate in connection therewith.

(d) BIAL or its Affiliate shall promptly forward any and all medical questions or inquiries which it receives in relation to the Licensed Product in the Field in the Territory to NBIX in accordance with all applicable laws.

(e) The Parties shall timely cooperate and establish the procedures reasonably necessary (such as periodic meetings via teleconference or videoconference) to ensure the consistency and correctness of the medical information provided by the Parties.

7.8 Recalls and Withdrawals:

(a) Notification and Determination: In the event that any Agency threatens or initiates any action to recall or withdraw a Licensed Product from the market in or outside the Territory, the Party receiving notice thereof shall promptly notify the other Party of such communication, but in no event later than […***…] after receipt thereof. NBIX, as the Approval holder for the Licensed Products in the Territory, shall determine whether to initiate any recall or withdrawal of such Licensed Product in the Territory, including the scope of such recall or withdrawal (*e.g.*, a full or partial recall, or a temporary or permanent recall); provided, however that to the extent practicable and appropriate based on the reasons for the recall or withdrawal, before NBIX initiates a recall or withdrawal, the Parties shall promptly discuss in good faith the reasons therefor, provided that such discussions shall not delay any action that any Party reasonably believes has to be taken in relation to any recall. In the event of any such recall or withdrawal, NBIX shall implement any necessary action to conduct such recall or withdrawal. As the manufacturer of Licensed Products, BIAL shall use a batch tracing system which will allow NBIX to identify, on a prompt basis, customers within the Territory or patients enrolled in

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Development Studies in the Territory who have been supplied with Licensed Product of any particular batch(es), and to recall such batches from such customers or patients, as the case may be. For clarity, all matters relating to a withdrawal or recall of a Licensed Product outside the Territory will be determined, coordinated and controlled by BIAL.

(b) **Cost Allocation**: All out-of-pocket and internal costs and expenses incurred by the Parties for implementing the recall or withdrawal or market notification of a Licensed Product ("**Recall Costs**") in the Territory shall initially be borne by each Party and subsequently be allocated between BIAL and NBIX as follows:

[…***…]**.**

(c) **Assistance for the Licensed Product**: Each Party shall promptly inform the other Party of any notification of any action by, or other information which it receives (directly or indirectly) from, any Regulatory Authority (together with copies of correspondence related thereto), which **(i)** raises any material concerns regarding the safety, efficacy or quality of a Licensed Product, **(ii)** indicates or suggests a potential material liability for either Party to Third Parties arising in connection with a Licensed Product or **(iii)** which indicates a reasonable potential for a recall or market withdrawal of a Licensed Product.

7.9. **Re-Manufacturing Costs**:

All out-of-pocket and internal costs and expenses incurred by BIAL in connection with the replacement, re-manufacturing, re-packaging or re-labeling of Licensed Products, including without limitation, where applicable, costs of the BIA 9-1067 API and other materials (collectively, "**Re-Manufacturing Costs**") shall be allocated between the Parties as follows:

[…***…]

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[…***…].

ARTICLE 8
COMMERCIALIZATION OF THE LICENSED PRODUCTS IN THE FIELD AND TERRITORY

8.1 General:

(a) NBIX shall be solely responsible for commercializing the Licensed Products within the Field and Territory and for the day-to-day commercial activities in the Territory at its sole expense and in accordance with all applicable laws and regulations.

(b) Notwithstanding anything in this Agreement to the contrary, […***…]:

[…***…].

8.2 Annual Commercialization Plan:

(a) NBIX shall prepare a draft annual commercialization plan ("**Annual Commercialization Plan**") for review, comment and approval by the JSC. The first draft Annual Commercialization Plan shall be provided to the JSC by […***…].

(b) NBIX shall submit to the JSC, for the JSC's review, comment and approval, a new Annual Commercialization Plan updated on a necessary basis but at least once a year by […***…] of each Calendar Year.

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(c) Each Annual Commercialization Plan shall, to the extent relevant when considering either the time to the first commercial sale of the Licensed Products or the time from the first commercial sale of the Licensed Products, provide an estimated plan for implementing each of the following activities, together with a reasonable description of the overall budget and the resources to be expended, which budget and resources must reflect an appropriate resource commitment for the applicable Commercial Year, and NBIX's reasonable justification for each of the expenditures set forth in such budget:

(i) Plans for conducting market research on the Licensed Products and their findings;

(ii) Market analysis including customer and competitor assessments, revised and updated as and when new compounds enter the market;

(iii) Plans for positioning, branding and key messages for the Licensed Products and any changes from previous Calendar Years, including promotional materials, campaigns and messaging by audience;

(iv) Plans and strategies for presenting the Licensed Products at national or international congresses or major meetings in the Territory;

(v) Market access plans for the Licensed Products including strategies and distribution plans with respect to managed care organizations, hospital systems, group purchasing organizations, physicians networks, pharmacies and any other private or government healthcare providers or reimbursement entities;

(vi) Sales force activity plans for the Licensed Products by sales territory, customer segmentation by prescribing decile, the minimum number of Details to be executed, sales training activities and promotional materials;

(vii) Sales forecast for the Licensed Products for the following […***…]; and

(viii) Relevant commercial or marketing information that is reasonably requested by the JSC.

(d) It is understood that the format in which the information within an Annual Commercialization Plan shall be provided by NBIX to the JSC shall be determined in good faith by NBIX .

(e) The JSC shall review and approve each Annual Commercialization Plan within […***…] of receipt thereof. NBIX shall be under the obligation to consider and adopt the JSC's comments, recommendations and proposed changes made to the Annual Commercialization Plan.

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(f) NBIX shall submit any proposed amendments to the Annual Commercialization Plan for JSC review, comment and approval within the period of […***…] after receipt thereof. NBIX shall be under the obligation to consider and adopt the JSC's comments, recommendations and proposed changes made to such proposed amendments to the Annual Commercialization Plan.

(g) The Parties agree, in order to manage the commercial collaboration, to set up a commercial subteam, operating under the JSC. NBIX shall at each such subteam meeting, provide a detailed update to BIAL summarizing, on an item by item basis, the implementation of the Annual Commercialization Plan and the results thereof, including, without limitation, commercial performance of the Licensed Products.

8.3 NBIX's Commercialization Obligations:

(a) NBIX shall use Commercially Reasonable Efforts to market and sell each Licensed Product in the Field in the US, and, subject to the terms of the rest of this Section 8.3, shall invest such resources for such marketing and sale that are consistent with its exercise of Commercially Reasonable Efforts.

(b) NBIX shall at all times market and promote the Licensed Products in accordance with the Approvals and applicable laws.

(c) In accordance with the Annual Commercialization Plan, NBIX shall use Commercially Reasonable Efforts:

(i) to launch each Licensed Product for each indication within the Field within […***…] after the grant of an Approval by each relevant Agency (and other Agency or other governmental or legal requirements necessary for launch) for such indications;

(ii) to ensure a competitive share of voice, including without limitation the agreed number and type of field based personnel, as set out in the then current Annual Commercialization Plan in order to maximize the commercial value of the Licensed Product for approved indications in the Territory during the Term; and

(iii) to employ or otherwise engage, prior to the anticipated first commercial sale of the Initial Product in the US, and maintain during at least the first […***…], at least the following resources to be utilized by NBIX in commercializing the Initial Product:

a. a field sales force of at least […***…] Detailing the License Products to movement disorder neurologists and other select neurologists who prescribe L-dopa to drive initial trial and adoption;

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b. a national accounts/payor group of at least […***…] presenting Licensed Products to key commercial, Medicare Part D, and Medicaid health plan payers and decision-makers to secure formulary coverage and/or to remove step therapy requirements or unreasonably high patient co-pays;

c. a medical science liaison force of at least […***…] engaging with payors and key opinion leaders/thought leaders in Parkinson's disease to develop advocacy and support for the Licensed Products. MSLs will also interface with patient advocacy organizations like the National Parkinson's Foundation and the Michael J. Fox foundation to build awareness and educate their constituencies;

d. a medical affairs and publications group of at least […***…] will support scientific communications, including presentation of key data at medical congresses such as the International Parkinson's and Movement Disorder Society annual meetings, the American Academy of Neurology, and other relevant scientific meetings. In addition, this group will respond to inbound questions from prescribers on off-label topics;

e. a brand team of at least […***…] will support Licensed Products by creating a branded campaign for health care professionals (sales materials, journal ads, website, etc.), building a speakers bureau to enable peer-to-peer education, branded booth and promotional activities at scientific meetings, and , if appropriate, direct-to-patient education and advertising to drive product requests.

(d) The Parties shall discuss and agree the first Sales forecast in Units of Initial Product for the […***…] (each a "**Commercial Year**") following the first commercial sale of the Initial Product in the US (the "**Agreed Sales Forecast**") at the JSC meeting following the receipt of meeting minutes from the pre-NDA meeting with the FDA confirming that there is sufficient or adequate information to file an NDA submission in the US. Thereafter the Agreed Sales Forecast shall be agreed on an annual basis for the following […***…] by the JSC following submission of the Annual Commercialization Plan.

(e) The Parties agree that, based on the assumptions set forth in **Exhibit 8.3(e)** (the **"Assumptions"**), the Agreed Sales Forecasts are expected to be consistent with achieving Net Sales of […***…] in the […***…] (the "**Net Sales Estimation**"). The Parties acknowledge and agree that such Assumptions are the basis for determining the first Agreed Sales Forecast but to the extent that […***…], then the Parties shall consider their impact on the Net Sales Estimation and, if any, the Parties shall discuss and agree a revised Net Sales Estimation and the Agreed Sales Forecasts that are consistent with achieving such a revised Net Sales Estimation.

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If the Parties cannot agree the Agreed Sales Forecast or the revised Net Sales Estimation, then the matter shall be referred to the President/CEO of each Party for resolution, and if such President/CEOs are not able to resolve the matter, it shall be […***…].

(f) Subject to Section 8.3(i), starting in the […***…] until and including the […***…], NBIX shall sell at least […***…] for such Commercial Year ("**Minimum Sales**").

(g) Subject to Section 8.3(i), in the event that NBIX fails to achieve the Minimum Sales in […***…] Commercial Year (i.e., […***…]), as NBIX's sole liability and BIAL's sole remedy for such failure, NBIX shall pay BIAL an amount corresponding to […***…] (the "**Difference**"). The Difference for the purposes of this Section 8.3(g) and Section 8.3(h) shall be calculated as […***…].

(h) Subject to Section 8.3(i), in the event that NBIX fails to achieve the Minimum Sales in any […***…] Commercial Years, including any Commercial Years in which NBIX has paid the Difference to BIAL, as NBIX's sole liability and BIAL's sole remedy for such failure (but shall not be NBIX's sole liability and BIAL's sole remedy to the extent that such failure was caused by a material breach of any of NBIX's other obligations under this Agreement), BIAL shall have the right at its discretion to **(i)** request NBIX to pay the Difference for such second Commercial Year or **(ii)** terminate the Agreement pursuant to Section 15.2(c).

(i) NBIX shall not be in breach of its Minimum Sales obligations to the extent that the failure to achieve Minimum Sales is a result of one or more of the following circumstances (as NBIX shall be under the obligation to demonstrate):

[…***…].

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8.4 Promotional Materials and Documents:

(a) In addition to the provisions of Section 2.1(e), all promotional materials and documents used by NBIX shall be prepared by reference to the Global Brand Identity for the Licensed Products as defined by BIAL, to the extent allowed under the laws and regulations in the Territory.

(b) NBIX shall provide BIAL with final copies of key promotional materials for the Licensed Product to be used by NBIX in the Territory. Notwithstanding the foregoing, all liability in connection with such promotional materials and their compliance with the Approvals, applicable laws and regulations shall lie solely with NBIX, except as may be provided otherwise in the Co-Promotion Agreement.

(c) NBIX shall provide BIAL with drafts of core promotional materials for the Licensed Product to be used by NBIX in the Territory for BIAL's review and comment within the period of […***…] upon receipt thereof. NBIX shall be under the obligation to take into good faith consideration all BIAL's reasonable comments. Notwithstanding the foregoing, all liability in connection with such promotional claims and their compliance with the Approvals, applicable laws and regulations shall lie solely with NBIX.

8.5 Sales Information:

(a) NBIX shall, through the JSC, and at all times upon BIAL's written reasonable request, keep BIAL informed of the status of the commercialization of the Licensed Products in the Territory.

(b) Notwithstanding the above, NBIX shall provide BIAL, by the […***…] after the end of each calendar month, with a summary of Net Sales, Net Sales Volume and Net Selling Price for the preceding calendar month for the Licensed Products in the Territory. All such information shall be NBIX's Confidential Information.

ARTICLE 9
COOPERATION, DATA SHARING AND PUBLICATIONS

9.1 Cooperation:

(a) Each Party shall keep the other Party reasonably informed through the JSC and any relevant subcommittees as to its and its Affiliates' development, regulatory, manufacturing (to the extent required in the Supply Agreement), and commercialization efforts, as applicable, with respect to the Licensed Products in the Field, in the case of BIAL outside the Territory, and in the case of NBIX, inside the Territory.

