**Exhibit 10.2**

***CONFIDENTIAL***

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH “[\*\*\*]”. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT UNDER RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934.

**API COMMERCIAL SUPPLY AGREEMENT**

**by and between**

**.**

**and**

**.**

**Dated as of May 25, 2011**

**API COMM** **ERCIAL SUPPLY AGREEMENT**

THIS API COMMERCIAL SUPPLY AGREEMENT (this “Agreement”) is entered into and dated as of the 25th day of May, 2011 (the “Effective Date”) by and between ., a corporation organized under the laws of Ireland and having its principal office at First Floor, Block 3, The Oval, Shelbourne Road, Ballsbridge, Dublin 4, Ireland (“”), and ., a corporation organized under the laws of South Korea and having its principal offices at 15-1, Dongsu-dong, Naju-si, Jeollanam-do 520-330 Korea (“”). and are sometimes referred to herein individually as a “Party” and collectively as the “Parties.”

**RECITALS**

WHEREAS, is engaged in the research, development and commercialization of proprietary pharmaceutical products;

WHEREAS, is a company that has developed substantial expertise in manufacturing polyunsaturated fatty acids, including the Compound (as defined herein), for use in nutritional supplement and pharmaceutical products; and

WHEREAS, the Parties desire to enter into a supply agreement pursuant to which will manufacture a certain active pharmaceutical ingredient for .

NOW, THEREFORE, in consideration of the foregoing recitals, mutual covenants, agreements, representations and warranties contained herein, the Parties hereby agree as follows:

Article I

Definitions

“Additional Expansions” has the meaning in Section 3.1(a) of this Agreement.

“Adverse Event” has the meaning in Section 6.7(a) of this Agreement.

“Affiliate” means a corporation or non-corporate business entity that, directly or indirectly, controls, is controlled by, or is under common control with the Person specified, for so long as such control continues. An entity will be regarded as in control of another entity if: (a) it owns, directly or indirectly, at least fifty percent (50%) of the voting securities or capital stock of such entity, or has other comparable ownership interest with respect to any entity other than a corporation; or (b) it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or non-corporate business entity, as applicable, whether through the ownership or control of voting securities, by contract or otherwise.

“Agreement” means this API Commercial Supply Agreement, including all Schedules hereto. “” has the meaning in the preamble of this Agreement.

“ Confidential Information” has the meaning provided in Section 13.1 of this Agreement.

“ Intellectual Property” means any and all Intellectual Property relating to the Product (as defined below) or the development or manufacture thereof that was (a) owned, licensed or controlled by or Affiliates as of the Effective Date, or (b) developed or acquired by or Affiliates after the Effective Date.

“ License” has the meaning provided in Section 8.3 of this Agreement.

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“API” means [\*\*\*].

“API Price” has the meaning provided in Section 3.1(a) of this Agreement.

“API Product Developments” has the meaning provided in Section 8.2(a) of this Agreement. “API Specifications” mean all specifications set forth on Schedule 5.1 to this Agreement. “Approved Representatives” has the meaning provided in Section 5.4(a) of this Agreement.

“Calendar Quarter” means each three (3) month period beginning each January 1, April 1, July 1 and October 1 during the Term. The initial Calendar Quarter shall begin on the Effective Date and end on June 30, 2011, and the last Calendar Quarter shall end on the expiration or earlier termination date of the Term.

“Calendar Year” means each twelve (12) month period beginning each January 1 during the Term. The initial Calendar Year shall begin on the Effective Date and end on the first December 31 during the Term, and the last Calendar Year shall begin on January 1 of the last year of the Term and end on the expiration or earlier termination date of the Term.

“Certificate of Analysis” means a document identified as such and provided by to in the form set forth in Schedule 6.2 that (a) sets forth the analytical test results for a specified lot of API shipped to or its designee hereunder and includes a certified quality control protocol, (b) states that such API is in conformance with the Drug Application and API Specifications, and (c) states that such API is manufactured in accordance with the API Specifications, Legal Requirements and cGMPs.

“Certificates” has the meaning provided in Section 6.2 of this Agreement.

“Change of Control” means any proposed transaction or series of transactions which shall result in (a) any Person other than a Party having direct or indirect ownership of more than fifty percent (50%) of the voting stock or assets of such Party or an Affiliate that controls such Party by Persons who are not shareholders of such Party or the Affiliate that controls such Party as of the Effective Date, or (b) the merger of a Party with or into a Third Party in a transaction in which such Party is not the surviving or acquiring Person.

“” has the meaning in the preamble of this Agreement.

“ Approval(s)” means the approval of the Facility as a cGMP facility for the manufacture of the API by the FDA and, as applicable, by any other applicable Governmental Body having jurisdiction to approve the Facility.

“ Confidential Information” has the meaning provided in Section 13.2 of this Agreement.

“ Intellectual Property” means (a) all Intellectual Property owned, licensed or controlled by as of the Effective Date, and (b) all Intellectual Property developed or acquired by after the Effective Date that does not relate to the Product or the development or manufacture of the Product, except that Intellectual Property developed by related to the API shall be included in Intellectual Property.

“’s Initial Minimum Capacity” has the meaning provided in Section 4.1 of this Agreement. 3

“’s Minimum Capacity” has the meaning provided in Section 4.1 of this Agreement. “CMC” means the chemistry, manufacturing and controls section(s) and data in a Drug Application. “Commercial Launch Forecast” has the meaning provided in Section 2.4(a) of this Agreement. “Compound” means ethyl ester of eicosapentaenoic acid.

“Confidential Information” has the meaning provided in Section 13.3 of this Agreement.

“Consent” means any consent, authorization, permit, certificate, license or approval of, exemption by, or filing or registration with, any Governmental Body or other Person.

“Current Good Manufacturing Practices” or “cGMPs” means all applicable standards relating to manufacturing practices for intermediates, active pharmaceutical ingredients or finished pharmaceutical products, including without limitation (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 210 and 211, The Rules Governing Medicinal Products in the European Community, Volume IV Good Manufacturing Practice for Medicinal Products, and Q7A Good Manufacturing Practice Guidance For Active Pharmaceutical Ingredients (ICH Q7A), and (b) the principles promulgated by any applicable Governmental Body having jurisdiction over the manufacture of the API, in the form of laws, rules or regulations, in each case as in effect at the Effective Date and as amended, promulgated or accepted by any applicable Governmental Body from time to time during the Term.

“Days” (whether or not the word is capitalized) means, except where specified otherwise, calendar days.

“Development and Process Validation Plan” means the development and validation plan to be agreed to by the Parties within [\*\*\*] days of the Effective Date.

“DMFs” has the meaning provided in Section 7.5 of this Agreement.

“Drug Application” means a ‘new drug application’ (as such term is used under the United States Federal Food, Drug and Cosmetic Act) filed with the FDA for the Product, including, without limitation, any supplements thereto, any product license or any equivalent drug application or similar pharmaceutical product approval for the Product administered by any foreign Governmental Body, or supplement, extension or renewal of any of the foregoing.

“Effective Date” has the meaning in the preamble of this Agreement.

“Effective Supply Date” means the date of completion of the Expansion in accordance with Sections 4.1 and 4.2 of this Agreement.

“Expansion” has the meaning set forth in Section 4.1 of this Agreement.

“Facility” means ’s manufacturing facility located at [\*\*\*] (as the same may be expanded as provided herein), or such other FDA approved facility as agreed in writing by the Parties.

“FDA” means the United States Food and Drug Administration, or any successor agency thereof. “Force Majeure Event” has the meaning provided in Section 14.1 of this Agreement. 4

“Governmental Body” means any nation or government, any state, province or other political subdivision thereof, any entity with legal authority to exercise executive, legislative, judicial, regulatory or administrative functions, or any division of the FDA (as applicable) and any other applicable counterpart agency or foreign equivalent that administers the Legal Requirements.

“Indemnified Party” has the meaning provided in Section 11.3 of this Agreement.

“Indemnifying Party” has the meaning provided in Section 11.3 of this Agreement.

“Initial Manufacturing Process” has the meaning provided in Section 5.4(a) of this Agreement. “Initial Term” has the meaning provided in Section 15.1 of this Agreement.

“Intermediate” means a material produced during steps in the synthesis of API that must undergo further molecular change or processing before it becomes API.

“Intellectual Property” means (a) patents, patent rights, provisional patent applications, patent applications, designs, registered designs, registered design applications, industrial designs, industrial design applications and industrial design registrations, including any and all divisions, continuations, continuations-in part, extensions, restorations, substitutions, renewals, registrations, revalidations, reexaminations, reissues or additions, including supplementary certificates of protection, of or to any of the foregoing items; (b) copyrights, copyright registrations, copyright applications, original works of authorship fixed in any tangible medium of expression, including literary works (including all forms and types of computer software, including all source code, object code, firmware, development tools, files, records and data, and all documentation related to any of the foregoing), musical, dramatic, pictorial, graphic and sculptured works; (c) trade secrets, technology, developments, discoveries and improvements, know-how, proprietary rights, formulae, confidential and proprietary information, technical information, techniques, inventions, designs, drawings, procedures, processes, models, formulations, manuals and systems, whether or not patentable or copyrightable, including all biological, chemical, biochemical, toxicological, pharmacological and metabolic material and information and data relating thereto and formulation, clinical, analytical and stability information and data which have actual or potential commercial value and are not available in the public domain; (d) trademarks, trademark registrations, trademark applications, service marks, service mark registrations, service mark applications, business marks, brand names, trade names, trade dress, names, logos and slogans, Internet domain names, and all goodwill associated therewith; and (e) all other intellectual property or proprietary rights worldwide, in each case whether or not subject to statutory registration or protection.