(b) BIAL shall have the right to inform its licensees outside the Territory of NBIX's development, regulatory and commercialization efforts and activities with respect to the Licensed

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Products in the Field in the Territory solely for the purpose of the development, manufacture, registration and commercialization of the Licensed Products in their respective territory outside the Territory. BIAL shall, to the extent Controlled by BIAL, keep NBIX informed of BIAL's licensees' development, regulatory and commercialization efforts and activities with respect to the Licensed Products in the Field in their respective territories solely for the purpose of NBIX's development, registration and commercialization of the Licensed Products in the Territory. BIAL acknowledges and agrees that, as of the Effective Date, it has the right to keep NBIX informed of its Existing Licensees' development, regulatory and commercialization efforts and activities with respect to the Licensed Products in the Field in their respective territories. […***…].

(c) Each Party shall cooperate as reasonably requested by the other Party in an effort to ensure that the development of the Licensed Products within the Field is coordinated worldwide; *provided however* that this shall not be interpreted or construed as limiting BIAL's and NBIX's rights and obligations, or expanding BIAL's or NBIX's obligations, in each case under this Agreement.

9.2 Data Sharing:

(a) NBIX and BIAL, respectively, shall provide to each other access to or a copy of their respective Data, free of charge and in a timely fashion and as promptly as possible upon request of each of BIAL or NBIX. Each Party shall have the right to use and reference such Data for the purpose of, as applicable, developing, manufacturing, registering and/or commercializing the Licensed Products **(i)** with respect to NBIX in the Field and in the Territory during the Term and after expiration (but not after termination) of this Agreement and **(ii)** with respect to BIAL outside the Territory during and after the Term.

(b) BIAL shall have the right to sublicense its right to use and cross-reference NBIX's Data to BIAL's Affiliates outside the Territory and to BIAL's or BIAL's Affiliates' licensees outside the Territory to use and cross-reference Data of NBIX in seeking Marketing Authorizations for Licensed Products in their respective territories outside the Territory

(c) BIAL and its Affiliates existing licensees to the Licensed Products as of the Effective Date are set forth on **Exhibit 9.2(c)** (the "**Existing Licensees**"). BIAL shall, to the extent Controlled by BIAL, grant the right to NBIX to use and cross-reference the Existing Licensees' Data inside the Territory. […***…]. BIAL shall use reasonable efforts to obtain from its and its Affiliates' future licensees outside the Territory the right and license to provide to NBIX, without any further payment

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obligations, access to, and the right to use and reference, the Data (including all data required by an Agency) owned or controlled by such licensees.

(d) For clarity, none of NBIX, BIAL, BIAL's Affiliates or BIAL's or its Affiliates' licensees shall be obligated to successfully obtain Data and the provisions of this Section 9.2 shall only apply to the extent such Data are actually obtained.

9.3 Publications:

(a) Each Party recognizes that the publication of papers regarding results of research and clinical studies and other information regarding the Licensed Products, including oral presentations and abstracts, could contribute to not only the profits of the Parties but also the development of science and technology in the world, provided, however, that such publications are subject to reasonable control to protect the other Party's Confidential Information. Accordingly:

(i) BIAL shall have the right to review and comment on any material, manuscript or abstract proposed for disclosure or publication by NBIX, such as by written, visual or other form of presentation, manuscript or abstract, relating to the Licensed Products, and

(ii) NBIX shall have the right to review and comment on any material, manuscript or abstract proposed for disclosure or publication by BIAL, such as by written, visual or other form of presentation, manuscript or abstract, relating to the Licensed Products.

(b) Before any such material, abstract or manuscript is submitted for publication or presentation, the Party proposing publication ("**Publishing Party**") shall deliver its complete copy, in English language, to the other Party at least […***…] prior to submitting the material, abstract or manuscript to a Publishing Party or initiating any other disclosure. Such other Party shall make reasonable efforts to expedite review of such materials, abstract or manuscripts, and shall return such items as soon as practicable to Publishing Party with appropriate comments, if any, but in no event later than […***…] from the date of delivery to the non-publishing Party. Publishing Party shall comply with the other Party's request to delete references to the other Party's Confidential Information in any such material, abstract or manuscript and agrees to delay any submission for publication or other public disclosure for a period of at least additional […***…] for the purpose of allowing the preparation and filing of appropriate patent applications.

(c) Neither Party may publish a paper in the event that the other Party objects based on sound scientific reasons and provides written justification for such objection. If such justification is acceptable to the Publishing Party, then the Publishing Party shall edit the proposed publication in accordance with the other Party's comments. In the event that there still exists a dispute between the Parties in respect of a proposed publication, the dispute shall be submitted to the JSC and shall be decided in accordance with the mechanism set forth in Section 5.4(ix) and Section 5.7(c)(iii).

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(d) For clarity, nothing in this Section 9.3 shall affect either Party's obligations under applicable laws, regulations and guidelines to disclose any data relating to the development of Licensed Products.

9.4 Use of BIAL Know-How, NBIX Know-How, Data, publications and other regulatory documents:

(a) NBIX:

(i) NBIX shall only use and disclose BIAL Know-How, Data, publications and regulatory documents Controlled by BIAL and provided pursuant to Sections 2.6 and 9.2 to its Affiliates and Third Party contractors as required or useful to develop, file, obtain and maintain Approval of and commercialize Licensed Products in the Field in the Territory pursuant to the licenses granted to NBIX under this Agreement.

(ii) NBIX may use and disclose such BIAL Know-How, Data, publications and regulatory documents Controlled by BIAL to NBIX Affiliates and Third Party contractors in connection with development activities, marketing activities, medical education activities, professional services activities and public relations activities; or for purposes of obtaining consultation services in the normal course of business (such as business consultants, advertising agencies, law firms, accounting firms, etc.) in each case solely to the extent necessary or useful for development, filing, obtaining and maintaining Approvals and commercialization of Licensed Products in the Field in Territory. Any disclosure of such Data, publications and regulatory documents shall be subject to Article 13 and NBIX shall be responsible for the conduct of such NBIX's Affiliates and NBIX's Third Party contractors in respect of such Data.

(iii) NBIX may not use (or permit any Affiliate or Third Party to use) any such BIAL Know-How, Data, publications and regulatory documents outside the Territory, or outside the Field, or for any products other than the Licensed Products.

(b) BIAL:

(i) BIAL shall only use and disclose NBIX Know-How, Data, regulatory filings, publications and regulatory documents Controlled by NBIX and provided pursuant to Sections 9.2 and 9.3 to BIAL's Affiliates, and to BIAL's or BIAL's Affiliates' licensees outside the Territory, as required or useful to develop, file for, obtain and maintain Marketing Authorization for, and commercialize Licensed Products in the Field outside the Territory pursuant to the licenses granted by NBIX to BIAL under this Agreement.

(ii) BIAL may use and disclose such Data, regulatory filings, publications and regulatory documents to Affiliates and Third Party contractors in connection with development activities, marketing activities, medical education activities, professional services activities and

public relations activities; or for purposes of obtaining consultation services in the normal course of business (such as business consultants, advertising agencies, law firms, accounting firms, etc.) in each case solely to the extent necessary for development, filing, obtaining and maintaining Marketing Authorization and commercialization of Licensed Products in the Field outside the Territory. Any disclosure of such Data shall be subject to Article 13 and BIAL shall be responsible for the conduct of such BIAL's Affiliates and BIAL's or BIAL's Affiliates' licensees in respect of such Data.

(iii) BIAL may not use (or permit any Affiliate or Third Party to use) any such Data, regulatory filings, publications and regulatory documents inside the Territory, or outside the Field or for any products other than the Licensed Products or products comprising BIA 9-1067.

9.5 Maintenance of Records:

Each Party shall, in accordance with its same practice for its own products or compounds, maintain records for the minimum period by law applicable to such records, in sufficient detail and in good scientific manner appropriate for Patent and regulatory purposes, which shall fully and properly reflect works done and results achieved by or on behalf of each Party in the performance of development activities pursuant to this Agreement.

9.6 No Insider Trading:

BIAL acknowledges that NBIX is a publicly traded company and that under this Agreement BIAL will learn of material, non-public information regarding NBIX. BIAL understands that federal and state securities laws prohibit employees of BIAL from purchasing or selling NBIX securities while in possession of any such information and from disclosing such information to others.

ARTICLE 10
DEVELOPMENT INTELLECTUAL PROPERTY

10.1 Ownership of Development Intellectual Property: All Development Intellectual Property conceived solely by the employees of a Party shall be owned by that Party. Development Intellectual Property conceived by employees of both Parties shall be jointly owned by the Parties, each having an equal and undivided interest in such Development Intellectual Property.

(a) Any Development Intellectual Property that BIAL Controls or is jointly owned by the Parties shall, with respect to the Territory, be encompassed by the licenses set forth in Section 2.1 without additional consideration other than the payments set forth in Article 3.

(b) The Parties agree that, to the extent it is required by the laws of any country, the Parties shall execute necessary documentation to reflect or record any licenses under jointly owned Developmental Intellectual Property granted to the other Party in accordance with this Agreement.

10.2 Prosecution of BIAL Patents covering Development Intellectual Property, Joint Patents and NBIX Patents:

(a) Each Party shall have the right, at its own expense, to file, prosecute, maintain, defend and enforce the Patents covering Development Intellectual Property which are owned or Controlled solely by that Party, subject to the remainder of this Section 10.2. Upon filing of such Patents of BIAL, it shall become a BIAL Patent as set forth in the definition of BIAL Patents. Upon filing of such Patents of NBIX, it shall become a NBIX Patent as set forth in the definition of NBIX Patents.

(b) BIAL shall have the right to file, prosecute and maintain inside and outside the Territory any Joint Patents; provided however that BIAL shall provide NBIX with a copy of such Patents to be filed by BIAL and a copy of communications between its agents and any patent office regarding such Joint Patents, within a reasonable deadline prior to submitting such Joint Patents and communications to the patent office. Provided that NBIX responds within the specified deadline, BIAL shall consider or cause its agents to consider, in good faith, any reasonable comments NBIX may have regarding such Joint Patents or communication, provided that the final prosecution decisions shall rest solely with BIAL. NBIX shall be responsible for any expenses that it may incur in providing its comments.

(c) NBIX shall provide BIAL with a copy of any NBIX Patents to be filed by NBIX and a copy of communications between its agents and any patent office regarding such NBIX Patents, within a reasonable deadline prior to submitting such NBIX Patents and communications to the patent office. Provided that BIAL responds within the specified deadline, NBIX shall consider or cause its agents to consider, in good faith, any comments BIAL may have regarding that NBIX Patents or communications, provided that final prosecution decisions shall rest with NBIX. BIAL shall be responsible for any expenses that it may incur in providing its comments. NBIX shall pay all official taxes, annuities, renewal and maintenance fees required to keep in force all issued NBIX Patents covering Development Intellectual Property solely owned or Controlled by NBIX.

(d) BIAL has the right to file a Patent covering Development Intellectual Property Controlled by NBIX in any country in which NBIX decides not to file. NBIX shall notify BIAL of the decision not to file a Patent in a particular country within […***…] of making that decision, but not later than […***…] prior to the time when any statutory bar might foreclose filing of a Patent in that country. Upon receipt of such notification, BIAL shall have the option to assume full responsibility, at its own discretion and expense, to file a Patent in any such country under the name of NBIX. Following the filing of such Patent under the name of NBIX, NBIX shall cooperate and assist BIAL, at BIAL's expense, in executing a written assignment of the NBIX Patent to BIAL and provide at BIAL's expense any other conveyance instruments, documents or assistance as may be reasonably necessary or desirable to assign ownership to BIAL or to support the prosecution of such Patent, at BIAL's sole expense. In the event that such Patent becomes the subject of an opposition or related proceeding, or if any Patent(s) to issue becomes involved in any adversary proceeding (e.g. litigation, invalidity or revocation

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proceedings), BIAL shall provide NBIX notice of such proceeding and BIAL shall provide NBIX reasonable opportunity to comment to BIAL.

(e) NBIX shall advise BIAL if it no longer desires to continue prosecution or pay maintenance fees on any NBIX Patent either in the Territory or outside the Territory. Such notification shall be in writing and be provided not less than […***…] before the expiration of a response period or the payment due date for a maintenance fee. Upon receipt of such notification, BIAL shall have the option, exercisable upon written notification to NBIX, to assume the prosecution and/or maintenance of the NBIX Patent, in which event NBIX shall reasonably cooperate with and assist BIAL, at BIAL's expense, in executing a written assignment of the NBIX Patent to BIAL and provide at BIAL´s expense any other conveyance instruments, documents or assistance as may be reasonably necessary or desirable to assign ownership to BIAL or to support the prosecution and maintenance of such Patent, at BIAL's sole expense. For clarity, in the event that a NBIX Patent is assigned to BIAL pursuant to this Section 10.2(e), it shall be deemed to be a BIAL Patent under this Agreement, provided that if BIAL subsequently determines not to continue prosecution or pay maintenance fees, Section 10.2(f) shall not apply to such previously assigned Patent.