“Legal Requirements” means any and all local, municipal, state, provincial, federal and international laws, statutes, ordinances, rules or regulations now or hereafter enacted or promulgated by any Governmental Body applicable to the development, approval, manufacture, sale, shipment or licensing of any pharmaceutical products, ingredients for inclusion therein, or any aspect thereof, and the obligations of or , as the context requires, under this Agreement, including, without limitation, applicable laws, statutes, ordinances, rules and regulations of South Korea, as well as the United States Federal Food, Drug and Cosmetic Act, as amended, and the rules and regulations promulgated thereunder.

“Losses” means, collectively, any and all claims, liabilities, damages, losses, costs, expenses, including reasonable fees and disbursements of counsel and any consultants or experts and expenses of investigation, obligations, liens, assessments, judgments, fines and penalties imposed upon or incurred by an Indemnified Party.

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“Material Third Party Supplier” means a Third Party Supplier that provides materials used in the cGMP manufacture, testing or processing of cGMP Intermediate or API.

“[\*\*\*] Forecast” has the meaning provided in Section 2.4(b) of this Agreement.

“Nonconformity” has the meaning provided in Section 6.4(a) of this Agreement.

“Nonconforming API” means API that is subject to a Nonconformity.

“Party” and “Parties” have the meanings given such terms, respectively, in the preamble of this Agreement.

“Person” means any individual, corporation, company, partnership, trust, incorporated or unincorporated association, joint venture or other entity of any kind.

“Pre-Approval Inspection” means an inspection of manufacturing operations, records and facilities conducted prior to approval of a new product by the FDA or by any other applicable Governmental Body having jurisdiction to approve the Facility as a cGMP facility for the manufacture of the API.

“Product” means (a) ’s AMR101 product, and (b) any finished pharmaceutical product of that incorporates the API supplied by pursuant to this Agreement.

“Purchase Orders” has the meaning provided in Section 2.5 of this Agreement.

“Quality Agreement” means the agreement identified in Section 5.6 of this Agreement. “Secondary Supplier” has the meaning set forth in Section 2.5 of this Agreement.

“Second Expansion” has the meaning provided in Section 4.3 of this Agreement.

“Shipment Date” means the date specified by in a Purchase Order that shall ship the API in accordance with this Agreement.

“Subcontractor” means any Third Party that performs any of the activities with respect to the manufacture and supply of API under this Agreement on ’s behalf.

“Term” has the meaning provided in Section 15.1 of this Agreement.

“Third Party” means any Person other than the Parties or their respective Affiliates.

“Third Party Materials” means (a) all raw materials, components, work-in-process and other ingredients required to manufacture the API, and (b) all packaging materials used in the manufacture, storage and shipment of the API.

“Third Party Supplier” means any Third Party that provides to any Third Party Materials for any API produced under this Agreement.

“Validation” means a procedure for establishing documentation evidence that a specific system or facility is constructed and operates according to a predetermined set of specifications, protocols and guidelines.

“Validation Batch” has the meaning provided in Section 4.2 of this Agreement.

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Article II

Sale and Purchase of API

2.1 General.

(a) Development and Process Validation Plan. Subject to the terms and conditions of this Agreement, agrees to conduct the Development and Process Validation Plan.

(b) Manufacture of API. Subject to the terms and conditions of this Agreement, agrees to manufacture API at the Facility for sale to . may not manufacture API at locations other than the Facility without the prior written Consent of , such Consent not to be unreasonably withheld or delayed and as provided in the Quality Agreement. For the avoidance of doubt, the Parties agree that this Agreement does not obligate to purchase all of its requirements of the API from , nor does it obligate to purchase any particular volumes of API from except as expressly set forth herein, nor does it obligate to sell the API exclusively to except as set forth in Section 2.3. retains the right to engage or appoint additional suppliers and contract manufacturers of the API from time to time in its sole discretion and retains the right to supply API to Third Party customers and to appoint Third Party distributors of the API from time to time in its sole discretion.

2.2 Minimum Purchase Requirement and Supply of Development Quantities. agrees to purchase from , and agrees to supply to , (a) no more than [\*\*\*] batches (each batch shall be in a quantity of [\*\*\*], which shall include the quantity of the Validation Batches) of API upon the Validation of the Initial Manufacturing Process pursuant to the Development and Process Validation Plan, (b) [\*\*\*] of API annually (or such prorated amount in the case of a partial year) following [\*\*\*], and (c) [\*\*\*] of API annually (or such prorated amount in the case of a partial year) following [\*\*\*]. From time to time during ’s expansion activities, as may be reasonably necessary, and upon no less than ten (10) days’ advance written notice, shall deliver to (at no cost) quantities of API not to exceed two (2) kilograms for to evaluate and test.

2.3 Limited Exclusivity; Capacity Allocation.

(a) During the Term (i) shall not export, sell or distribute a [\*\*\*] product incorporating Compound having a purity level greater than [\*\*\*] that [\*\*\*] for use in [\*\*\*], (ii) shall not export, sell or distribute Compound having a purity level greater than [\*\*\*] to any Third Party that exports, sells or distributes a [\*\*\*] product incorporating the Compound that [\*\*\*] for use in [\*\*\*], (iii) shall not export, sell or distribute a [\*\*\*] product incorporating Compound having a purity level greater than [\*\*\*] for use in the [\*\*\*], and (iv) shall not export, sell or distribute Compound having a purity level greater than [\*\*\*] to any Third Party for use in a [\*\*\*] product in the [\*\*\*]; provided, however, for the avoidance of doubt, the prohibitions in this Section 2.3 shall not apply to (A) sales of a generic form of [\*\*\*], (B) [\*\*\*] in ’s export, sale or distribution of Compound having a purity level greater than [\*\*\*] to any Third Party that exports, sells or distributes a [\*\*\*] product incorporating the Compound that [\*\*\*] for use in the [\*\*\*]; and (C) [\*\*\*] in ’s export, sale or distribution of Compound having a purity level greater [\*\*\*] to any Third Party for use in a [\*\*\*] product in the [\*\*\*].

(b) Except as set forth in Section 2.3(a), above, shall be entitled to maximize its capacity utilization of the Facility by manufacturing products for Third Parties or itself in addition to the API; provided, however, that if is expected to be unable to supply all of the API forecast by and all of the needs of such other Persons, shall allocate such Facility capacity on a first priority basis to .

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(c) This Section 2.3 shall expire in the event does not order the minimum annual quantities set forth in Section 2.2(b) or (c), as applicable, in any Calendar Year. For purposes of determining the quantities ordered by in a Calendar Year, (i) all quantities subject to Purchase Orders placed in such Calendar Year, (ii) all quantities of Validation Batches of API purchased pursuant to Section 5.4(a) in such Calendar Year, (iii) all quantities ordered from a Secondary Supplier due to ’s failure to supply API hereunder in such Calendar Year, and (iv) all quantities ordered from a Secondary Supplier due to a Force Majeure Event in such Calendar Year shall be included in such determination.

2.4 Forecasts.

(a) Not later than [\*\*\*] following the Effective Date, shall provide with a [\*\*\*], nonbinding forecast of the quantity of API projects it may purchase from beginning [\*\*\*] prior to the anticipated commercial launch of the Product (the “Commercial Launch Forecast”). shall submit an updated Commercial Launch Forecast (which shall also be nonbinding) within [\*\*\*] after [\*\*\*].

(b) Not later than [\*\*\*] after the [\*\*\*], shall, on a [\*\*\*] basis, provide with a [\*\*\*] rolling forecast of the quantity intends to order during each [\*\*\*] (each such forecast referred to herein as a “[\*\*\*] Forecast”). The forecast amount for the first [\*\*\*] of the [\*\*\*] Forecast shall be binding on both Parties. The forecast amounts for the remaining [\*\*\*] of each [\*\*\*] Forecast, i.e., [\*\*\*], shall be non-binding forecast amounts. shall not be obligated to supply API in excess of the binding forecast amounts contained in the [\*\*\*] Forecasts. Notwithstanding anything in this Agreement to the contrary, (i) in no event shall be obligated to manufacture during a [\*\*\*] prior to the Expansion more than its then-existing [\*\*\*] capacity divided by [\*\*\*] and (ii) in no event shall be obligated to manufacture in [\*\*\*] following the Expansion more than ’s [\*\*\*] divided by [\*\*\*].

2.5 Purchase Orders. From time to time, shall deliver to one (1) or more purchase orders (“Purchase Orders”) for the aggregate API volumes in each binding portion of a [\*\*\*] Forecast. Each Purchase Order shall specify the volumes of API ordered, the Shipment Date and the destination for delivery of the API. The Purchase Orders may be delivered electronically or by other means to such location as shall designate. shall deliver such API to ’s carrier on the Shipment Date specified by ; provided, however, that the Shipment Date is no less than [\*\*\*] after the date of the submission of the Purchase Order. In the event that shall not be able to deliver API to ’s carrier by the Shipment Date specified in a Purchase Order, shall notify promptly in writing upon discovery of its inability to comply with the terms of this Section 2.5; provided, however, that such notification shall not relieve of any liability for failure to deliver API to ’s carrier on such Shipment Date.

If fails to meet the Purchase Order or any portion thereof on or before the applicable Shipment Date, in addition to other remedies that may be available to under the Legal Requirements, may purchase the shortage of such API from Third Parties and shall pay to the difference in price of such API purchased from a Third Party (a “Secondary Supplier”) and the API Price for the API shortage; *provided*, however, that in no event shall such payment exceed an amount equal to the volume of shortage times [\*\*\*] of the then applicable API Price that is charging to for API.

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If fails to order API in the amount specified in the binding portion of the [\*\*\*] Forecast, in addition to other remedies that may be available to under the Legal Requirements, shall pay to [\*\*\*] of the then current API Price that is charging to for API for the volume of API under the binding portion of the [\*\*\*] Forecast less the actual amount ordered by .

If fails to purchase the relevant minimum yearly purchase requirement as set forth above, in addition to other remedies that may be available to under the Legal Requirements, shall pay to [\*\*\*] of the then current API Price that is charging to for API for the relevant minimum yearly purchase requirement as set forth above less the actual amount purchased by in the relevant year.

2.6 Accommodations. From time to time, may deliver to a Purchase Order for API volumes in excess of those specified in any binding portion of a [\*\*\*] Forecast. shall notify in writing as to whether is able to supply the excess volume of API, but shall not otherwise be obligated to supply the excess volume of API.

2.7 Meetings. Unless otherwise mutually agreed, the Parties shall meet or otherwise communicate no less than [\*\*\*] to discuss the progression of the Development and Process Validation Plan, the Expansion, the Second Expansion, the forecasts delivered by pursuant to this Agreement and other matters relevant to the supply of API hereunder. The Parties shall use commercially reasonable efforts to accommodate technical meetings requested by both Parties.

Article III

Financial Matters

3.1 API Price.

(a) API Price. Schedule 3.1 to this Agreement sets forth the price for API (the “API Price”) based on (i) the aggregate [\*\*\*] represented by Purchase Orders in a Calendar Year (such aggregate quantities and associated pricing are delineated in Tier 1 of Matrix I and Tier 1, 2, 3, 4, 5 and 6 of Matrix II of Schedule 3.1) and (ii) timely completion of the Expansion and/or the Second Expansion (the associated pricing are delineated in Matrices I and II of Schedule 3.1). In the event expands the Facility beyond the Second Expansion (“Additional Expansions”), the Parties will negotiate in good faith the price of the API supplied in excess of [\*\*\*] per year based on a tiered pricing scheme that recognizes relevant investments, the efficiencies in the manufacturing processes of the expanded Facility and any change in ’s cost of manufacturing API.

(b) Calculation. Following ’s first delivery of a [\*\*\*] Forecast in each [\*\*\*] during the Term of this Agreement, shall estimate:

(i) The aggregate forecast orders for such [\*\*\*] to estimate whether pricing Tier 1 of Matrix I or Tier 1, 2, 3, 4, 5 or 6 of Matrix II (as set forth in Schedule 3.1) is applicable.

(ii) The aggregate [\*\*\*] subject to the pricing set forth in Schedule 3.1. Up to [\*\*\*] shall be subject to Matrix I pricing (as set forth in Schedule 3.1) once the Expansion is completed. In the event invests in the Second Expansion, up to [\*\*\*] shall be subject to Column A of Matrix II pricing (as set forth in Schedule 3.1) once the Second Expansion is completed. In the event does not invest in the

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Second Expansion, up to [\*\*\*] shall be subject to Column B of Matrix II pricing (as set forth in Schedule 3.1) once the Second Expansion is completed. All other amounts shall be subject to subsequent negotiation between the Parties. For the avoidance of doubt, the API Prices listed in Schedule 3.1 for quantities in excess of [\*\*\*] are target prices and are subject to good faith negotiations. Furthermore, in the event the price for Column B of Tier 1 or Tier 2 of Matrix II (currently marked as “TBD”) becomes necessary, and shall negotiate in good faith to reach an agreement on such prices.

Based on such estimates in (i) and (ii) above, shall advise in writing, and provide supporting documentation and calculations, of the weighted average API Price under Schedule 3.1. shall thereafter have the right to review ’s calculation of the weighted average API Price and consult with with respect thereto. In the event does not agree with ’s calculation of the weighted average API Price, the Parties shall use their respective commercially reasonable efforts to agree to the proper calculation of the weighted average API Price. In the event the Parties are unable to agree within [\*\*\*], the dispute shall be resolved as provided in Section 16.5. The API Price determined by this subsection (b) shall be the API Price invoiced and paid for Purchase Orders submitted during such [\*\*\*] (and retroactively applied to any Purchase Orders delivered in such [\*\*\*] prior to the determination of such API Price). Such API Price, however, shall be subject to a year-end retroactive adjustment pursuant to subsection (c) below.

(c) Annual Adjustment. Within [\*\*\*] after each December 31 during the Term of this Agreement and within [\*\*\*] following the termination of this Agreement, will determine:

(i) The aggregate [\*\*\*] represented by Purchase Orders in the prior Calendar Year to determine whether pricing Tier 1 of Matrix I or Tier 1, 2, 3, 4, 5 or 6 of Matrix II (as set forth in Schedule 3.1) is applicable. shall include in such determination the aggregate amount of API, if any, for which submits a purchase order to a Secondary Supplier in such Calendar Year due to (A) ’s failure to supply API hereunder and/or (B) a Force Majeure Event. Any Validation Batches of API purchased pursuant to Section 5.4 in such Calendar Year shall also be included. In the case of a partial year, the aggregate [\*\*\*] represented by Purchase Orders in such prior partial year shall be annualized in such determination.

(ii) The aggregate [\*\*\*] for the pricing is set forth in Schedule 3.1 based on (A) timely completion of the Expansion and ’s investment in the Second Expansion and (B) the limits set forth in Section 3.1(b).

(iii) The aggregate amounts paid to under Purchase Orders issued in the prior Calendar Year.

Based on such determinations set forth in (i), (ii) and (iii) above, shall advise in writing, and provide supporting documentation and calculations, of (A) the weighted average API Price for such prior Calendar Year, (B) the aggregate purchase price for all API subject to all Purchase Orders issued in the prior Calendar Year, and (C) the difference between (1) the aggregate amounts paid to under Purchase Orders issued in the prior Calendar Year and (2) the aggregate purchase price for all API subject to all Purchase Orders issued in the prior Calendar Year. shall thereafter have the right to review ’s calculations and consult with with respect thereto. In the event does not agree with ’s calculations, the Parties shall use their respective commercially reasonable efforts to

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agree to the proper calculations. In the event the Parties are unable to agree within thirty (30) days, the dispute shall be resolved as provided in Section 16.5. The API Price for such prior Calendar Year, the aggregate purchase price for all API subject to all Purchase Orders issued in the prior Calendar Year, and the difference between (x) the aggregate amounts paid to under Purchase Orders issued in the prior Calendar Year and (y) the aggregate purchase price for all API subject to all Purchase Orders issued in the prior Calendar Year determined by this Subsection (c) shall be the final determinations thereof. In the event that (x) the aggregate amounts paid to under Purchase Orders issued in the prior Calendar Year are greater than (y) the aggregate purchase price for all API subject to all Purchase Orders issued in the prior Calendar Year, shall pay the difference within [\*\*\*] of the final determination thereof. In the event that (x) the aggregate amounts paid to under Purchase Orders issued in the prior Calendar Year are less than (y) the aggregate purchase price for all API subject to all Purchase Orders issued in the prior Calendar Year, shall pay the difference within [\*\*\*] of the final determination thereof. In addition, the final API Price for the prior Calendar Year determined by this Subsection (c) shall be the price for API subject to Purchase Orders placed in the prior Calendar Year but not invoiced prior to final determination of the API Price, and shall invoice such amounts accordingly.

(d) Packaging. The Parties hereby agree that shall be responsible for up to [\*\*\*] of the cost of each packaging container used for transportation of the API to . The rest of the cost of each such packaging container shall be borne by .

(e) Price Adjustment. Effective from the [\*\*\*] anniversary date of the Effective Supply Date, shall be entitled to make an adjustment to the API Prices listed in Schedule 3.1 in accordance with the methodology described in Schedule 3.1(e) by giving written notice of such new API Prices at least [\*\*\*] prior to the relevant anniversary of the Effective Supply Date. may request in writing that make such an API Price adjustment, if applicable, by providing such written notice at least [\*\*\*] prior to the relevant anniversary of the Effective Supply Date. If so requested by , shall provide written notice of such new API Prices, if applicable, at least [\*\*\*] prior to the relevant anniversary of the Effective Supply Date. Within [\*\*\*] from the date of receipt of written notice of any API Price change, may request to provide its API Price adjustment records to an independent, mutually agreed upon, reputable certified public accounting firm, which will audit such records and certify whether the price adjustments notified by are correct and in accordance with the methodology described in Schedule 3.1(e). Such certification shall be made in writing on the auditing firm’s letterhead and delivered to at least [\*\*\*] prior to the relevant anniversary of the Effective Supply Date. No increase in the API Prices may occur until the audit has been completed and the price adjustment has been certified as described above. In the event the audit reveals that the increase is appropriate, shall bear the cost of the audit, and shall pay the increased API Prices for API in purchase orders from the relevant anniversary of the Effective Supply Date. In the event the audit reveals that the increase is not appropriate, then shall bear the cost of the audit and the API Prices of API may not increase. The increase of the API Prices of API shall be deemed accepted by if fails to make a timely request for an audit as described above or the requested audit is not completed at least [\*\*\*] prior to the relevant anniversary of the Effective Supply Date.