(f) BIAL shall provide NBIX with a copy of any BIAL Patents to be filed by BIAL in the Territory covering Development Intellectual Property solely owned or Controlled by BIAL and a copy of communications between its agents and any patent office regarding such BIAL Patents in the Territory, within a reasonable deadline prior to submitting such BIAL Patents and communications to the patent office. Provided that NBIX responds within the specified deadline, BIAL shall consider or cause its agents to consider, in good faith, any comments NBIX may have regarding such BIAL Patents or communication, provided that final prosecution decisions shall rest with BIAL. NBIX shall be responsible for any expenses that it may incur in providing its comments. BIAL shall pay all official taxes, annuities, renewal and maintenance fees required to keep in force all issued BIAL Patents in the Territory covering Development Intellectual Property solely owned or Controlled by BIAL. If BIAL desires to discontinue the maintenance or prosecution, or payment of a maintenance fee, with respect to any Patent in the Territory included in the BIAL Patents under this Section 10.2(f), it shall notify NBIX in writing not less than […***…] before the deadline of a response period or the payment due date for a maintenance or other applicable fee. In the absence of any notification by NBIX within such […***…] period, BIAL may discontinue the maintenance or prosecution of such BIAL Patent in the Territory. Upon receipt of such notification by NBIX, NBIX shall have the option to assume, at its discretion and expense, the prosecution and maintenance of the affected Patent(s) in the Territory, in which event BIAL shall reasonably cooperate with and assist NBIX, at NBIX's expense, in executing a written assignment of such BIAL Patent to NBIX and provide at NBIX´s expense any other conveyance instruments, documents, or assistance as may be reasonably necessary or desirable to assign ownership of the Patents or to support of the prosecution of the application. Any expenses incurred by NBIX for the prosecution and maintenance of the affected Patent(s) are not refundable under any circumstances. For clarity, in the event that a BIAL Patent is assigned to NBIX pursuant to this Section 10.2(f), it shall

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be deemed to be a NBIX Patent under this Agreement, provided that if NBIX subsequently determines not to continue prosecution or pay maintenance fees, Section 10.2(e) shall not apply to such previously assigned Patent.

(g) Subject to BIAL's right set out below to assign Joint Patents in the Territory to NBIX if BIAL no longer wishes to prosecute or maintain them, BIAL shall file, prosecute and maintain Joint Patents in the Territory, covering Development Intellectual Property jointly-owned by the Parties. All costs including legal fees, official taxes, annuities, renewal, and maintenance fees required to prosecute all such applications and keep in force all issued Joint Patents that are jointly owned by the Parties, shall be shared equally by the Parties with respect to Joint Patents in the Territory and borne by BIAL with respect to Joint Patents outside the Territory. If BIAL desires to discontinue its participation in the prosecution of any Joint Patents or maintenance fee of an issued Joint Patent in the Territory, it shall notify NBIX in writing not less than […***…] before the expiration of a response period or the payment due date for a maintenance fee. Upon receipt of such notification, NBIX shall have the option to assume full responsibility, at its discretion and expense, for the prosecution and maintenance of the affected Joint Patent(s) in the Territory, in which event BIAL shall reasonably cooperate with and assist NBIX, at NBIX's expense, in executing a written assignment of the Joint Patent to NBIX and provide at NBIX´s expense any other conveyance instruments, documents, or assistance as may be necessary or desirable to establish ownership of the Joint Patent or to support the prosecution of the Joint Patents.

(h) Neither Party may grant a license under a Joint Patent filed in or outside the Territory without the express written consent of the other Party; provided, however, that BIAL may license BIAL's and NBIX's interest in a Joint Patent outside the Territory without the express written consent of NBIX and without accounting to NBIX; provided that any such license shall be subject to BIAL's rights under the NBIX License post termination and expiry of this Agreement.

ARTICLE 11
PATENT PROSECUTION AND MAINTENANCE

11.1 **Prosecution and Maintenance of BIAL Patents Controlled Solely by BIAL**: BIAL shall, at BIAL's expense, file, maintain and prosecute or cause to be filed, maintained, prosecuted or continue to maintain and prosecute to issuance in the Territory the BIAL Patents (excluding the BIAL Patents addressed in Article 10). BIAL shall timely pay all official taxes, annuities, renewal and maintenance fees required to keep in force all issued Patents included in such BIAL Patents in the Territory. If BIAL desires to discontinue the maintenance or prosecution, or payment of a maintenance fee, on any Patent included in the BIAL Patents, it shall notify NBIX in writing not less than […***…] before the deadline of a response period or the payment due date for a maintenance fee. In the absence of any notification by NBIX within such […***…] period, BIAL may discontinue the maintenance or prosecution of such BIAL Patent. Upon receipt of such notification by NBIX, NBIX shall have the option to assume, at its discretion and expense, the prosecution and maintenance of the affected Patent(s) in the Territory, in which event BIAL shall reasonably cooperate with and assist

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NBIX, at NBIX's expense, in executing a written assignment of such BIAL Patent in the Territory to NBIX and provide at NBIX's expense any other conveyance instruments, documents, or assistance as may be reasonably necessary or desirable to assign ownership of the Patents or to support of the prosecution of the application. Any expenses incurred by NBIX for the prosecution and maintenance of the affected Patent(s) are not refundable under any circumstances. For clarity, in the event that a BIAL Patent is assigned to NBIX pursuant to this Section 11.1, it shall be deemed to be a NBIX Patent under this Agreement.

11.2 **Abandonment of Opposition Contest**: Notwithstanding the foregoing Section 11.1, in the event that BIAL is not willing to defend an opposition, *inter parties* review, post grant review, re-examination, nullity action, or other similar action ("**Opposition Contest**"), BIAL shall provide NBIX with advance written notice of any decision by BIAL not to defend such Opposition Contest in the Territory relating to a BIAL Patent. NBIX shall have a reasonable time period from receipt of such notice to elect to continue prosecuting and defending such Patent. In the event NBIX elects not to do so within […***…] after receipt of BIAL's notification, BIAL may discontinue prosecuting and defending such BIAL Patent. NBIX shall bear the cost of such an Opposition Contest that NBIX elects to continue, and any expenses or fees paid by NBIX in defending such an Opposition Contest shall not be refundable under any circumstances BIAL shall, at NBIX's request and expense, provide NBIX with reasonable assistance including providing available documents and making witnesses available reasonably requested or required by NBIX to continue prosecuting and defending such patent or patent applications, including cooperation of any consultants of BIAL, at NBIX's expense. BIAL, at its own expense, shall have the right to participate in such Opposition Contest, or designate its own counsel to so participate, throughout each step of the Opposition Contest; provided that all decisions and conduct of activities in such Opposition Contest shall be the exclusive right of NBIX, further provided that NBIX shall take in good faith consideration any and all comments provided by BIAL.

11.3 **Notices of Issued Patent**: BIAL shall notify NBIX promptly but at least within […***…] of the issuance of each US and Canadian Patent included among the BIAL Patents along with the date of issuance and the Patent number for each such Patent.

11.4 **Patent Term Extension**:

(a) In the event that applicable law in the Territory provides for the extension of the term of any BIAL Patent, BIAL shall have the exclusive right, but not the obligation, following a good faith consultation with NBIX, to seek BIAL Patent term extensions (including any patent term extension certificates, supplemental protection certificates and the like available under applicable law) in the Territory in relation to any such BIAL Patent. NBIX agrees to cooperate with BIAL including without limitation to provide necessary information and assistance as BIAL may reasonably request in obtaining such extension.

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(b) In the event that applicable law outside the Territory provides for the extension of the term of any NBIX Patent, NBIX shall have the exclusive right, but not obligation, to seek NBIX Patent term extensions (including any patent term extension certificates, supplemental protection certificates and the like available under applicable law), provided however that NBIX may only reference a Marketing Authorization of BIAL with the prior written consent of BIAL, which BIAL may withhold or refuse in its absolute discretion. If BIAL gives such consent, BIAL agrees to cooperate with NBIX including without limitation to provide necessary information and assistance as NBIX may reasonably request in obtaining such extension. NBIX may not, directly or indirectly, exercise this right such that it has the effect of preventing BIAL from obtaining an extension of a BIAL Patent. For clarity, unless specifically authorized by BIAL, NBIX has no right to a Marketing Authorization for any product containing BIA 9-1067 outside the Territory.

(c) In the event that applicable law in the Territory provides for the extension of the term of any NBIX Patent, NBIX shall have the exclusive right, but not the obligation, to seek NBIX Patent term extensions (including any patent term extension certificates, supplemental protection certificates and the like available under applicable law). NBIX may not, directly or indirectly, exercise this right such that it has the effect of preventing BIAL from obtaining an extension of a BIAL Patent.

(d) With respect to the Joint Patents, BIAL shall have the exclusive right, but not the obligation, to seek Joint Patent term extensions (including any patent term extension certificates, supplemental protection certificates and the like available under applicable law) outside the Territory in relation to any such Joint Patent and NBIX shall have the exclusive right, but not obligation, to seek Joint Patent term extensions (including any patent term extension certificates, supplemental protection certificates and the like available under applicable law) in the Territory in relation to such any Joint Patent. NBIX may not, directly or indirectly, exercise this right such that it has the effect of preventing BIAL from obtaining an extension of a BIAL Patent. The Parties understand and agree that an application of Joint Patent term extensions shall be made in the name of the Parties, and if a Party has the exclusive right to seek such Joint Patent term extension determined to do so, the other Party agrees to cooperate with such Party including without limitation to provide necessary information and assistance as such Party may reasonably request in obtaining such extension.

(e) Should the law require the Party not having the exclusive right as set forth herein ("**Non-extension Party"**) to apply for such an extension directly, the Party having the exclusive right as set forth herein ("**Extension Party**") shall cooperate with the Non-extension Party in obtaining such an extension and shall execute such documents and take such additional actions as the Non-extension Party may reasonably request in connection therewith. Should applicable law in the Territory require that any such authorization be held in the name of the Non-extension Party, such authorization shall be held by the Non-extension Party solely for the benefit of and in trust for the Extension Party and, upon termination or expiration of the Term of this Agreement, the Non-extension Party agrees to assign such authorization to Extension Party, its Affiliate or nominee and to provide any other conveyance, instruments, documents or assistance as may be necessary or desirable to establish ownership of such

authorization in Extension Party. Notwithstanding anything to the contrary contained herein, the Parties shall use reasonable efforts to agree upon a joint strategy relating to patent term extensions with respect to BIAL Patents, Joint Patents and NBIX Patents, but, in the absence of mutual agreement with respect to any extension issue, Extension Party shall have the final decision making authority, except as otherwise set forth in this Agreement.

11.5 Patent Certifications:

(a) Each Party will immediately give written notice to the other of any certification of which it becomes aware that has been filed pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), or § 355(j)(2)(A)(vii)(IV) (or any amendment or successor statute thereto or Canadian equivalent statute) claiming that the BIAL Patents, Joint Patents or NBIX Patents covering the Licensed Product are invalid, unenforceable, and/or that infringement will not arise from the manufacture, use, offer for sale or sale, of such Third Party product by a Third Party. BIAL shall have the first right, but shall not be obligated, to bring suit against the Third Party that filed the certification. If BIAL decides not to bring infringement proceedings against the Third Party making such a certification with respect to any BIAL Patent or Joint Patent and a Licensed Product, BIAL will give notice to NBIX of its decision not to bring suit within […***…] after receipt of notice of such certification (or, if the time period permitted by law is less than […***…], within half of the time period permitted by law for NBIX to commence such action). NBIX shall then have the right, but shall not be obligated, to bring suit against the Third Party that filed the certification. Any suit by either Party may be in the name of either or both Parties, as may be required by law. For this purpose, the Party not bringing suit will execute such legal papers necessary for the prosecution of such suit and will provide assistance at the other Party's expense as may be reasonably requested by the Party bringing suit, including joining such action as a party. In any event, the Party bringing the suit shall **(i)** seek approval of the law firm selected to litigate such action from the other Party (such approval not to be unreasonably withheld or delayed) and **(ii)** provide regular updates from its counsel on the status of such action to the other Party. In addition, the Party not bringing suit has the right to be present, but not to actively participate, for all depositions, settlement negotiations, and other significant meetings or hearings.

(b) If BIAL commences infringement proceedings against the Third Party, BIAL will be solely responsible for the expenses and costs of prosecuting that lawsuit, even if BIAL names NBIX as a co-plaintiff or otherwise brings NBIX into the lawsuit. BIAL will seek the advice of and consult with NBIX regarding the strategy and prosecution of the lawsuit. In no event will BIAL dismiss or otherwise resolve such lawsuit without the participation of and express written consent of NBIX, which shall not be unreasonably withheld, conditioned or delayed.

(c) If NBIX commences infringement proceedings against the Third Party, NBIX will be solely responsible for the expenses and costs of prosecuting that lawsuit, even if NBIX names BIAL as a co-plaintiff or otherwise brings BIAL into the lawsuit. NBIX will seek the advice of and consult with BIAL regarding the strategy and prosecution of the lawsuit. In no event will NBIX dismiss or

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otherwise resolve such lawsuit without the participation of and express written consent of BIAL, which shall not be unreasonably withheld, conditioned or delayed.

ARTICLE 12
INFRINGEMENT

12.1 Infringement of the BIAL Patents:

(a) If either Party identifies a Third Party infringement of an issued BIAL Patent or Joint Patent in the Territory (other than via a certification notice mentioned under Section 11.5) it shall promptly (within […***…]) notify the other Party of the alleged infringement. NBIX will have […***…], from the date that NBIX either receives a notice of alleged infringement from BIAL or provides such a notice to BIAL, to: […***…]. NBIX shall have the initial right, at its own expense, to enforce BIAL Patents and Joint Patents in the Territory. If NBIX initiates a suit against the infringer, BIAL shall cooperate with NBIX, at NBIX's expense, including joining in the action as a party to the extent necessary to permit NBIX to pursue the action. NBIX shall assume all costs of any action it pursues against the Third Party and shall reimburse BIAL for its costs (including reasonable attorneys' fees and expenses) of assisting in the action as requested by NBIX.

(b) If NBIX does not complete one of the three actions described in Section 12.1(a) within […***…] after the notice, BIAL may initiate the action against the infringer and NBIX shall cooperate fully with BIAL, at BIAL´s expense, including joining the action to the extent necessary to permit BIAL to pursue the action. BIAL shall assume all costs of asserting a claim of infringement against the Third Party, and shall reimburse NBIX for its costs (including reasonable attorneys' fees and expenses) of assisting in the action.

(c) Any damages or other monetary awards recovered in any action brought by one of the Parties against an infringer of a BIAL Patent or Joint Patent in the Territory shall be applied to the reimbursement of the Parties for their respective out-of-pocket expenses (including reasonable attorneys' fees and expenses) incurred in prosecuting such infringement action on a pro rata basis based upon their respective out-of-pocket expenses until all such expenses have been recovered, and any remaining balance, if any, will be divided […***…]) to NBIX and […***…]) to BIAL. The Party who initiated a lawsuit as specified in this Section may only settle any law suit or agree the terms of any sublicense that in each case would in any manner alter, diminish, or be in derogation of the other Party's rights under this Agreement, with the prior written consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed.

(d) Any action under Section 11.5 shall be subject to the terms of Section 11.5 and not Sections 12.1(a) and (b).

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12.2 Alleged Infringement of Third Party Patents:

(a) If either Party becomes aware that the development, making, packaging, labelling, handling, storage, importation, transportation, use, distribution, promotion, offer for sale, marketing or sale of a Licensed Product within the Territory infringes or is alleged to infringe a patent of a Third Party (each, an "**Alleged Infringement**"), it shall promptly, but in any event no later than […***…] after becoming aware, notify the other Party.

(b) The Parties shall thereafter attempt to agree upon a course of action which may include, without limitation: […***…]. In the event that the Parties do not agree upon a course of action pursuant to the preceding sentence within […***…] after learning of such Alleged Infringement, NBIX […***…]; provided however, that with respect to an Alleged Manufacturing Infringement, […***…]. If NBIX declines to assume control of the defense of any Alleged Infringement in the Territory, then NBIX shall provide an explanation to BIAL regarding its decision to decline to assume control, and then BIAL shall have the right, but not the obligation, to assume such defense, at BIAL's expense. Upon request of the Party controlling the defense of any such action, the other Party shall, at the controlling Party's expense, join in any such litigation and will have the obligation to reasonably cooperate with the controlling Party (including giving testimony and producing documents lawfully requested, and using its reasonable efforts to make available to the other such employees who may be helpful with respect to such suit, investigation, claim or other proceeding). The controlling Party shall only have the right to settle any Alleged Infringement and agree the terms of such settlement (which may include a license), with the other Party's consent, which shall not be unreasonably withheld.

(c) In the event that **(i)** the development, making, packaging, labelling, handling, storage, importation, transportation, use, distribution, promotion, offer for sale, marketing or sale of a Licensed Product is deemed by a court of competent jurisdiction to infringe a claim of a patent(s) owned or controlled by a Third Party in the Territory, or **(ii)** NBIX or its Affiliate obtains a license under such patent(s) in settlement of such claims with the consent of BIAL (such consent shall not be unreasonably

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withheld or delayed), or **(iii)** NBIX determines that it is commercially necessary to pay royalties or other fees to a Third Party to obtain a license to practice any Third Party's rights in order for NBIX to carry out the activities envisaged by this Agreement in the Territory as well as to avoid the infringement of a claim of a patent(s) owned or controlled by a Third Party in the Territory ("**Third Party License**"), during the Term, then […***…].

(d) In the event there is an Alleged Manufacturing Infringement, **(i)** if BIAL determines it is commercially necessary to modify the process(es) for making or packaging the relevant Licensed Product to avoid the Alleged Manufacturing Infringement, all costs related to such modification (hereinafter "**Process Modification Costs**"), and/or **(ii)** if the Parties determine that it is commercially necessary to pay royalties or other fees to obtain Third Party License to avoid the Alleged Manufacturing Infringement in the Territory, then all such costs, license fees and royalties for such Third Party License, and **(iii)** all Losses (as defined in Section 16.1 hereof) resulting from such Alleged Manufacturing Infringement in the Territory (such costs, fees, and Losses described in clauses (i), (ii), and (iii) of this sentence shall be referred to as "**Alleged Manufacturing Infringement Costs**"), then, notwithstanding any other provision of this Agreement, any and all Alleged Manufacturing Infringement Costs shall […***…]; provided however that, in the event there is also an alleged manufacturing infringement outside the Territory which requires the incurrence of Process Modification Costs, then the Process Modification Costs […***…]:

[…***…]:

NBIX Portion = […***…]

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NBIX Portion = […***…]

NBIX Portion = […***…]

NBIX Portion = […***…]

In addition, if BIAL determines the appropriate action to take in response to an Alleged Manufacturing Infringement is to modify the process(es) for making or packaging a Licensed Product to avoid the Alleged Manufacturing Infringement, then such activities will be undertaken as a collaborative effort between the Parties and overseen by the JSC.

ARTICLE 13
CONFIDENTIALITY

13.1 Confidential Information:

(a) As used in this Agreement, the term "**Confidential Information**" means, with respect to a Party, all data, know-how and other information, whether written or oral, technical or non-technical, that is disclosed by or on behalf of such Party (including by or on behalf of or through a parent, subsidiary, Affiliate, contractor or licensee) to the other Party (including by or on behalf of or through a parent, subsidiary, Affiliate, contractor or licensee) in the performance of this Agreement, the SDEA, the Supply Agreement and the Quality Agreement. Confidential Information may include BIAL Know-How, NBIX Know-How, commercial information, Development and Regulatory Plans, Development Studies protocols, financial statements, reports, pricing, trade secrets, secret processes, formulas, customer data (including customer lists), business information, business methods, business plans, and pricing, cost, supplier and manufacturing information, All Confidential Information shall remain the property of the disclosing Party. In addition, all information disclosed by BIAL under that certain Confidentiality Agreement between the Parties dated June 10, 2015 (the "**Confidentiality Agreement**"), shall be deemed BIAL's Confidential Information, and any use or disclosure thereof by NBIX that is permitted under this Agreement shall not be deemed a breach of the Confidentiality Agreement.

(b) The term "Confidential Information" does not include any such items for which the receiving Party can show by competent written proof or other reasonable support that such item:

(i) was known to and existed in documentary or other physical form in the possession of the receiving Party at the time of disclosure;

(ii) subsequent to the receipt hereunder, is made available to the receiving Party on a non-confidential basis by a Third Party which is legally entitled to make such information available;

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(iii) was or becomes publicly known through no fault of the receiving Party; or

(iv) is independently developed by employees or agents of the receiving Party without access to Confidential Information disclosed hereunder.

13.2 Obligations of Confidentiality: Subject to the provisions in Section 13.1(b), during the Term and for as long as the Confidential Information relating thereto is not made public by the disclosing Party, each Party agrees:

(a) to preserve the confidentiality of all Confidential Information received from the other Party, and not to disclose any such Confidential Information to a Third Party without first obtaining the written consent of the disclosing Party, except as may be otherwise provided herein;

(b) to take all necessary steps to ensure that Confidential Information received from the other Party is securely maintained and to inform those who are authorized to receive such Confidential Information of their obligations under this Agreement; and

(c) to use any and all Confidential Information received from the other Party solely in connection with, or as permitted by, this Agreement (including exercising its rights and performing its obligations hereunder) and for no other use.

13.3 Right to Disclose:

(a) Nothing herein shall be construed as preventing either Party from disclosing any Confidential Information received from the other Party to its officers, directors and employees, Affiliates, distributors, licensees, sublicensees, consultants, professional advisors, agents and contractors (the "**Representatives**"), in each case where such person or entity has a reasonable need to know such Confidential Information, provided that the Representatives have undertaken similar written obligations of confidentiality and non-use with respect to the Confidential Information.

(b) Nothing contained in this Article restricts the Parties or their respective Affiliates from disclosing the other Party's Confidential Information as reasonably required for: **(i)** seeking any Marketing Authorization or other authorization required under or for the purposes of this Agreement, **(ii)** regulatory, tax or customs reasons, **(iii)** audit purposes, **(iv)** the development, manufacture, use, sale, external testing or marketing trials of products in a manner consistent with the terms of this Agreement, the SDEA, the Supply Agreement and the Quality Agreement, or **(v)** the filing or prosecuting Patents as contemplated by this Agreement, without violating the above secrecy provision (it being understood that publication of such Patents within […***…] of filing will not violate such secrecy provisions), or **(vi)** by court order or other government order or request. With respect to disclosing Confidential Information pursuant to a court order or other government order or request, prompt notice of such order or request shall be provided to the disclosing Party and, to the extent legally possible, the disclosure shall not occur until the disclosing Party either approves the disclosure or has had the

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opportunity to seek a protective order or other appropriate remedy to curtail such disclosure. In the event that the disclosing Party is unsuccessful in preventing the disclosure of Confidential Information to the court or government, the other Party shall take reasonable efforts to protect the confidentiality of the Confidential Information and will disclose only that portion of Confidential Information which it is legally required to disclose.

13.4 Disclosure of Financial and Other Terms:

(a) Except as required by applicable laws, treaties or agreements (including securities laws and regulations), the Parties agree that the terms of this Agreement, the SDEA, the Supply Agreement and the Quality Agreement will be considered Confidential Information of both Parties.

(b) Notwithstanding the foregoing, **(i)** either Party may disclose such terms as are required to be disclosed in its publicly-filed financial statements or other public statements, in order to comply with applicable laws, regulations or stock exchange rules, provided that, to the extent legally possible, such Party shall provide the other Party with a copy, in English language, of the proposed text of such statements or disclosure sufficiently in advance of the scheduled release or publication thereof to afford such other Party a reasonable opportunity to review and comment upon the proposed text, and **(ii)** either Party has the right to disclose this Agreement (but, for the avoidance of doubt, not any other Confidential Information of the other Party) under a confidentiality obligation no less protective than that set forth in this Agreement (but which may be of shorter duration, but at least […***…]), to any potential acquirer, merger partner, providers of financing, or potential providers of financing and their advisors.

(c) Neither Party shall make any other statement to the public regarding the execution and/or any other aspect of the subject matter of this Agreement except as provided in Section 13.5 and except: **(i)** where disclosure is required under applicable laws and **(ii)** either Party may use the text of a statement previously approved in writing by the other Party.

13.5 Publicity/Use of Names.

(a) Except as otherwise provided in this Agreement, neither Party nor any of its Affiliates or Third Party licensee shall use the name, trademark, trade name or logo of the other Party or any of its Affiliates or Third Party licensee, or the names of their respective employees, in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by law.

(b) Each Party may issue a press release announcing the entry into this Agreement in a form approved by the Parties in writing as of the Effective Date. Neither Party nor any of its Affiliates shall originate any other publicity, news release or other public announcement including, without limitation, online announcement or disclosure, written or oral, relating to the terms or conditions contained in this Agreement, or the existence of and information about any performance, including, without limitation,

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any Development Studies, conducted by any Party and/or any of its Affiliates under this Agreement without the prior written approval, and agreement upon the nature and text of such announcement or disclosure, of the other Party, which approval and agreement shall not be unreasonably withheld or delayed. For clarity, BIAL shall have the right to provide its or its Affiliates' licensees outside the Territory with a copy of each draft copy of announcement of NBIX for their review and comment.

(c) Notwithstanding the foregoing, either Party may make such disclosures without the prior consent of the other Party if such disclosure is required by law; *provided, however,* that any disclosure required by law shall be subject to the last sentence of Section 13.3(b) *mutatis mutandis*.

(d) The Party desiring to make any public announcement or other disclosure, as provided above, shall inform the other Party of the proposed announcement or disclosure in reasonably sufficient time, and in any event at least […***…], to the extent practicable with respect to legally required disclosures, prior to public release, and shall provide the other Party with a written copy thereof, in English language, in order to allow such other Party to comment upon such announcement or disclosure.

(e) The Parties acknowledge that no further approval is required for disclosure of information for which consent has previously been obtained and information of a similar nature to that which has been previously disclosed publicly with respect to the subject matters contained in this Agreement and/or the existence of and information about any performance conducted under this Agreement or related to Licensed Product in any country in and outside the Territory.

(f) The Parties agree that generally they shall make press releases simultaneously; *provided, however,* that in the event that one Party informs the other Party that it does not desire to make a press release, such Party shall not be obligated to make such press release and the other Party may make a unilateral press release on its own behalf subject to the provisions of this Section 13.5.