3.2 Commercial Invoices. may invoice for API on or before the Shipment Date of such API to or its designee pursuant to Section 3.5(a). All invoices shall be commercial invoices and shall include the following: (a) ‘Commercial Invoice’ written on the top of the document, (b) the date of the invoice, (c) the number of the Purchase Order, (d) an invoice number, (e) the quantity of API, (f) the total amount being invoiced, and (g) a reference to this Agreement, and shall be submitted to:

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3.3 Payment. Payments for API invoiced consistent with Section 3.2 above shall be due [\*\*\*] from the date of shipment, subject in each case to ’s right to dispute invoice amounts and/or delay the payment of invoiced amounts disputed by in good faith, including, without limitation, the rights set forth in Article VI.

3.4 Payment Denominations. The API Price, all invoiced amounts and all payments to be made under this Agreement shall be in [\*\*\*].

3.5 Shipment; Title; Transport.

(a) General. All API shall be shipped [\*\*\*] (as defined in INCOTERMS® 2010) [\*\*\*]. Subject to Section 3.1(d), shall package the API for shipment (including but not limited to containers, packaging, container closure systems and labeling) in accordance with the API Specifications, ’s reasonable instructions and its customary practices therefor. In the event of any conflict between ’s packaging instructions and ’s customary practices, the Parties shall endeavor in good faith to resolve such conflict as quickly as practicable. shall include the following with each shipment of the API: (i) the Purchase Order number; (ii) the lot and batch numbers; (iii) the quantity of the API; (iv) the Certificates, as applicable; and (v) such customs and other documentation as is necessary or appropriate. shall ship API to the destination designated by within [\*\*\*] of the manufacture date for Purchase Orders of quantities up to [\*\*\*] and [\*\*\*] of the manufacture date for Purchase Orders of quantities exceeding [\*\*\*].

(b) Title/Risk of Loss. Title to and risk of loss for any API shall pass from to when such API is [\*\*\*]; provided, however, that nothing in this Article III shall in any manner limit ’s rights under Article VI. If API is rejected by after delivery under this Agreement, and such API is to be returned to , then title to and risk of loss for such rejected API shall pass from to when such API is [\*\*\*]. All returned API shall be shipped [\*\*\*] (as defined in INCOTERMS 2010)

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[\*\*\*].

(c) Single Order. To the extent reasonably possible, API which is purchased in a single order shall be delivered by in a single shipment, unless directs that such API should be delivered to more than one location.

(d) Shelf Life. The API shall have a minimum shelf life of [\*\*\*] as of the applicable date of manufacture. The minimum shelf life set forth in the immediately preceding sentence is based on existing stability data. In the event future stability data justifies a longer shelf life, the Parties agree to discuss in good faith an extended minimum shelf life as of the applicable date of manufacture.

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3.6 Taxes.

(a) shall pay and otherwise be responsible for all applicable sales, VAT, goods, services, transfer and similar taxes in connection with the supply of API pursuant to this Agreement, excluding any income tax or taxes levied with respect to gross receipts, payable by under the Legal Requirements with respect to amounts payable under this Agreement.

(b) Any tax that one Party is required to withhold and pay on behalf of the other Party 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 such assistance as may reasonably be necessary to enable that other Party to claim exemption therefrom or credit therefor and in each case shall furnish the Party on whose behalf amounts were withheld proper evidence of the taxes paid on its behalf. Each Party shall comply with reasonable requests of the other Party to take any proper actions that may minimize any withholding obligation.

Article IV

Capacity, Expansion

4.1 Capacity. Within [\*\*\*] after the Effective Date, shall expand the Facility’s capacity to supply annually [\*\*\*] of API (with design capacity of [\*\*\*] annually) as further detailed in Schedule 4.1 (the “Expansion”). In the event that the Expansion is not complete (as described in Section 4.2) within such [\*\*\*] period, shall provide a written request to extend such period accompanied with a summary of the progression of the Expansion and steps needed to complete the Expansion. Upon submission of such request, shall have an additional [\*\*\*] period to complete the Expansion. Following completion of the Expansion, shall maintain at all times during the Term the capacity to supply no less than [\*\*\*] of API each Calendar Year (“’s Initial Minimum Capacity”). ’s capacity as further expanded in accordance with this Agreement, together with ’s Initial Minimum Capacity, shall be referred to herein as “’s Minimum Capacity.”

4.2 Completion. The Expansion will be deemed to be completed for purposes of this Agreement if all of the requirements set forth in Schedule 4.1 have been satisfied and has manufactured [\*\*\*] successful, consecutive batches (each batch shall be in a quantity of [\*\*\*]) of API (each a “Validation Batch”) in the expanded Facility that satisfy the requirements of this Agreement.

4.3 Second Expansion. Upon [\*\*\*], will initiate a second expansion of the Facility to expand the capacity to [\*\*\*] of API (with a design capacity of [\*\*\*]) each Calendar Year (the “Second Expansion”), provided, however, the Parties shall mutually agree on the timing and schedule of such expansion activity. The summary plan for the Second Expansion is set forth in Schedule 4.5, and shall submit a detailed development and validation plan for the Second Expansion within thirty (30) days of the later to occur of [\*\*\*] and [\*\*\*]. The Second Expansion will be deemed completed for purposes of this Agreement if all the requirements set forth in Schedule 4.5 have been satisfied and has manufactured [\*\*\*] successful, consecutive Validation Batches in the expanded Facility that satisfy the requirements of this Agreement.

Article V

Manufacture of API

5.1 General. shall manufacture, test, package, store, handle, label, release and ship all API in accordance with the applicable Drug Applications, API Specifications, cGMPs, Legal Requirements, this Agreement and the Quality Agreement.

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5.2 API Specification Changes.

(a) Requested Changes. During the Term, except as set forth in Section 5.2(c), shall not be entitled to change the API Specifications related to ’s performance of its obligations hereunder related to API unless it receives the Consent of , which Consent shall not be unreasonably withheld or delayed. If requests, and approves, a discretionary change to the API Specifications, shall make all revisions to the API Specifications requested by . retains the right and responsibility for final approval of the API Specifications. shall pay all documented reasonable amounts incurred in implementing a change to the API Specifications requested by under this Section 5.2(a). For all changes to the API Specifications requested by pursuant to this Section 5.2, shall, in its discretion, following consultation with , if reasonably practicable, either (i) perform, or arrange for the performance of, all development work in connection therewith or (ii) have perform such development work at the Facility at ’s expense. For the avoidance of doubt, Section 5.2(a)(i) does not give any right to use or disclose (A) any Intellectual Property (except as may be permitted by any express license from ), or (B) any Confidential Information (except as may be permitted under Article XIII hereof). agrees to use commercially reasonable efforts to minimize its costs associated with any API Specification change. At the request of , shall evaluate the estimated costs and timing of potential revisions to the API Specifications.

(b) Changes. shall not make any revisions to the API Specifications, the manufacturing process or Material Third Party Suppliers, without prior written Consent of , which Consent shall not be unreasonably withheld or delayed. If the Parties implement a change in the API Specifications or the manufacturing process under this Section 5.2, they shall negotiate any changes in any affected Purchase Order to provide reasonable accommodation for changed circumstances. The costs of revisions requested by under this Section 5.2(b) shall be borne by without any increase in the API Price.

(c) Changes Mandated by Legal Requirements. Notwithstanding anything in subsections (a) and (b) of this Section 5.2 to the contrary, (i) shall implement all changes to the API Specifications intended to maintain compliance with Legal Requirements, to bring the API Specifications into compliance with Legal Requirements or to accommodate the demands or requests of any Governmental Body; (ii) unless such changes are generally applicable to the Facility or ’s manufacture of other products, the Parties shall bear equally the expense of any of such changes; and (iii) if the changes are generally applicable to the Facility or ’s manufacture of other products, shall bear the expense of any of such changes. Notwithstanding the foregoing, if changes to Legal Requirements generally affecting manufacturers of drugs containing the Compound significantly increase the cost for to supply API hereunder, then the Parties agree to negotiate in good faith any appropriate adjustments to this Agreement.

5.3 Storage and Handling Obligations. When storing and handling API, Third Party Materials, Nonconforming API or API-derived wastes, shall comply with, and shall maintain all storage facilities in compliance with, the API Specifications, cGMPs, Legal Requirements and the Quality Agreement.

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5.4 Validations and Stability Studies.

(a) Initial Manufacturing Process Validation. shall as soon as practicable complete the Validation of the manufacturing process for the API in connection with the Expansion (the “Initial Manufacturing Process”) in accordance with activities set forth in the Development and Process Validation Plan at no additional cost to . The Development and Process Validation Plan shall, among other things, include activities necessary to establish the Facility as a cGMP facility, a validation plan and appropriate protocols. Without limiting the foregoing, will provide process progress reports to no less frequently than [\*\*\*], which reports shall include, without limitation, reasonable details related to construction, equipment installation and process implementation, subject to redaction of any Confidential Information. Promptly following completion of Validation of the Initial Manufacturing Process, shall deliver a final report to that includes a summary of regulatory data and documentation respecting the manufacture of the API, without disclosing any confidential process information, all in compliance with applicable FDA guidelines and any other applicable Legal Requirements but subject to redaction of any Confidential Information.

(i) The Parties shall participate in project teleconferences with each other as reasonably requested by the other Party to successfully complete the Validation of the Initial Manufacturing Process. During development and Validation of the Initial Manufacturing Process, will accommodate in person technical meetings at the Facility and technical inspections as reasonably requested by . Without limiting the foregoing, during process development and in support of API process characterization and Validation activities, will be permitted to conduct reviews of the Facility and the pertinent records maintained by , subject to restriction on access to all Confidential Information, in connection with the conduct of manufacturing, storage and testing of API, all upon ’s request and with reasonable notice to permit to support such technical reviews.