(g) All press releases of NBIX related to Licensed Products or where the Licensed Products are mentioned shall include a phrase to the effect that all rights to Licensed Products and BIA 9-1067 are licensed from BIAL in the same manner as set forth in Section 2.1(f).

13.6 **Consequences of Breach**: The Parties understand that monetary damages may be inadequate or insufficient to protect any breach of any of the provisions of this Article 13 by either Party or its officers, directors and employees, its Affiliates, distributors, licensees, sublicensees and contractors, or any other person or entity acting in concert with it or on its behalf. Accordingly, the non-breaching Party will be able to seek all remedies available at law or in equity, including the right to request injunctive relief, specific performance of the provisions of this Article 13 and/or to claim damages in a court of competent jurisdiction.

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ARTICLE 14
REPRESENTATIONS AND WARRANTIES

14.1 **Representations and Warranties by BIAL**: BIAL hereby represents and warrants to NBIX as of the Effective Date, that:

(a) Exhibit 2.1 attached hereto **(i)** contains a true and complete list of the BIAL Patents in the Territory as of the Effective Date and **(ii)** includes all Patents owned or in-licensed by BIAL in the Territory that claim or cover BIA 9-1067 or any Licensed Product.

(b) Exhibit 2.3 attached hereto contains the […***…] trademarks selected by BIAL for the Territory as of the Effective Date;

(c) BIAL is the sole owner of the entire right, title and interest in and to the BIAL Patents and the Trademarks as at the Effective Date, free and clear from any mortgages, pledges, liens, security interests, conditional and instalment sale agreements, encumbrances, charges or claims of any kind. BIAL has the full power, authority and legal right to enter into this Agreement, to perform its obligations hereunder and to license them to NBIX on the terms of this Agreement and, together with its Affiliates, to perform BIAL's obligations hereunder, and to the Knowledge of BIAL no person or governmental authority, has any claim of ownership with respect to BIAL Patents listed on Exhibit 2.1 and/or Trademarks listed on Exhibit 2.3 as of the Effective Date;

(d) to the Knowledge of BIAL but having made no investigations, no Third Party is infringing or is threatening to infringe or make unauthorized use of any of the BIAL Patents or the BIAL Know How or Trademarks in the Territory;

(e) there are no pending or, to the Knowledge of BIAL, threatened actions, suits, claims, interference proceedings or governmental investigations in any court, arbitration, patent office, administrative or other tribunal in the Territory by or against BIAL or its Affiliates involving BIA 9-1067, the BIAL Patents, the BIAL Know How or Trademarks. In particular, there is no pending or, to the Knowledge of BIAL threatened product liability action nor intellectual property right litigation inside or outside the Territory (other than the trademark oppositions and cancellation action which BIAL has informed NBIX of), including, but not limited to, a challenge to the validity or ownership of BIA 9-1067, the BIAL Patents or the BIAL Know How or Trademarks, relating to BIA 9-1067;

(f) there are no pending or, to the Knowledge of BIAL, threatened claims or actions claiming that the development, manufacture, sale, offering for sale, importation or use of the Licensed Products in the Territory would infringe the intellectual property rights of any Third Party;

(g) to the Knowledge of BIAL, the development, manufacture, sale, offering for sale, importation and use of the Initial Product for the Initial Indication in the Territory will not infringe or misappropriate the valid and issued patent rights of any Third Party;

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(h) to the Knowledge of BIAL, the claims of the issued BIAL Patents are valid and enforceable.

(i) it has not previously granted rights under the BIAL Patents, BIAL Know-How and/or Trademarks, or any portion thereof, that conflict with the rights and licenses granted to NBIX under this Agreement for the Territory;

(j) all necessary consents, approvals and authorizations of all Regulatory Authorities, other governmental authorities and other persons or entities required to be obtained by BIAL in order to enter into this Agreement have been obtained;

(k) To the Knowledge of BIAL, BIAL it has materially complied with GCP, GMP and GLP in connection with the development of BIA 9-1067 and other applicable laws, rules and regulations; and

(l) BIAL has not intentionally withheld or concealed from NBIX **(i)** any material written information requested by NBIX and in BIAL's possession or Control as of the Effective Date relating to the Initial Product (other than with respect to the Manufacturing Know-How) or **(ii)** any material information requested by NBIX and in BIAL's possession or Control relating to the BIAL Patents.

14.2 **Representations and Warranties by NBIX**: NBIX hereby represents and warrants to BIAL as of the Effective Date that:

(a) all necessary consents, approvals and authorizations of each Agency, other governmental authorities and other persons or entities required to be obtained by NBIX in order to enter into this Agreement have been obtained; and

(b) the First Development and Regulatory Plan represents all NBIX's plans for its activities in respect of the development of the Licensed Products, which are developed based on the information provided by BIAL prior to the Effective Date, and it has not intentionally withheld or concealed from BIAL any material information relating to NBIX's intended activities in respect of BIA 9-1067 and/or the Licensed Products; and

(c) there are no Competing Products under development or being commercialized in the Field in the Territory that are Controlled by or on behalf of NBIX or its Affiliates; and

(d) there are no compounds or drug products under development by NBIX or its Affiliates which would be covered by any of the BIAL Patents; and

(e) there are no NBIX Patents or NBIX Know-How.

14.3 **Mutual Representations and Warranties**: Each Party hereby represents and warrants to the other Party as of the Effective Date, that:

(a) Such Party is a corporation duly organized, validly existing and in good standing under the laws of its place of incorporation.

(b) The execution and delivery of this Agreement by such Party has been duly authorized by all necessary corporate actions on the part of such Party. Such Party has full power, authority and legal right to execute and deliver this Agreement and to perform its obligations hereunder. This Agreement has been duly executed and delivered by such Party, is a legal and valid obligation binding upon such Party and enforceable against such Party in accordance with its terms, except as such enforceability may be limited by applicable insolvency and other laws affecting creditors' rights generally or by the availability of equitable remedies.

(c) The execution, delivery and performance of this Agreement does not and will not violate **(i)** the organizational documents or by-laws of such Party, or **(ii)** any provision of any agreement or other instrument or document to which such Party is a party or by which any of its assets or properties is bound or affected.

14.4 Negation of Implications: Except as expressly stated herein, nothing in this Agreement will be construed as:

(a) An obligation on the part of either Party to bring or prosecute actions or suits against Third Parties for infringement of any of the Patents or other intellectual property rights of the Parties;

(b) Conferring on either Party a right to use in advertising, publicity, or otherwise any trademark, service mark, or trade name of the other Party; or

(c) Granting by implication, estoppel, or otherwise, any licenses or rights under patents or other intellectual property of a Party other than those rights expressly granted herein.

14.5 Non Reliance; Disclaimer:

(a) The warranties and representations of each Party set forth in this Agreement are intended for the sole and exclusive benefit of the other Party hereto, and may not be relied upon by any Third Party.

(b) NBIX waives any right it may have to rescind this Agreement for any misrepresentation by BIAL.

(c) EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE LICENSED PRODUCTS OR ANY PATENTS, KNOW-HOW, TRADEMARKS OR OTHER INTELLECTUAL PROPERTY DISCLOSED, DEVELOPED, OR LICENSED UNDER THIS AGREEMENT. EXCEPT TO THE EXTENT

EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE LICENSED PRODUCTS OR ANY PATENTS, KNOW-HOW, TRADEMARKS OR OTHER INTELLECTUAL PROPERTY DISCLOSED, DEVELOPED, OR LICENSED UNDER THIS AGREEMENT, INCLUDING WITHOUT LIMITATION ANY WARRANTY OR REPRESENTATION OF NON-INFRINGEMENT, MERCHANTABILITY, AND FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 15
TERM AND EXPIRATION AND TERMINATION OF THIS AGREEMENT

15.1 Term:

(a) This Agreement commences as of the Effective Date and shall remain in force, on a Licensed Product by Licensed Product and country by country basis, unless otherwise terminated in accordance with any of the provisions of this Article 15, until the last day of the first Calendar Quarter during which a Generic Product in respect of such Licensed Product is sold in such country […***…] in such country in such Calendar Quarter (the "**Term**").

(b) Upon the expiration of this Agreement in respect of a Licensed Product in a country in the Territory, the licenses granted to NBIX in Section 2.1 and 2.2 shall (save with respect to the Trademark) become fully-paid, perpetual and irrevocable in respect of such Licensed Product (but not, for the avoidance of doubt, in respect of any other Licensed Product) in such country (but not, for the avoidance of doubt, in respect of the other country within the Territory) and shall include the right to manufacture and have manufactured such Licensed Product.

(c) Upon NBIX's written request […***…] prior to the estimated expiration of the Term in respect of a Licensed Product, the Parties shall negotiate in good faith the terms under which BIAL may continue to supply such Licensed Product to NBIX after the Term and shall use reasonable efforts to conclude such negotiation and enter into a supply agreement containing such terms prior to expiration of the Term, provided that if the Parties fail to enter into such agreement prior to the end of the Term, the Supply Agreement shall continue to govern the supply of such Licensed Product for […***…] post expiration of this Agreement.

(d) After the Term and if BIAL is not supplying a certain Licensed Product, NBIX shall pay BIAL a royalty of […***…] percent ([…***…]%) of Net Sales of such Licensed Product sold by NBIX and/or its Affiliates under or in relation to the Trademark. Such royalties shall be paid by NBIX to BIAL within […***…] following the end of each Calendar Quarter together with a statement showing the aggregate gross sales in value and in Units, the type and value of deductions made in calculation of Net

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Sales, the aggregate Net Sales in such Calendar Quarter and the amount of royalties due to BIAL in respect of that Calendar Quarter. BIAL shall have the right to audit all of the foregoing pursuant to, *mutatis mutandis*, Paragraphs 1.7(a) and (b) of **Exhibit 4**.

15.2 **Termination for Cause**: Prior to expiration of the Term as set forth in Section 15.1, either Party may terminate this Agreement, without prejudice to any other remedies available to it at law or in equity, upon the occurrence of any of the following events (each, a "**Termination Event**"):

(a) either Party may terminate this Agreement upon written notice to the other Party, if the other Party materially breaches or defaults in the performance of any of its obligations hereunder (except an alleged breach by NBIX of any obligation requiring it to use Commercially Reasonable Efforts) and such breach is uncurable or it fails to cure such breach or default within […***…] (or […***…], solely with respect to a payment breach) following receipt of written notice from the non-breaching Party specifying the breach or default in reasonable detail; provided, however, that the Parties shall meet in person and discuss in good faith the alleged breach or default and potential cures (if applicable) for such alleged breach or default within the […***…] or […***…] day timeframe (as applicable) prior to such termination becoming effective.

(b) If it is determined in accordance with Sections 17.1(d) and 17.1(e) that NBIX has breached any of its obligations to use Commercially Reasonable Efforts and if NBIX fails to take the action to remedy the breach or default described by the arbitrator in its decision within the period set out in the arbitrator's decision, BIAL may terminate this Agreement by giving, at any time within three months after the end of that period, not less than thirty (30) days' notice;

(c) by BIAL pursuant to Section 7.3(b) or 7.3(c) upon […***…] days written notice to NBIX; or by BIAL pursuant to Section 8.3(h) upon […***…] days written notice to NBIX;

(d) by either Party if the other Party voluntarily files or a resolution is passed for its administration, winding up, or dissolution, or should a trustee administrative or other receiver, manager, administrator, liquidator or similar officer be appointed for all or any of its retained business assets or operations or it enters into or proposes any composition or arrangement with its creditors generally or anything similar to the foregoing occurs in any applicable jurisdiction;

(e) Within thirty (30) Business Days of receipt of a Change of Control Notice, BIAL may elect, by giving […***…] notice in writing to NBIX, to terminate this Agreement if NBIX has undergone a Change of Control involving any of the following circumstances (i) to (iii):

(i) the Third Party involved in the Change of Control, whether by absorption of, absorption by, acquisition of, acquisition by, consolidation or merger with, NBIX or otherwise (the "**Change of Control Entity**") is developing, importing, using, promoting, distributing, commercializing, offering for sale or selling a Competing Product in and/or outside the Territory and such Change of Control Entity:

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(A) does not provide notice to BIAL within […***…] of the Change of Control of its intention to divest itself of such Competing Product;

(B) having provided such notice to BIAL, does not use Commercially Reasonable Efforts to divest itself of such Competing Product within […***…] of such Change of Control ; and

(C) having provided such notice to BIAL, does not actually divest itself of such Competing Product within the earlier of ***(1)*** […***…] of such Change of Control or ***(2)*** such timeframe ordered by the Federal Trade Commission of the US; or

(ii) the Change of Control Entity is or has been within […***…] engaged in litigation (in court, arbitral tribunal or otherwise) against BIAL, or written correspondence exists threating litigation or allegations of infringement of any Patent, trademarks or other intellectual property right of BIAL or its Affiliates, whether or not relating to the Licensed Products and in and/or outside the Territory; or

(iii) the Change of Control Entity (together with the NBIX entity or assets it has acquired) does not have the capabilities (including, without limitation, the financial capability) and resources (including, without limitation, know-how and personnel) at least comparable to NBIX's capabilities and resources to meet the obligations under this Agreement.

(f) In the event that NBIX undergoes a Change of Control prior to the first Approval and such Change of Control does not involve any of the circumstances under Section 15.2(e), BIAL may also elect to terminate this Agreement within […***…] of receipt of the Change of Control Notice, by giving […***…] notice in writing to NBIX (such notice hereinafter referred to as the "**Section 15.2(f) Notice**"); provided however that, […***…]), then the Agreement shall not be terminated but shall continue in full force and effect as modified by the foregoing written confirmation.

15.3 **Termination For Convenience**: NBIX may terminate this Agreement in its entirety for any or no reason, upon:

(a) […***…] prior written notice to BIAL if such notice is given prior to the first NDA Approval of the Initial Product in the US, in which case:

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(i) if such termination notice is provided ***(A)*** prior to or after first learning from the FDA that no Phase III Study is required or ***(B)*** after learning that a single Phase III Clinical Study […***…] is required for NDA submission, NBIX shall pay to BIAL […***…] US Dollars (US$[…***…]) within […***…] of the date of such notice.

(ii) Should the fee in Section 15.3(a)(i) not be payable, NBIX shall be under the obligation to complete all ongoing development activities prior to the conclusion of the termination notice period or such other period reasonably necessary to complete such activities.

(b) […***…] prior written notice to BIAL if such notice is given after the first NDA Approval of the Initial Product in the US.

15.4 **Waiver of Termination Event**: The right of either Party to terminate this Agreement as provided in Sections 15.2 or 15.3 shall not be affected in any way by such Party's waiver or failure to take action upon the occurrence of a previous Termination Event.

15.5 **Rights and obligations upon Termination of the Agreement**: If this Agreement is terminated:

(a) All licenses granted by BIAL under this Agreement shall terminate save that during the wind-down periods referenced in this Section 15.5 (if applicable), the license granted to NBIX with respect to Licensed Products in the Field in the Territory shall be non-exclusive and limited to the activities expressly contemplated by this Section 15.5, and, without limiting the foregoing, BIAL shall have the right to engage one or more other distributors and/or licensees of the Licensed Products in the Field in the Territory;

(b) If this Agreement is terminated by BIAL in accordance with Section 15.2(a), 15.2(b) or 15.2(c), NBIX and its Affiliates shall not use, develop, import, promote, distribute, market, commercialize, offer for sale or sell within the Field and Territory, any Competing Product for the period of one (1) year after the date of termination;

(c) NBIX shall promptly assign to BIAL, or to its Affiliate or nominee, all right, title and interest in and to any INDs for Licensed Products and/or BIA-9-1067 (including the BIA-9-1067 IND) in the Territory and NBIX shall notify the FDA and other applicable Agencies in writing that ownership of such INDs has been assigned to BIAL or its Affiliate or nominee;

(d) NBIX shall promptly assign to BIAL or its Affiliate or nominee, any Approval(s), and any pending or approved NDAs for any Licensed Products in the Territory;

(e) Any Patent term extensions of a NBIX Patent covering or relating to BIA 9-1067 shall be assigned to BIAL, its Affiliate or nominee;

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(f) The NBIX License shall convert to an exclusive, fully paid-up, royalty-free, irrevocable, perpetual and worldwide (including the Territory) license;

(g) NBIX shall promptly assign and deliver to BIAL or its Affiliate documents, material, data, reports, Regulatory Authority or development correspondence, rights and information, Controlled by NBIX, directly relating to or concerning BIA 9-1067 or the relevant Licensed Products; and

(h) At the written request of BIAL, NBIX shall assign to BIAL or to its Affiliate or nominee any Licensed Product-specific Third Party agreements, to the furthest extent possible, provided that such assignment is permitted under the Licensed Product-specific agreement or is accepted by the Third Party. In the event such assignment is not requested by BIAL or is not accepted by such Third Party, then the rights of such Third Party with respect to Licensed Products shall terminate upon termination of this Agreement. NBIX shall use Commercially Reasonable Efforts to ensure that such Third Parties (if its contract is not assigned to BIAL pursuant to this Section 15.5(h)) shall transition any remaining Licensed Products back to BIAL in the manner set forth in this Section 15.5, and to include provisions requiring compliance with these provisions in the agreements with Third Parties.

(i) At BIAL's discretion and upon BIAL's written request which shall be delivered prior to the effective date of the termination, during a period starting on the date of notice of termination and not exceeding six (6) months following the effective date of termination:

(A) the Parties shall work together in good faith to adopt a plan to wind-down any development activities with respect to the Licensed Products in the Territory in an orderly and reasonable fashion or, at BIAL's election, promptly transition such development activities to BIAL or its designee, at NBIX's expense (except in the event of termination by NBIX for a BIAL breach pursuant to Section 15.2 hereof, in which case it shall be at BIAL's expense), with due regard for patient safety and the rights of any subjects that are participants in any Clinical Trials of Licensed Products and take any actions the Parties deem reasonably necessary or appropriate to avoid any human health or safety problems and in compliance with all applicable laws. NBIX shall perform or cause to be performed its outstanding non-cancellable obligations with respect to the development of any Licensed Products that existed or accrued prior to the notice date of termination; and

(B) NBIX shall continue, to the extent that NBIX continues to have an inventory of Licensed Products, to fulfil orders received from customers for Licensed Products in the Territory prior to the effective date of termination. For the Licensed Products sold by NBIX or its Affiliates after the effective date of termination, NBIX shall continue to make payments to BIAL in accordance with the terms and conditions of this Agreement. Notwithstanding the foregoing, NBIX and its Affiliates shall cease such activities upon sixty (60) days' written notice given by BIAL at any time after the effective date of a termination requesting that such activities cease. Within […***…] after BIAL has given notice to NBIX requesting the cessation of

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activities pursuant to the provision of this Section 15.5(i)*(B)*, NBIX shall notify BIAL of an estimate of the quantity of Licensed Products and shelf life remaining in NBIX's inventory and BIAL shall have the right, but not the obligation, to purchase any such quantities of Licensed Products from NBIX at a price mutually agreed by the Parties. To the extent BIAL does not purchase such quantities, NBIX may sell such quantities during the period of […***…] after the receipt by NBIX of a notice specifying that BIAL does not intend to purchase such quantities within the shelf life remaining for such Licensed Products.

15.6 **Survival**: The following terms and provisions will survive the termination or expiry of the Agreement: Articles 1, 13 (for the period as specified therein) and 16 (in respect of claims resulting from activities occurring or failing to occur prior to termination or expiry); and Sections 2.1(a), 2.1(b), 2.1(c) and 2.1(h); 2.5 (in respect of liabilities accruing prior to termination or expiry); 2.6(c)(iii); 2.7(b) and 2.7(c); 3.1(b). 3.1(c), 3.2, 3.3 and 3.4 (all in respect of payments that have become due prior to termination or expiry); 7.5 (b) and 7.5(c); 7.7(b); 7.8 (in respect of recall events occurring prior to termination or expiry); 9.2(a) and 9.2(b); 9.4(b); 9.5; 9.6; 10.1(first paragraph); 10.2(g); 10.2(h); ; 15.1(b), 15.1(c) and 15.1(d); 15.5; 15.6; 15.7; 17.1; 17.2; 17.4; 17.6; 17.7; 17.8; 17.9; 17.10; 17.11; 17.13 and 17.14.

15.7 **Accrued Rights and Obligations**: Expiration or any early termination of this Agreement will not relieve the Parties of any obligation or liability accruing prior to such termination or expiration, including, without limitation, the payment obligations set forth in Article 3.

ARTICLE 16
INDEMNIFICATION

16.1 **Indemnity by BIAL**: In addition to any other remedy available to NBIX, except as otherwise provided in Section 16.2, BIAL shall indemnify, defend and hold harmless NBIX and its Affiliates and their respective agents, employees, directors and officers (collectively, the "**NBIX Indemnitees**") from and against any liabilities, assessments, fines, losses, expenses, costs, interest and penalties (including reasonable legal and other professional adviser's fees and disbursements) (collectively, "**Losses**") resulting from any Third Party claims, suits and demands, whether or not such Losses were foreseeable at the Effective Date (each, a "**Claim**"), to the extent that such Losses arise from:

(a) alleged or actual bodily injury or property damage resulting from BIAL's failure to supply the Licensed Products in accordance with the Product Specifications;

(b) the gross negligence or intentional misconduct of any of BIAL, its Affiliates or its or their agents, directors, officers or employees in performing its or their obligations under the Agreement;

(c) any material breach by BIAL of its obligations and warranties under this Agreement, the Supply Agreement, or the Co-Promotion Agreement;

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(d) BIAL's failure to comply with applicable laws and regulations; or, in the case of any allegation arising pursuant to BIAL's promotional efforts under the Co-Promotion Agreement, any allegation that BIAL failed to comply with applicable laws and regulations; and

(e) the activities of the BIAL Representatives in the Territory after BIAL exercises its Co-Promotion Option pursuant to Section 2.10, except to the extent such activities specifically fall within the scope of the then current Co-Promotion Plan or have otherwise been agreed between the Parties or approved by NBIX (for the avoidance of doubt, this shall not be interpreted or construed as limiting NBIX indemnification obligations under Section 16.2).

except, in each case (a)-(e), to the extent that such Losses arise from the negligence or intentional misconduct of any NBIX Indemnitee or NBIX's breach of this Agreement, the Supply Agreement or the Co-Promotion Agreement.

16.2 **Indemnity by NBIX**: In addition to any other remedy available to BIAL, except as otherwise provided in Section 16.1, NBIX shall indemnify, defend and hold harmless BIAL, its Affiliates and their respective agents, employees, directors and officers (collectively, the "**BIAL Indemnitees**") from and against any Losses resulting from any Third Party Claims, to the extent that such Losses arise from:

(a) alleged or actual bodily injury or property damage resulting from the labelling, handling, storage, transportation, use, distribution, promotion, marketing, offer for sale or sale of the Licensed Products by or on behalf of NBIX;

(b) the use, effects or safety of any Licensed Products in the Territory;

(c) any claim of infringement or misappropriation of any patent, patent application, trade secret, copyright, trademark, trademark application, or other proprietary right arising out of the manufacturing, development, labelling, handling, storage, importation, transportation, use, commercialization, distribution, promotion, marketing, offer for sale or sale of the Licensed Products in the Territory by or on behalf of NBIX;

(d) the gross negligence or intentional misconduct of NBIX, its Affiliates or its or their agents, directors, officers or employees in performing its or their obligations under this Agreement, the Supply Agreement or the Co-Promotion Agreement;

(e) any material breach by NBIX of its obligations and warranties under this Agreement, and

(f) NBIX's failure in the Territory to comply with applicable laws and regulations, including the terms of the applicable Approvals;

except, in each case (a)-(f), to the extent that such Losses arise from the negligence or intentional misconduct of any BIAL Indemnitee or BIAL's breach of this Agreement, the Co-Promotion Agreement or the Supply Agreement.

16.3 **Conditions of Indemnification**: All indemnification claims in respect of any indemnitee seeking indemnity under Section 16.1 or 16.2, as applicable (collectively, the **"Indemnitees"** and each an "**Indemnitee**") will be made solely by the corresponding Party (the **"Indemnified Party"**). The Indemnified Party will give the indemnifying Party (the **"Indemnifying Party"**) prompt written notice (an **"Indemnification Claim Notice"**) of any Losses and any legal proceeding initiated by a Third Party against the Indemnified Party as to which the Indemnified Party intends to make a request for indemnification under Section 16.1 or 16.2, as applicable, but in no event will the Indemnifying Party be liable for any Losses that result from any delay in providing such notice which materially prejudices the defense of such proceeding. Each Indemnification Claim Notice shall contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss are known at such time). Together with the Indemnification Claim Notice, the Indemnified Party will furnish promptly to the Indemnifying Party copies of all notices and documents (including court papers) received by any Indemnitee in connection with the Third Party Claim. If an Indemnified Party seeks indemnification under this Article 16, the Indemnifying Party **(i)** may assume control and direction of any such claim at its expense, **(ii)** may use legal counsel of its choice, **(iii)** shall keep the Indemnified Party informed of the progress of the claim, **(iv)** shall consult with the Indemnified Party on the nature of any defense, and **(v)** shall not settle any such claim without the approval of the Indemnified Party, such approval not to be unreasonably withheld or delayed, unless such settlement is for money damages only. The Indemnified Party and its Indemnitees shall cooperate fully with the Indemnifying Party and its legal representatives in the investigation of any action with respect to a Claim covered by this indemnification.

16.4 **Limitation of Liability**:

(a) Nothing in this Agreement excludes or limits each Party's liability for: **(i)** death or personal injury caused by that Party's negligence; **(ii)** fraud or fraudulent misrepresentation; or **(iii)** any liability which cannot legally be excluded or limited.

(b) Subject to Sections 16.1, 16.2, and 16.4(a), and except for damages available for breach of Article 13, neither Party shall be liable, whether in contract, tort (including negligence or breach of statutory duty), misrepresentation or otherwise in connection with this Agreement for any indirect, special or consequential loss or damage, howsoever arising. In addition to the foregoing, neither Party shall be liable, whether in contract, tort (including negligence or breach of statutory duty), misrepresentation or otherwise in connection with this Agreement for any: **(i)** loss of profit; **(ii)** loss of revenue; **(iii)** loss of business; or **(iv)** loss of anticipated savings; in each case whether direct or indirect.