(ii) In conjunction with the foregoing Validation pursuant to the Development and Process Validation Plan, will produce process Validation Batches. shall be required to purchase Validation Batches of API provided that they comply with the API Specifications and Validation acceptance criteria and are otherwise in compliance with the terms of this Agreement. The establishment and Validation of the Initial Manufacturing Process shall be deemed to be complete upon the manufacture of such [\*\*\*] successful, consecutive Validation Batches that comply with the API Specifications and Validation criteria and are otherwise in compliance with the terms of this Agreement and the Development and Process Validation Plan.

(iii) With the prior written consent of the other Party, a Party may engage in teleconferences, in person meetings, Facility reviews, quality assurance audits, records reviews and other activities under this Agreement through its (or its Affiliates’) employees or consultants with a bona fide need to know, but only to the extent necessary for the Party to exercise its rights and discharge its obligations under this Agreement, provided that (A) each such employee and consultant has executed a written confidentiality agreement containing use and disclosure restrictions at least as protective as those set forth in Article XIII, and (B) any consultant shall be reasonably acceptable to (such persons, “Approved Representatives”).

(b) Process Validation for Improved Manufacturing Processes. The Parties acknowledge that or may from time to time desire to pursue strategies and

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efficiencies for improving the manufacturing processes for the API. Each Party agrees to reasonably evaluate and discuss any such suggestions for improvements that the other Party reasonably believes in good faith may result in significant cost or time savings in the manufacturing process.

(c) General. Without limiting the foregoing, shall perform at no additional cost to on an on-going basis all Validations and stability studies required by the applicable Drug Applications, the API Specifications, cGMPs or Legal Requirements in connection with the regular course of manufacturing the API for commercial supply.

(d) Duties. In performing its duties under this Section 5.4, shall perform the following tasks, consistent with the Quality Agreement:

(i) implement and operate an ICH complaint stability program;

(ii) notify ’s head of regulatory affairs, or his or her designee, promptly, but within not more than [\*\*\*], if any batch of API fails any stability tests; and

(iii) report to ’s head of regulatory affairs, or his or her designee, promptly, but within not more than [\*\*\*], any Nonconformity, significant atypical results, deviations or adverse trends exhibited during final release or stability testing.

(e) Manufacturing Process Review. At either Party’s reasonable request, the Parties shall promptly meet, in person or telephonically, for the purpose of reviewing such matters related to manufacturing of the API as may be specified by a Party, including discussing strategies for improving the API manufacturing processes.

(f) Confidential Information. Notwithstanding anything to the contrary contained in this Agreement, may redact or limit from any deliveries of or access to data, reports or any other information to any Third Party confidential information or Confidential Information, at ’s sole discretion; provided, however, that may not redact or limit any Confidential Information that is reasonably necessary for to comply with all Legal Requirements. In this regard, the Parties agree that all process information related to the manufacture of API, whether contained in a DMF or otherwise, shall, subject to Section 13.4, constitute Confidential Information and shall not be disclosed to under any circumstances, notwithstanding anything herein to the contrary; provided, however, shall provide the relevant Governmental Body with all information necessary to support ’s Drug Application filings in a timely manner. Furthermore, for the avoidance of doubt, subject to Section 13.4, all information provided to under this Section 5.4 is Confidential Information and nothing in this Section 5.4 shall be construed as giving any right to use or disclose (A) any Intellectual Property (except as may be permitted by any express license from ), or (B) any Confidential Information (except as may be permitted under Article XIII hereof).

5.5 Third Party Materials.

(a) General. shall be responsible for procuring, inspecting, testing and releasing adequate Third Party Materials that comply with cGMP and this Agreement as necessary to meet a Purchase Order for API. shall perform all testing of Third Party Materials required by the applicable API Specifications, cGMP, Legal Requirements, this Agreement and the Quality Agreement.

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(b) Audits. shall be responsible for selecting all Third Party Suppliers of materials for API and periodically performing audits of each such Material Third Party Supplier as necessary to ensure compliance with Section 5.5(a). shall provide the results of any such audit, including copies of any reports prepared in connection with any such audit, within [\*\*\*] of the audit’s completion.

(c) Materials Certifications. shall prepare or cause to be prepared by its Third Party Suppliers all certifications as to any Third Party Materials required by cGMPs or Legal Requirements.

5.6 Quality Agreement. Within [\*\*\*] following the Effective Date, the Parties shall enter into a quality agreement with such scope, terms and conditions as are customary within the pharmaceutical industry (such agreement, the “Quality Agreement”). In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement, the provisions of this Agreement shall govern.

5.7 Compliance with Specifications, cGMPs and Legal Requirements. shall be responsible for identifying and implementing, in accordance with its obligations under Section 5.1, any actions required to bring , Material Third Party Suppliers and Third Party Suppliers of starting materials for the Compound into compliance with API Specifications, cGMPs and Legal Requirements. shall implement any such changes as soon as reasonably practicable (even if, in the case of cGMPs and Legal Requirements, a later effective date is specified), unless the required effective date for implementing such change falls after the effective date of any termination of this Agreement for which notice has been previously given.

Article VI

Testing and Quality Assurance

6.1 Quality Assurance; Quality Control; Retains.

(a) shall implement and perform operating procedures and controls for sampling, ICH stability, release and other testing of Third Party Materials and API, and for Validation, documentation and release of the API and such other quality assurance and quality control procedures as required by the API Specifications, cGMPs, Legal Requirements, this Agreement and the Quality Agreement. Without limiting the foregoing, shall establish an ICH stability program that collects no less than [\*\*\*] data. shall consult with with respect to the details of the stability program, including analytical methods and stability container requirements.

(b) shall maintain for a period of time required by Legal Requirements, but in no event less than [\*\*\*] after the expiration date of such API (i.e., a total of [\*\*\*] from manufacture, subject to Section 3.5(d)), such quantities of the API from each batch of the API as are sufficient to conduct [\*\*\*] full testings of the API in accordance with this Agreement.

6.2 Testing of API. Prior to release of the API, shall test the API in accordance with the Validation testing procedures described in the (a) applicable Drug Applications, (b) API Specifications, (c) cGMPs, (d) Legal Requirements, (e) Quality Agreement and (f) those procedures and in-plant quality control checks applicable to any products packaged by . shall provide with a copy of the records pertaining to

such testing if reasonably requested, subject to redaction of any Confidential Information. Additionally, shall provide with a Certificate of Analysis and/or any other certificate required by any applicable Governmental Body for release

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of API (collectively, the “Certificates”) for each batch of API. shall be under no obligation to accept any shipment of API without the accompanying Certificates. For the avoidance of doubt, all information provided to under this Section 6.2 is Confidential Information and nothing in this Section 6.2 shall be construed as giving any right to use or disclose (A) any Intellectual Property (except as may be permitted by any express license from ), or (B) any Confidential Information (except as may be permitted under Article XIII hereof).

6.3 Holds, Rejections and Revocation of Acceptance.

(a) General. may test or cause to be tested the API delivered by for a Nonconformity or reasonably suspected Nonconformity (as described below in Section 6.4). During such testing, at ’s reasonable request, shall provide appropriate analytical reference standards for such testing to or its designee. If wishes to hold the API delivered to it by for investigation of a Nonconformity or reasonably suspected Nonconformity, shall so notify stating the basis for the hold. ’s failure to comply with provisions of this Section 6.3 and 6.4, including timely notification of of any Nonconformity, shall be deemed to be an irrevocable acceptance of any such relevant API by .

(b) Independent Testing. If the Parties disagree as to whether API subject to hold, rejection or revocation of acceptance is subject to a Nonconformity, ’s and ’s respective designees shall confer to review samples and/or batch records, as appropriate, and shall initiate a formal investigation. If the disagreement is not resolved within [\*\*\*], then samples, batch records and other data relating to the batch in dispute shall promptly be submitted for testing and evaluation to a mutually acceptable independent Third Party (including a qualified testing laboratory to perform such testing using validated methods) mutually approved in writing by the Parties. The findings of such independent Third Party shall be binding on the Parties, absent manifest error. The expenses incurred by the Parties for the testing and evaluation by the Third Party shall be borne by unless has claimed that the API is subject to a Nonconformity, and the API in question is ultimately found not to be Nonconforming API.

(c) Interim Replacement. During the pendency of any dispute concerning whether API is subject to a Nonconformity, shall replace the shipment under dispute, at the request of , as soon as reasonably practicable.

6.4 Nonconformity.

(a) Nonconformity. If, within [\*\*\*] following manufacture of a batch of API, either Party becomes aware or has a reasonable basis to believe that any batch or shipment of API may have a Nonconformity, at any time regardless of the status of ’s testing and quality assurance activities, such Party shall notify the other Party within [\*\*\*] of becoming aware of a Nonconformity. “Nonconformity” means a product characteristic that (i) results from ’s failure to manufacture, test, package, store, label, release or ship API in accordance with the API Specifications, cGMPs, ICH guidelines, Legal Requirements, this Agreement or the Quality Agreement, (ii) causes any API to fail to conform to the API Specifications, cGMPs or Legal Requirements, or (iii) constitutes an adulteration. In the event of a Nonconformity or reasonably suspected Nonconformity identified within [\*\*\*] following manufacture of an affected batch of API, the Parties shall immediately (and in any case within [\*\*\*]) conduct an investigation in accordance with Section 6.8 below and, until resolution of the investigation, handle the API as provided in Section 6.4(b) below.