ARTICLE 17
MISCELLANEOUS

17.1 Dispute Resolution:

(a) It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. Any dispute, controversy or claim arising out of, relating to, or in connection with this Agreement, including any question regarding its existence, validity or termination ("**Dispute**") will be submitted in the first instance to the CEO of BIAL, or such person's designee of equivalent or superior position, and the CEO of NBIX, or such person's designee of equivalent or superior position.

(b) Except to the extent that final decision-making authority is specifically provided in any provision in this Agreement, if the CEO of BIAL and the CEO of NBIX cannot resolve the Dispute within […***…] after such Dispute is posed to each Party's CEO, then the Parties shall attempt in good faith to resolve such dispute through mediation with a mutually agreed mediator. If the mediation of such dispute does not commence within […***…] (or such other period of time mutually agreed upon by the Parties) of the receipt of a written request for such mediation by the other Party, or if the dispute is not resolved within […***…] (or such other period of time mutually agreed upon by the Parties) of commencing such mediation, or if the Parties are unable to agree upon a mediator, then except with respect to Excluded Claims, either Party may proceed to arbitration under Sections 17.1(c) to (g) (inclusive).

(c) Subject to Section 17.1(k), any Dispute shall be referred to and finally resolved by arbitration under the Rules of the LCIA, which rules are deemed to be incorporated by reference into this Section. Any arbitration commenced pursuant to this Section 17.1(c) shall be administered by the LCIA. The appointing authority shall be the LCIA. The standard LCIA Administrative Procedures and Schedule of Costs shall apply. The place of arbitration shall be London, UK. The language to be used in the arbitral proceedings shall be English.

(d) If such Dispute relates to **(i)** an amount less than […***…] Euro (€[…***…]) in controversy, including claims and counterclaims, or **(ii)** if only injunctive relief is requested, or **(iii)** any of NBIX's diligence obligations to use Commercially Reasonable Efforts, there will be one (1) arbitrator, who shall be selected jointly by NBIX and BIAL in accordance with the LCIA Rules, within […***…] of receipt by respondent of a copy of the demand for arbitration. If NBIX and BIAL are not able to select such one (1) arbitrator, then LCIA shall finally select one (1) arbitrator whom it believes to be neutral and impartial for the Parties. Such arbitrator will have […***…] from the date of appointment to render a decision.

(e) If the dispute relates to any of NBIX's obligations to use Commercially Reasonable Efforts, the arbitrator's decision in accordance with Section 17.1(d) shall include reasons as to whether

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or not NBIX has complied with its diligence obligations to use Commercially Reasonable Efforts and, subject to Section 17.1(f), if such decision is that NBIX has not complied, such decision will set out a detailed plan as to how the position can be remedied in a reasonable period of time that shall not be more than […***…].

(f) If an arbitrator acting in accordance with Sections 17.1(d) and 17.1(e) has previously decided that NBIX has breached a certain obligation to use Commercially Reasonable Efforts and NBIX has cured such breach, but subsequently, under the procedure set out in Section 17.1(d), an arbitrator decides that NBIX has breached the same obligation (i.e. the obligation to use Commercially Reasonable Efforts under the same Section of the Agreement) , then NBIX shall not have the right to cure such breach and BIAL may terminate the Agreement by giving […***…] prior written notice following the decision.

(g) In the case of any Dispute other than that specified in Section 17.1(d) above, there will be three (3) neutral and impartial arbitrators, one appointed by NBIX and one appointed by BIAL, in both cases within […***…] of receipt by respondent of a copy of the demand for arbitration, and the third arbitrator, who shall serve as chair of the arbitral tribunal, will be appointed by agreement of the Party-appointed arbitrators within […***…] of the appointment of the second arbitrator. The arbitration shall be conducted as expeditiously as practicable, and the Parties and the arbitrators shall use their best efforts to hold the hearing on the merits no later than […***…] after the appointment of the arbitration tribunal and the arbitrators shall use their best efforts to issue a final award within […***…] after the close of the hearing.

(h) Any arbitrator appointed in accordance with Sections 17.1(d) and (e) shall have significant experience with the arbitration of similar large, complex, commercial disputes between pharmaceutical companies. All arbitration proceedings shall be conducted in the English language. The Parties agree that only documents directly relevant to the issues in Dispute must be produced in any such arbitration.

(i) In addition to damages, the arbitration tribunal may award any remedy provided for under applicable law and the terms of this Agreement, including, without limitation, specific performance or other forms of injunctive relief. The arbitration tribunal is not empowered to award damages in excess of compensatory damages, and each Party hereby irrevocably waives any right to recover punitive, exemplary and multiplied (including without limitation treble) damages with respect to any Dispute. The arbitration award must be in writing and will state, in English and in reasonable detail, the findings of fact and conclusions of law on which it is based. The arbitration award shall be final and binding on the Parties and shall not be appealable except for error in arbitration procedure, or as otherwise provided for by applicable treaty or law and may be entered and enforced in any court having competent jurisdiction.

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(j) Each Party shall bear its own costs and expenses and attorneys' fees in the arbitration, except that the arbitrators may order the non-prevailing Party to bear all or an appropriate part (reflective of the relative success on the issues) of the costs and expenses and reasonable attorneys' fees incurred by the prevailing Party based on the relative merits of each Party's positions on the issues in the Dispute. The Party that substantially prevails in the arbitration proceeding shall be reimbursed any payments it has made in respect of the arbitrators' fees and expenses and any administrative fees of arbitration.

(k) As used in this Section, the term "**Excluded Claim**" means a dispute, controversy or claim that concerns **(**a**)** the validity, enforceability or infringement of a patent, trademark or registered copyright or **(ß)** any antitrust, anti-monopoly or competition law or regulation, whether or not statutory. Excluded Claims shall be brought in the courts in the applicable country in the Territory where the patent, trademark or copyright is registered or the antitrust, anti-monopoly or competition law or regulation has allegedly been breached. If the subject matter of the Excluded Claim is relevant to the subject matter of a pending dispute that is subject to arbitration then the Excluded Claim must also be brought only within the arbitration and not in the courts in order to avoid multiple proceedings and forum shopping.

17.2 **Interim Measures**: Notwithstanding Section 17.1, either Party may, without inconsistency with this Agreement, apply to a court to seek pre-arbitral provisional injunctive relief to maintain the status quo or prevent irreparable harm, pre-arbitral attachment, or any other relief or order in aid of arbitration proceedings and the enforcement of any award. Without prejudice to such provisional remedies as may be available under the jurisdiction of a court, the arbitration tribunal will have full authority to grant provisional remedies and to direct the Parties to request that any court modify or vacate any temporary or preliminary relief issued by such court, and to award damages for the failure of any Party to respect the arbitrator(s)' orders to that effect.

17.3 **Force Majeure**: If any circumstance beyond the reasonable control of either Party occurs which delays or renders impossible the performance of that Party's obligations under this Agreement on the dates herein provided (a "**Force Majeure**"), such obligation shall be postponed for such time as the event of Force Majeure exists, provided such Party notifies the other Party in writing as soon as practicable. The Party so affected shall give to the other Party a good faith estimate of the continuing effect of the Force Majeure condition and the anticipated duration of the affected Party's non-performance. Notwithstanding the foregoing, if the period of any previous actual non-performance of a Party because of Force Majeure conditions plus the anticipated future period of non-performance because of such conditions shall exceed an aggregate of […***…], then then the Parties shall promptly meet and discuss in good faith appropriate measures to minimise the impact of the Force Majeure for both Parties, including without limitation a possible amendment to this Agreement or the termination thereof. Events of Force Majeure shall include, without limitation, war, revolution, invasion, insurrection, riots, mob violence, sabotage or other civil disorders, acts of God, earthquake, tsunami, limitations imposed by exchange control regulations or

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foreign investment regulations or similar regulations, laws, regulations or rules of any government or governmental agency, any inordinate delays in the regulatory review or governmental approval process that are within the sole control of such government or governmental agency. A Party shall be considered affected by an event of Force Majeure to the extent that any of its suppliers or contractors is affected by such an event.

17.4 Assignment:

(a) Neither Party may, except as set forth in Sections 15.2(e) and 17.4(b), assign, transfer or otherwise dispose of this Agreement or any rights or obligation hereunder to any Affiliate or Third Party without the prior written consent of the other Party.

(b) BIAL may assign or transfer this Agreement, in whole or in part, or any right or obligation hereunder without NBIX's consent **(i)** to any of its Affiliates or **(ii)** to a Third Party successor in connection with its merger, acquisition or transfer or sale of all or substantially all of its assets related to Licensed Products in the Territory or the business relating thereto.

(c) Any attempted or purported assignment or transfer of rights or obligations other than provided herein shall be void.

17.5 Performance by Affiliates and subcontractors: Either Party may exercise any of its respective rights and perform any of its respective obligations hereunder through any of its Affiliates or contractors (in the case of NBIX, pursuant to Section 2.5). However, either Party shall remain responsible for the full and complete performance of and compliance with all of its obligations and duties under this Agreement and for all activities of its Affiliates and contractors to the same extent as if such activities had been undertaken by such Party itself.

17.6 No Third Party Beneficiaries:

(a) Subject to Section 17.6(b), this Agreement does not confer any right upon any person or entity other than NBIX and BIAL and their respective successors and permitted assigns to enforce any provision of this Agreement (whether under the Contracts (Rights of Third Parties) Act 1999 or otherwise).

(b) The Affiliates of the Parties and the agents of the Parties and their Affiliates' directors, officers, employees and agents may enforce the provisions of Article 16 subject to and in accordance with Section 16.3 and the provisions of the Contracts (Rights of Third Parties) Act 1999.

(c) The rights of the Parties to terminate, rescind or agree any variation, waiver or settlement under this Agreement are not subject to the consent of any person that is not a party to this Agreement.

17.7 Waiver: The rights and remedies of either Party in respect of this Agreement shall not

be diminished, waived or extinguished by the granting of any indulgence, forbearance or extension of time granted by that Party to the other Party nor by any failure of, or delay in ascertaining or exercising any such rights or remedies. Any waiver of any breach of this Agreement shall be in writing. The waiver by either Party of any breach of this Agreement shall not prevent the subsequent enforcement of that provision and shall not be deemed to be a waiver of any subsequent breach of that or any other provision.

17.8 **Governing Law**: This Agreement and any dispute or claim arising out of or in connection with it (whether contractual or non-contractual in nature such as claims in tort, from breach of statute or regulation or otherwise) shall be governed by and construed in accordance with the laws of England and Wales, without reference to its conflicts of law principles.

17.9 **Unenforceable Provisions**: Any provision hereof that is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective only to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof or affecting the validity or enforceability of such provision in any other jurisdiction. The Parties will replace such ineffective provision for such jurisdiction with a valid and enforceable provision which most closely approaches the idea, intent, and purpose of this Agreement, and in particular, the provision to be replaced.

17.10 **Relationship Between the Parties**: The Parties' relationship, as established by this Agreement, is solely that of independent contractors. Neither Party may pledge the credit of the other Party nor represent itself as being the other Party nor an agent, partner, employee or representative of the other Party and neither Party may hold itself out as such nor as having any power or authority to incur any obligation of any nature, express or implied, on behalf of the other. Nothing in this Agreement, and no action taken by the Parties pursuant to this Agreement, creates, or is deemed to create, a partnership or joint venture or relationship of employer and employee or principal and agent between the Parties.

17.11 **Entire Agreement**:

(a) This Agreement, including the exhibits attached hereto, and the agreements referred to herein contain the entire agreement between the Parties in relation to its subject matter and supersedes any prior arrangement, understanding written or oral agreements between the Parties in relation to such subject matter.

(b) The Parties acknowledge that this Agreement has not been entered into wholly or partly in reliance on, nor has either Party been given, any warranty, statement, promise or representation by the other or on its behalf other than as expressly set out in this Agreement.

(c) Each Party agrees that the only rights and remedies available to it arising out of or in connection with any warranties, statements, promises or representations will be for breach of contract

and irrevocably and unconditionally waives any right it may have to any claim, rights or remedies including any right to rescind this Agreement which it might otherwise have had in relation to them.

(d) All warranties, conditions, terms and representations not set out in this Agreement whether implied by statute or otherwise are excluded to the extent permitted by law.

17.12 **Amendments**: The Parties may from time to time during the continuance of this Agreement modify, vary or alter any of the provisions of this Agreement, but only by written agreement of the Parties.

17.13 **Notices**: All communications, reports, payments and notices required by this Agreement will be addressed to the Parties at their respective addresses set forth below or to such other address as requested by a Party by notice in writing to the other Party.

(a) If to BIAL:

BIAL – Portela & Ca, S.A.
Attention: Chief Executive Officer
À Avenida da Siderurgia Nacional
4745-457 S. Mamede do Coronado
Portugal
Fax: +351 229 866 199

with a copy to:

BIAL – Portela & Ca, S.A.
Attention: Legal Director
À Avenida da Siderurgia Nacional
4745-457 S. Mamede do Coronado
Portugal
Fax: +351 229 866 190

(b) If to NBIX:

Neurocrine Biosciences, Inc.
Attention: Chief Executive Officer
12780 El Camino Real
San Diego, CA 92130
USA

Fax: +1-858-777-3488

with a copy to:

Neurocrine Biosciences, Inc.
Attention: Chief Legal Officer
12780 El Camino Real
San Diego, CA 92130
USA
Fax: +1-858-777-3488

(c) All such notices, reports, payments, and communications will be made by First Class mail, postage prepaid or by reputable overnight courier providing evidence of receipt, or by facsimile (and promptly confirm by mail or overnight courier), and will be considered made as of the date of confirmed receipt.

17.14 **Language**: This Agreement is entered into in the English language. All amendments or correspondence concerning or relating to this Agreement, the Supply Agreement, the Quality Agreement, the Co-Promotion Agreement (if any), or the SDEA, and all notices given and all documentation to be delivered by either Party to the other under this Agreement shall be in writing in the English language.

17.15 **Counterparts**: This Agreement may be executed simultaneously in any number of counterparts, but all such counterparts taken together will constitute one and the same agreement. This Agreement will be treated in all manner and respects and for all purposes as an original agreement or instrument and will be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person.

< Signature page follows >

IN WITNESS WHEREOF, and intending to be legally bound, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

BIAL – PORTELA & CA, S.A.

By: /s/ António Portela
Name: António Portela
Position: Chief Executive Officer

Date: 2/9/2017

By: /s/ Isabel Morgado
Name: Isabel Morgado
Position: Member of the Board of Directors

Date: 2/9/2017

NEUROCRINE BIOSCIENCES, INC

By: /s/ Kevin Gorman
Name: Kevin Gorman
Position: Chief Executive Officer

Date:

EXHIBIT 2.1

BIAL Patents

[…***…]

*** Confidential Treatment Requested for pages 90-92.

Omitted pages have been filed separately with the Commission.

EXHIBIT 2.1(g)

Cooperation Terms

1. Trade Meetings: If, in respect of a Licensed Product, **(i)** BIAL or one of its Affiliates or licensees outside the Territory wishes to attend any professional or trade meeting, including scientific congresses, inside the Territory or **(ii)** NBIX or one of its Affiliates wishes to attend any professional or trade meeting, including scientific congresses, outside the Territory, then each such Party shall provide reasonable advance notice to the other Party. The Parties shall endeavour to cooperate in respect of their attendance in organized events and organizing non-core events relating to the Licensed Product during such meeting; provided, however, that in the event such events occur in the territory of other BIAL's licensees, […***…]. In no event shall any such activities of BIAL or its Affiliates or licensees be directed at sales of Licensed Products by or on behalf of BIAL or its Affiliates in the Territory, and in no event shall any such activities of NBIX or its Affiliates be directed at sales of Licensed Products by or on behalf of NBIX or its Affiliates anywhere in the world except in the Territory. Each Party shall bear its own costs of participation at any such meeting.

2. Key Opinion Leaders:

(a) The Parties acknowledge that, from time to time, NBIX or its Affiliates may be interested in engaging Outside Territory KOLs for the purposes of providing consultancy services to NBIX in connection with the Licensed Products within the Territory. To the extent that such services or interactions with such KOLs are not intended as or otherwise constitute a promotional, marketing or development activity outside the Territory, NBIX shall have the right to conduct such activities outside the Territory; provided, however, that NBIX shall previously inform BIAL of such any activities and coordinate such activities with BIAL. For the avoidance of doubt, confidential advisory boards and confidential consultancy meetings with KOLs do not constitute promotional, marketing or development activity.

(b) The Parties acknowledge that, from time to time, BIAL or its Affiliates or licensees may be interested in engaging Territory KOLs for the purposes of providing consultancy services to BIAL in connection with Licensed Products outside the Territory. To the extent that such services or interactions with KOLs are not intended as or otherwise constitute a promotional or marketing activity in the Territory, BIAL shall have the right to conduct such activities inside the Territory; provided, however, that BIAL shall previously inform NBIX of such any activities and coordinate such activities with NBIX. For the avoidance of doubt, confidential advisory boards and confidential consultancy meetings with KOLs do not constitute promotional or marketing activity.

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3. **Co-Promotion Plan:** In accordance with Section 2.10(b), BIAL shall have the right to conduct commercialization activities in the Territory in order to prepare a Co-promotion Plan and NBIX shall assist in the provision of data and information as reasonably requested by BIAL and if not previously provided as part of the Annual Commercialization Plan.

EXHIBIT 2.3

Trademarks

[…***…]

*** Confidential Treatment Requested for pages 95-97.

Omitted pages have been filed separately with the Commission.

EXHIBIT 2.4

BIAL Logo

[…***…]

*** Confidential Treatment Requested

EXHIBIT 2.6(b)

Transfer Plan

[…***…]

*** Confidential Treatment Requested for pages 99-100.

Omitted pages have been filed separately with the Commission.

EXHIBIT 2.10(b)

Final Position Arbitration Procedure

Final position arbitration shall be commenced and conducted as follows:

1. Arbitrator: The determination of terms and conditions of the proposed Co-Promotion Agreement that remain unresolved after good faith negotiations shall be referred to and decided and settled by a single independent arbitrator selected by the LCIA with input from both NBIX and BIAL. Such arbitrator must be have at least […***…] years of experience in negotiating and structuring co-promotion and/or co-commercialization arrangements in the pharmaceutical field for specialty products. Selection of the arbitrator shall be made within […***…] after the date of the first notice of demand and within […***…] after any resignation, disability or other removal of such arbitrator.

2. Costs of Arbitration: The cost of arbitration proceedings, including the arbitrator's compensation and expenses, hearing room charges and court reporter transcript charges shall be borne by the Parties equally or otherwise as the arbitrator may determine.

3. Location of Proceedings: All arbitration proceedings shall be held in London, England, unless the Parties agree otherwise, at a location selected by the Parties.

4. Conduct of Arbitration:

(a) Pre-hearing Conference. Within […***…] after appointment, the arbitrator shall hold a pre-hearing conference to establish the framework of substantive provisions to be included in a Co-Promotion Agreement proposal by the Parties, schedules for exchange of exhibits and witness lists, for arbitration briefs, for the hearing, and to decide procedural matters and all other questions that may be presented.

(b) Not less than […***…] before the date of the hearing, each Party shall deliver to the arbitrator its final position with respect to the Co-Promotion Agreement or a specific term or terms thereof in dispute, which shall include in all instances a draft of a Co-Promotion Agreement containing all provisions sought by the submitting Party and which the submitting Party is willing to execute upon the conclusion of the arbitration if the submitting Party prevails in such arbitration, such final position(including the draft Co-Promotion Agreement) delivered by BIAL being referred to as "**BIAL's Final Position**" and such final position (including the draft Co-Promotion Agreement) delivered by NBIX being referred to as "**NBIX's Final Position**"). If either Party fails to timely deliver its

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final position or its final draft Co-Promotion Agreement, that Party shall be deemed to have accepted the final position and draft Co-Promotion Agreement of the other Party. The arbitrator shall select mutually agreed upon provisions from such draft Co-Promotion Agreements, in their entirety, and may not determine an alternative or compromise to those provisions. With respect to other provisions where the Parties have not reached agreement, the arbitrator may select, on a provision by provision basis, either position proposed by a Party but in any event not an entirely alternative or compromise position. In making his/her determination, the arbitrator shall take into account usual industry practice and a position that is fair to both Parties taking into consideration the capabilities and resources then existing for the respective Parties. No less than […***…] before the date of the hearing, the arbitrator shall deliver to each Party the draft Co-Promotion Agreements as determined by the arbitrator.

(c) Hearing Procedures:

(i) The hearing shall be conducted to preserve its privacy and to allow reasonable procedural due process. Rules of evidence need not be strictly followed, and the hearing shall be streamlined.

(ii) The hearing should be held on consecutive business days without interruption to the maximum extent practicable.

(iii) No pre-hearing discovery shall be permitted or taken in the resolution of any matter subject to the provisions hereof.

(iv) Expert reports may be utilized.

(v) Charts, graphs, and summaries shall be utilized to present voluminous data, provided that the underlying data was made available to the opposing Party […***…] prior to the hearing.

(vi) The arbitrator shall establish all other procedural rules for the conduct of the arbitration in accordance with the rules of arbitration of the LCIA.

5. Governing Law: This arbitration provision shall be governed by, and all rights and obligations specifically enforceable under and pursuant to, the laws of England and Wales.

6. Award: The arbitrator shall issue his or her decision by delivering written notice to each Party setting forth the arbitrator's decision regarding the terms of the proposed Co-Promotion Agreement and any other award of fees or expenses. Any award of fees or expenses rendered by the arbitrator shall be final. The arbitrator's decision shall be final.

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7. **Confidentiality**: The Parties hereto will maintain the substance of any proceedings hereunder in confidence and the arbitrator, prior to any proceedings hereunder, will sign an agreement whereby the arbitrator agrees to keep the substance of any proceedings hereunder in confidence.

8. **Time Frame**: To the fullest extent practicable pre-hearing conferences and hearing procedures shall be expedited and the Parties shall use their best reasonable efforts to conclude the dispute resolution proceeding herein within […***…] to the event feasible and practicable under the circumstances. Under no circumstances shall the conclusion of such dispute resolution proceeding extend beyond […***…] except by mutual consent of each Party.

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EXHIBIT 4

Certain Supply Terms

1.1 […***…]

*** Confidential Treatment Requested for pages 104-110.

Omitted pages have been filed separately with the Commission.

EXHIBIT 6.3(a)

[…***…]

*** Confidential Treatment Requested for pages 111-114.

Omitted pages have been filed separately with the Commission.

EXHIBIT 6.4

BIAL Studies

[…***…]

*** Confidential Treatment Requested

EXHIBIT 8.3(e)

Assumptions (for the Agreed Sales Forecasts)

[…***…]

*** Confidential Treatment Requested for pages 116-117.

Omitted pages have been filed separately with the Commission.

EXHIBIT 9.2(c)

Existing Licensees

[…***…]

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Exhibit 99.5

Neurocrine Announces Proposed Convertible Senior Notes Offering

San Diego, CA— (PRNewswire)—April 25, 2017—Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced its intention to offer, subject to market and other conditions, $450.0 million aggregate principal amount of convertible senior notes due 2024 (the "notes") in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended (the "Securities Act"). Neurocrine also expects to grant the initial purchasers of the notes a 30-day option to purchase up to an additional $67.5 million aggregate principal amount of notes.

The notes will be senior unsecured obligations of Neurocrine and will accrue interest payable semiannually in arrears. The notes will be convertible in certain circumstances into cash, shares of Neurocrine's common stock, or a combination of cash and shares of Neurocrine's common stock, at Neurocrine's election. The interest rate, initial conversion rate and other terms of the notes will be determined at the time of the pricing of the offering.

Neurocrine intends to use the net proceeds from the offering for general corporate purposes, which may include commercialization expenses, clinical trial and other research and development expenses, capital expenditures, working capital and general and administrative expenses.

The offer and sale of the notes and the shares, if any, issuable upon conversion of the notes have not been and will not be registered under the Securities Act or applicable state securities laws, and the notes and such shares may not be offered or sold in the United States absent registration or an applicable exemption from the registration requirements of the Securities Act and applicable state securities laws. This press release shall not constitute an offer to sell or the solicitation of an offer to buy the notes or any shares issuable upon conversion of the notes, nor shall there be any sale of the notes or such shares, in any state or jurisdiction in which such offer, solicitation or sale would be unlawful.

About Neurocrine Biosciences

Neurocrine Biosciences is a San Diego based biotechnology company focused on neurologic, psychiatric and endocrine related disorders. In April of 2017 the FDA approved INGREZZA™ (valbenazine) capsules for the treatment of adults with tardive dyskinesia (TD). INGREZZA is a novel, selective vesicular monoamine transporter 2 (VMAT2) inhibitor, and is the first and only FDA-approved product indicated for the treatment of adults with TD. We market INGREZZA in the United States. The Company's three late-stage clinical programs are: elagolix, a gonadotropin-releasing hormone antagonist for women's health that is partnered with AbbVie Inc.; opicapone, a novel, once-daily, peripherally-acting, highly-selective catechol-o-methyltransferase inhibitor under investigation as adjunct therapy to levodopa in Parkinson's patients; and INGREZZA™ (valbenazine), a novel, once-daily, selective VMAT2 inhibitor under investigation for the treatment of Tourette Syndrome.

Forward-Looking Statements

In addition to historical facts, this press release contains forward-looking statements that involve a number of risks and uncertainties such as those, among others, relating to Neurocrine's

expectations regarding the completion, timing and size of its proposed offering. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties associated with market conditions, whether Neurocrine will offer the notes or be able to consummate the proposed offering at the anticipated size or on the anticipated terms, or at all, the satisfaction of closing conditions related to the proposed offering, as well as risks and uncertainties associated with Neurocrine's business and finances in general, and the other risks described in Neurocrine's annual report on Form 10-K for the year ended December 31, 2016. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

Contact Information

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