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(b) API That May Be Subject to a Nonconformity. Any batch or shipment of API that reasonably may be suspected to be subject to a Nonconformity shall be handled as follows and consistent with the Quality Agreement:

(i) such API held in inventory at shall be placed on “Hold” and shall not be shipped to or its designee, unless, upon completion of investigations pursuant to Section 6.8, such API is found to be not Nonconforming or it is directed otherwise by ;

(ii) any such API shipped to or its designee and held in stock by or its designee shall maintain a “hold” or “rejected” status and shall not be released into approved inventory of or its designee until the Parties have completed any investigations pursuant to Section 6.8; and

(iii) payment for such API whether shipped or unshipped shall [\*\*\*].

Upon learning of a Nonconformity, shall have the right to [\*\*\*].

(c) Remedy for Nonconforming API.

(i) In the event that any quantity of API is found to be Nonconforming API prior to it being converted into Product and notifies of such Nonconformity within [\*\*\*] following manufacture of such batch of API, then may, at ’s discretion: (1) [\*\*\*] and/or [\*\*\*]; *provided*, however, that, with respect to the payment payable pursuant to [\*\*\*], in no event shall such payment exceed an amount equal to [\*\*\*] times [\*\*\*] of [\*\*\*]. For clarity, once API has been delivered by under Section 3.5(a), it may not be reworked or reprocessed in the event it is found to be Nonconforming API.

(ii) In the event that any Nonconforming API is held in inventory at , then shall have such Nonconforming API destroyed.

(iii) In connection with the destruction of API, under Section 6.4(c)(i)(B)(3) or under Section 6.4(c)(ii) shall be solely responsible for compliance with all Legal Requirements in connection with the destruction and shall be liable for any Losses resulting from such destruction, and the Party not directing the destruction of such API, as the case may be, may, if it so requests, (A) be present at such destruction, or (B) receive written documentation of such destruction.

(iv) shall use commercially reasonable efforts to perform any replacement of Nonconforming API on a priority basis and shall deliver such replacement API as soon as possible.

(d) Credit/Reimbursement for Nonconforming API. In the event that is obligated to pursuant to Section 6.4(c), shall, at ’s discretion, reimburse or credit for (i) [\*\*\*] and [\*\*\*]. shall provide with such documentation as may reasonably request to confirm any of the foregoing charges, costs or expenses. shall pay any unused credit amounts under this Section as of the expiration or termination of this Agreement to within [\*\*\*] after this Agreement is terminated.

6.5 Quantitative Deficiencies. In the event determines there is a quantitative deficiency in any shipment, with respect to the API volumes indicated on the applicable Purchase

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Order(s), shall properly document such deficiency and notify thereof in writing. Upon such notice, may, at its option: (a) pay only for actual quantities delivered, or (b) pay only for actual quantities delivered and require to rectify any such deficiency by shipping the appropriate quantities of API to or as directed by , in which case shall be obligated to pay for any such additional quantities pursuant to the terms and conditions of this Agreement. shall use commercially reasonable efforts to rectify any such deficiency on a priority basis and deliver such additional quantities of API as soon as possible.

6.6 Product Complaints Reports.

(a) Received by . Any and all complaints of which becomes aware relating to the Product shall promptly be forwarded to ’s head of regulatory affairs, or his or her designee, consistent with the Quality Agreement. Without limiting the foregoing, shall forward any such complaint that might be associated with an Adverse Event (as defined below in Section 6.7) no later than [\*\*\*] following its receipt.

(b) Received by . shall as soon as possible inform of any and all complaints that receives which implicate ’s manufacturing or other processes at the Facility. Notification shall be given by telephone, with a facsimile confirmation immediately following.

6.7 Adverse Events.

(a) Definition. For the purposes of this Agreement, “Adverse Event” shall mean any adverse event associated with the use of the Product in humans, whether or not considered drug-related, including but not limited to “adverse event” as defined in ICH guidelines.

(b) Notice to . shall notify ’s head of regulatory affairs, or any successor department specified by , as soon as possible, but no later than [\*\*\*] following its receipt, of information concerning a possible Adverse Event. Notification shall be given by telephone, with a facsimile confirmation immediately following. shall provide to all of the information has available concerning the Adverse Event and shall reasonably cooperate with any investigation conducted or directed by as set forth in Section 6.8 below.

(c) Notice to . To the extent an Adverse Event of which becomes aware implicates ’s manufacturing or other processes at the Facility, shall inform of such Adverse Event as soon as possible, but no later than [\*\*\*] following its receipt of such information, and shall disclose to any information has regarding that Adverse Event which implicates ’s manufacturing or other processes at the Facility. Notification shall be given by telephone, with a facsimile confirmation immediately following.

6.8 Investigations; ’s Obligations.

(a) General. The Parties shall investigate all reports of Nonconformity, Product complaints, out-of trend analytical results, out-of-trend manufacturing yields, stability failure and Adverse Events. The Parties shall act promptly and shall cooperate fully in such investigations.

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(b) Direction.

(i) Investigations Related to Product or API Following Shipment. shall have the sole right, in its discretion, to control and direct any or all aspects of an investigation conducted under this Section 6.8 with respect to matters related to API following shipment by or with respect to the Product. shall advise from time to time throughout such investigation of ’s intentions regarding control and direction of such aspects of the investigation. shall reasonably consult with and shall reasonably afford the opportunity to provide comments or suggestions regarding such investigation, which agrees to consider in good faith.

(ii) Investigations Related to API Prior to Shipment. shall have the sole right, in its discretion, to control and direct any or all aspects of an investigation conducted under this Section 6.8 to the extent related to API prior to its shipment by . shall advise from time to time throughout such investigation of ’s intentions regarding control and direction of such aspects of the investigation. shall reasonably consult with and shall reasonably afford the opportunity to provide comments or suggestions regarding such investigation, which agrees to consider in good faith.

(iii) Mutual Assistance. Upon written request by a Party in connection with an investigation, the other Party shall provide all reasonably requested testing results, assistance and information to the requesting Party in connection with an investigation of any Nonconformity, Product complaint or Adverse Event, including chemical/microbial analysis of complaint samples (if available), analysis of retained samples and review of batch records. The Party not directing an investigation shall have the right to conduct at its own expense any further tests it deems appropriate regarding such investigation provided that it shall share the results with the other Party. Any information provided by a Party shall be considered such Party’s Confidential Information and may be used or disclosed only as permitted under Article XIII hereof.

(c) Reporting.

(i) The Party directing an investigation shall provide to the other Party [\*\*\*], and [\*\*\*].

(ii) Any final report regarding a Nonconformity shall be submitted by within [\*\*\*] of the notification regarding that Nonconformity given under Section 6.4 above.

(iii) shall provide to a written report of [\*\*\*]. Each Party shall hold all communications related to such investigation, testing or other requested assistance in confidence, and those communications shall be subject to the terms of Article XIII hereof.

(d) Costs of Investigations. shall reimburse for [\*\*\*] incurred by in connection with [\*\*\*]. shall reimburse for [\*\*\*] incurred by in connection with [\*\*\*].

(e) Notwithstanding the foregoing, in the event it is determined in ’s reasonable discretion that API supplied by hereunder was not the cause of a Product complaint or Adverse Event, shall have no further obligation under this Section 6.8 except to reasonably cooperate with ’s investigation upon reasonable request by .

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6.9 Certain Product Events.

(a) Notification and Cooperation. In the event that shall be required (or shall voluntarily decide) to initiate a recall, withdrawal or field correction of, field alert report or comparable report with respect to any Product, shall notify ’s authorized quality assurance officer, and shall reasonably cooperate with to implement the same.

(b) Coordination of Efforts. In the event that becomes aware of information that may warrant taking any action with respect to any Product, shall immediately provide the head of regulatory affairs such information. The Parties shall cooperate with each other in determining the necessity and nature of such action; provided, however, that shall take no action to effect the same without the written concurrence of .

(c) Contacts and Statements. With respect to any recall, withdrawal, field correction, field alert report or comparable report with respect to any Product, or its designee shall make all contacts with the applicable Governmental Body and shall be responsible for coordinating all of the necessary activities in connection with any such recall, withdrawal, field correction, field alert report or comparable report. or its designee shall make all statements to the media, including press releases and interviews for publication or broadcast. agrees to make no statement to the media, unless otherwise required by Legal Requirements, and, in any such event, shall reasonably collaborate with on the content of any such statement.

(d) Other Notice. Notwithstanding anything herein, agrees to notify as promptly as possible of any incident pertaining to the Product or API that would require notification to any Governmental Body, including, but not limited to, fire, explosion, environmental event, serious injury or physical damage at the Facility or -controlled facility related to the API Third Party Materials, or Intermediate.

Article VII

Regulatory Matters

7.1 Consents. shall obtain and hold all Consents required to be obtained by under the Legal Requirements for the performance of its obligations under this Agreement and shall reasonably cooperate with with respect thereto. At all times, shall maintain and comply with all of the Consents which may from time to time be required by any Governmental Body having jurisdiction with respect to ’s manufacturing operations and facilities and otherwise to be obtained by to permit the performance of its then-current obligations under this Agreement. shall bear all expenses incurred in connection with its obligations under this Section 7.1. In the event any Consent held by relating to the Facility or its ability to manufacture the API in accordance with this Agreement is hereafter suspended or revoked, or has material restrictions imposed upon it by any Governmental Body affecting the API or the Facility, shall immediately provide written notification to identifying such material restrictions, a schedule of compliance and such other information related thereto as is reasonably requested by . Without limiting the foregoing, will cooperate with in a reasonable and timely manner in preparation for pre-approval inspection of API manufactured at the Facility by any Governmental Body.

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7.2 Establishment of cGMP Facility.

(a) shall use commercially reasonable best efforts to perform the work under the Development and Process Validation Plan relating to the Facility by the date or dates specified therein in order to establish the Facility as a cGMP facility by the date specified in the Development and Process Validation Plan and shall reasonably cooperate with with respect thereto.

(b) shall have the right, pursuant to the audit procedures in Section 9.2, to have its Approved Representatives undertake a quality assurance audit of ’s procedures and facilities for API production as soon as practicable after the date the Expansion is completed. If undertakes such an audit, shall provide with a written audit report and, if applicable, shall highlight therein areas where judges that needs to make changes to procedures or facilities in advance of any Pre-Approval Inspection. Both Parties shall cooperate in good faith to agree and implement the necessary changes. If ’s written audit report identifies any areas for improvement, within [\*\*\*] following delivery of ’s audit report, shall prepare an action plan (and promptly deliver a copy of such plan to for review and comment), which plan shall address the findings of the audit report and include accomplishment dates for corrective actions. Thereafter, once the Parties mutually agree on a corrective action plan, the Parties agree to amend the Development and Process Validation Plan to include such corrective actions.

(c) agrees to cooperate with by making its Approved Representatives available for consultation and advice to , as may be reasonably requested by , regarding implementation of cGMP and related procedural systems and any other matters as may be mutually agreed.

(d) shall use reasonable best efforts to be prepared for any Pre-Approval Inspection. will cooperate with in a reasonable and timely manner in preparation for such Pre-Approval Inspection.

7.3 Compliance. In carrying out their respective obligations under this Agreement, the Parties shall comply in all respects with cGMPs and the Legal Requirements, as applicable to such Party, in effect from time to time.

7.4 Drug Application Documentation.

(a) shall draft the CMC section of the Drug Application for the Product based on information to be provided by as follows: (i) the Quality Section for API manufacturing (in the CMC section) will be drafted by in the form of a DMF that will be sent to the FDA Documentation room by ; (ii) will make available to information in the DMF that does not constitute Confidential Information; and (iii) such access to the DMF will be only through a letter of access issued to by . Once the CMC section of the Drug Application for the Product is drafted by , if requested by , shall assist by critically reviewing and providing corrections to any relevant section of the ’s CMC in a timely fashion. agrees that may reference as the manufacturer of the API in ’s Drug Application and any other documentation required under any regulatory filings for the API, and will provide the relevant Government Body with all required documentation, including development and analytical reports to support such filings. shall own all regulatory files (excluding the DMFs) with respect to the API including without limitation regulatory data and documentation prepared by under this Section 7.4 respecting the

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manufacture of the API, including without limitation the CMC section of any Drug Application filed with the FDA related to the API. For the avoidance of doubt, (i) the DMFs shall be owned by , and (ii) all process information related to the manufacture of API, whether contained in a DMF or otherwise, shall, subject to Section 13.4, constitute Confidential Information and shall not be disclosed to under any circumstances, notwithstanding anything herein to the contrary; provided, however, shall provide the relevant Governmental Body with all information necessary to support ’s Drug Application filings in a timely manner.

(b) Upon reasonable request from , shall provide with information regarding Drug Applications, or discrete sections thereof, to the extent available and necessary for to perform its obligations under this Agreement; provided, however, that information provided hereunder shall not be provided or disclosed to any other Person without ’s prior Consent. In the event that any Governmental Body makes an inquiry of or provides any information to that is or may be related to a Drug Application, shall promptly forward such inquiry or information to .

7.5 DMFs. shall create and maintain the Drug Master Files for API in the [\*\*\*] (if designated by in its reasonable discretion) and other jurisdictions agreed to by the Parties (the “DMFs”). agrees to assist by making its Approved Representatives available for consultation and advice to , as may be reasonably requested by , regarding preparation and maintenance of the DMFs. hereby grants to the right to reference the DMFs in any relevant Drug Application or other documentation to the extent such reference is necessary for the approval and maintenance of a Drug Application. The Approved Representatives may share with any information they receive or obtain in connection with their activities under this Section 7.5. Additionally, from time to time during the Term, shall provide such information as may reasonably request related to the DMFs, which shall be handled by as Confidential Information, subject to Article XIII. shall own all regulatory files with respect to the API including without limitation the DMFs.

7.6 Regulatory Changes. The Parties will promptly notify each other of any material revisions, amendment of or additions to the DMFs and cGMPs and will confer with each other with respect to the best means to comply with such requirements.

7.7 Regulatory Inspections.

(a) Procedures. If is notified that API or the portion of the Facility relating to the supply of API will be subject to an inspection by any Governmental Body, shall:

(i) within [\*\*\*] advise ’s head of regulatory affairs, or his or her designee, by telephone and facsimile and provide all relevant information known to regarding such inspection;

(ii) reasonably cooperate with and allow any such inspection to the extent required by Legal Requirements;

(iii) direct all inquiries related to API, Product, any Drug Application or ’s Confidential Information covered by Article XIII of this Agreement to ;

(iv) have a consultant with the required expertise present for such inspections at ’s sole cost and expense. will provide a copy of the 483 inspection observations upon conclusion of the inspection and the 483 responses to when prepared and sent to the inspecting Governmental Body;

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(v) within [\*\*\*] (within [\*\*\*] if any serious or critical deficiencies are identified by the Governmental Body) send a copy of any inspection report observations issued by any Governmental Body related to the manufacture, generation, processing, storage, transportation, distribution, treatment, disposal or other management of API or Third Party Materials;

(vi) provide each proposed response to any inspection reports prepared in accordance with this Section 7.7 not less than [\*\*\*] before the required response date and consider any comments or suggestions received from in good faith; and

(vii) respond to all inspection report observations by any Governmental Body in a timely manner and take all appropriate corrective actions required or recommended by such Governmental Body.

Notwithstanding the foregoing provisions of this Section 7.7(a), nothing shall require to disclose information to specifically relating to any other customer of or those customers’ products to which the inspection relates.

(b) Notification. If any Governmental Body shall take any action which shall require a response or action by with respect to API, Product, API Specifications, Third Party Materials, the Facility or any operating procedure affecting the API, agrees [\*\*\*] to notify of the required response or action and, in the case of API, Product and/or API Specifications, shall proceed only with the prior advice and written Consent of , which shall not be unreasonably withheld or delayed. Notwithstanding anything contained in this Agreement to the contrary, shall not initiate or participate in any communications with any Governmental Body concerning the API, Product or the API Specifications unless required to do so by Legal Requirements or requested to do so by and only after consultation with .

7.8 Other Regulatory Matters. shall provide to each Governmental Body and, at ’s request, shall provide to , all documents and information requested by each such Governmental Body in support of ’s and ’s regulatory filings, including, without limitation, all relevant DMFs. Copies of all documents to be provided to any Governmental Body shall be provided to at least [\*\*\*] in advance of delivery to such Governmental Body, if possible, or otherwise as soon as practicable thereafter.

7.9 Confidential Information. Notwithstanding anything to the contrary contained herein, may redact or limit from any deliveries of or access to data, reports or any other information, any Third Party confidential information or Confidential Information, at ’s sole discretion; provided, however, that may not redact or limit any Confidential Information that is reasonably necessary for to comply with all Legal Requirements. In this regard, the Parties agree that all process information related to the manufacture of API, whether contained in a DMF or otherwise, shall, subject to Section 13.4, constitute Confidential Information and shall not be disclosed to under any circumstances, notwithstanding anything herein to the contrary; provided, however, shall provide the relevant Governmental Body with all information necessary to support ’s Drug Application filings in a timely manner. Furthermore, for the avoidance of doubt, subject to Section 13.4, all information provided to under this Article VII is Confidential Information and nothing in this Article VII shall be construed as giving any right to use or disclose (A) any Intellectual Property (except as may be permitted by any express license from ), or (B) any Confidential Information (except as may be permitted under Article XIII hereof).

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Article VIII

Intellectual Property

8.1 Ownership.

(a) Ownership. acknowledges and agrees that owns all rights in and to the Intellectual Property, including all Intellectual Property rights in and to the API and the documentation, specifications and processes associated with the API. Except as expressly provided in Section 8.3 below, nothing in this Agreement shall be deemed to transfer or convey, expressly or by implication, any license or any other right, title or interest in or to the Intellectual Property.

(b) Ownership. acknowledges and agrees that owns all rights in and to the Intellectual Property, including all Intellectual Property rights in and to the Product, the Drug Applications, and the documentation, specifications and processes associated with the Product that is not Intellectual Property. does not have, by virtue of this Agreement or otherwise, a license or any other right, title or interest in or to the Intellectual Property.

8.2 New Developments.

(a) API Product Developments. All Intellectual Property relating to the API or the development or manufacture of the API, that is conceived, reduced to practice, authored or otherwise invented, discovered, generated or developed in whole or in part by in the course of activities under this Agreement, whether patentable or not, and any authorship of works relating to the API that are created by , including but not limited to any trademarks, trade dress, trade secrets or copyrights, shall be “API Product Developments.”

(b) Ownership of API Product Developments. Subject to the rights and licenses granted in Section 8.3 below, shall own all right, title and interest in and to all API Product Developments and all rights to Intellectual Property arising therefrom.

(c) Patents. Notwithstanding any obligation of confidentiality between and under Section 13.3 hereto or any other agreement, , at its own expense, may elect to file and prosecute appropriate patent applications and maintain patents issuing therefrom covering such API Product Development. Upon ’s reasonable request and at its expense, shall take such reasonable actions as deems necessary or appropriate to assist in obtaining patent or other proprietary protection in ’s name with respect to all API Product Developments. If declines to pursue a patent for an API Product Development, shall be obligated to assign its rights to pursue such patent to and shall provide reasonable assistance if decides to file a patent application for an API Product Development.

8.3 Grant of License to API (including API Product Developments). Subject to the terms and conditions of this Agreement, hereby grants (a) a worldwide, non-exclusive, royalty-free, non-transferable (except in connection with a permitted assignment under Section 16.4), non-sublicensable license to use the API Product Developments for the manufacture and sale of Product using API supplied by , and (b) a worldwide, non-exclusive, royalty-free, non-transferable (except in connection with a permitted assignment under Section 16.4), non-sublicensable license to use

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the Intellectual Property (other than the API Product Developments) for the manufacture and sale of Product using API supplied by . This license shall terminate upon the later of (i) the expiration or termination of this Agreement or (ii) such time that is no longer in possession of API supplied by , including API that has been incorporated into Product that has not reached expiry. For the avoidance of doubt, regardless of the termination or expiration of this Agreement, shall have a license to use the Intellectual Property (including API Product Developments) for the manufacture and sale of the Product for so long as necessary to sell all inventory that incorporates API (including API Product Developments) provided by under this Agreement. The license granted in this Section 8.3 shall be referred to as the “ License.”

8.4 Infringement.

(a) shall promptly notify of any suspected or threatened infringement, misappropriation or other unauthorized use of the Intellectual Property licensed by to under the License that comes to ’s attention. The notice shall set forth the facts of such suspected or threatened infringement in reasonable detail. shall have the sole right, but not the obligation, to institute, prosecute and control, at its expense, any action or proceeding against the Third-Party infringer of such Intellectual Property. If institutes an action against such infringer, shall give reasonable assistance and authority to control, file and prosecute the suit as necessary at ’s expense. shall have the right to participate in the applicable action or proceeding with its own counsel at its own expense and without reimbursement hereunder. If elects to so participate, shall provide with an opportunity to consult regarding such action or proceeding.

(b) If elects not to bring any action or proceeding for infringement, misappropriation or other unauthorized use of the Intellectual Property licensed by to under the License, then it shall promptly advise of its decision, and thereafter shall have the right, but not the obligation, to institute, prosecute and control, at its expense, any action or proceeding against the Third-Party infringer of such Intellectual Property. If institutes an action against such infringer, shall give reasonable assistance and authority to control, file and prosecute the suit as necessary at ’s expense, and shall join such action if reasonably requested by or required by applicable Legal Requirements. shall have the right to participate in the applicable action or proceeding with its own counsel at its own expense and without reimbursement hereunder (except for any out-of-pocket costs and expenses incurred by following its joinder as a party to such action or proceeding pursuant to ’s reasonable request or as required by applicable Legal Requirements). If elects to participate (but is not joined as a party to such action or proceeding), shall provide with an opportunity to consult regarding such action or proceeding. shall retain any damages or other monetary awards that it recovers in pursuing any action under this Section 8.4(b).

(c) In the event that either Party exercises the rights conferred in this Section 8.4 and recovers any damages or other sums in such action or proceeding or in settlement thereof, such damages or other sums recovered shall first be applied to all out-of-pocket costs and expenses incurred by the Parties in connection therewith (including attorneys fees), unless such Party is expressly not entitled to reimbursement under this Section 8.4. If such recovery is insufficient to cover all such costs and expenses of both Parties, the controlling Party’s costs shall be paid in full first before any of the other Party’s costs. Each Party seeking reimbursement under this Section 8.4 shall furnish promptly to the other Party appropriate documentation of its out-of-pocket costs and expenses incurred.

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8.5 Data. As between and , shall be and remain the sole and exclusive owner of any and all data and information, in any form, relating to: (a) the business of ; (b) licensees, customers and suppliers of ; (c) the Product and the development and manufacture thereof (excluding ’s data and information related to the API); and (d) the API Specifications. All information provided to by under this Article VIII shall be handled by as Confidential Information, subject to Article XIII.

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Article IX

Information; Access; Audit Rights

9.1 Provision of Information.

(a) Data. shall provide to copies (in electronic or hard-copy form, as requested by ) of or access to data as may be reasonably requested from time to time by on a bona fide need-to-know basis, except as may be restricted for confidential information or trade secrets. shall provide final reports for batch failures, including recommendation for API disposition for all investigations involving (i) foreign matter or particulate contamination; or (ii) any test results indicating non-compliance with the applicable Drug Applications, cGMPs or the API Specifications.

(b) Annual Report. shall prepare and provide to a written annual report no later than [\*\*\*] following the end of each Calendar Year, documenting, subject to redaction of Confidential Information, (i) the prior Calendar Year’s batch records; (ii) packaging changes; (iii) process changes; (iv) changes in API testing methods performed pursuant to Article VI hereof; (v) changes in API Specifications; (vi) batches of API rejected or aborted; (vii) any other discrepancies that require reporting pursuant to cGMP or Legal Requirements; (viii) “trends” in the manufacture of API during the prior Calendar Year; and (ix) ICH stability data summary.

9.2 Audit and Inspection Rights. During the Term of this Agreement and thereafter during any applicable records retention period(s) under Section 9.3, Approved Representatives shall have the right, upon a prior written consent of , not to be unreasonably withheld or delayed, to audit and inspect those portions of the Facility (or the facility of a Material Third Party Supplier or Subcontractor, as the case may be) used in, and those documents and records related to, the manufacture, generation, storage, testing, treatment, holding, transportation, distribution or other handling or receiving of the API and Third Party Materials. Such audits may be conducted [\*\*\*] each [\*\*\*]; provided, however, that may conduct additional “for cause” audits during a [\*\*\*] to the extent supplies Nonconforming API or in the event of Product complaints or Adverse Events caused by Nonconforming API. may redact from such deliveries to any Third Party confidential information or Confidential Information. During such inspections, Approved Representatives shall have the right to audit and inspect all inventory of API and Third Party Materials contained at the Facility (or the facility of a Material Third Party Supplier or Subcontractor, as the case may be). agrees to reasonably cooperate and assist (and to require any Material Third Party Supplier or Subcontractor to cooperate and assist ) in connection with any audits or inspections pursuant to this Section 9.2. Audits or inspections under this Section 9.2 shall occur during business hours and shall be scheduled by Approved Representatives at least [\*\*\*] in advance; provided, however, that, in the event of an Adverse Event or any proposed or actual inspection by the FDA or other Governmental Body (whether of or a Material Third Party Supplier or Subcontractor) or other similar event or emergency involving any API or Third Party Materials, Approved Representatives shall have the right at any time, upon written notice to (or any Material Third Party Supplier or Subcontractor) of [\*\*\*], to conduct an audit or inspection of those affected portions of the Facility (or the facility of such Material Third Party Supplier or Subcontractor, as the case may be) used in the manufacture, generation, storage, testing, treatment, holding, transportation, distribution or other handling or receiving of API and Third Party Materials. shall ensure that Approved Representatives have access to Material Third Party Supplier’s and Subcontractor’s facilities in the manner set forth in this Section 9.2. shall as soon as practicable take any corrective action reasonably requested by in connection with this Section 9.2.

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9.3 Record Retention. Each Party shall maintain, in accordance with and for the period required under the applicable Drug Application, cGMPs and Legal Requirements, complete and adequate records pertaining to all activities in connection with, and facilities used for, the manufacture, generation, storage, testing, treatment, holding, transportation, distribution or other handling or receiving of the API, Third Party Materials and Product.

9.4 Confidential Information. Notwithstanding anything to the contrary contained in this Agreement, may redact or limit from any deliveries of or access to data, reports or any other information any Third Party confidential information or Confidential Information, at ’s sole discretion; provided, however, that may not redact or limit any Confidential Information that is reasonably necessary for to comply with all Legal Requirements. In this regard, the Parties agree that all process information related to the manufacture of API, whether contained in a DMF or otherwise, shall, subject to Section 13.4, constitute Confidential Information and shall not be disclosed to under any circumstances, notwithstanding anything herein to the contrary; provided, however, shall provide the relevant Governmental Body with all information necessary to support ’s Drug Application filings in a timely manner. Furthermore, for the avoidance of doubt, all information provided to under this Article IX is, subject to Section 13.4, Confidential Information and nothing in this Article IX shall be construed as giving any right to use or disclose (A) any Intellectual Property (except as may be permitted by any express license from ), or (B) any Confidential Information (except as may be permitted under Article XIII hereof).

Article X

Representations and Warranties

10.1 Representations and Warranties of . represents and warrants that:

(a) Compliance. The manufacture, generation, processing, distribution, transport, treatment, storage, disposal and other handling of any Third Party Materials and API by shall be in accordance with and conform to the API Specifications, cGMPs, ICH guidelines, all Legal Requirements, this Agreement and the Quality Agreement. The API shall comply with the applicable Drug Applications, cGMPs, API Specifications, ICH guidelines and Legal Requirements; shall be free from defects in materials and workmanship; and shall not be adulterated or misbranded within the meaning of applicable Legal Requirements.

(b) Status; Enforceability. is a validly existing corporation in good standing under the laws of the jurisdiction of its incorporation; the execution, delivery and performance of this Agreement by has been duly authorized by all requisite corporate action; this Agreement constitutes a legal, valid and binding obligation of , enforceable against in accordance with the terms hereof; and the execution, delivery and performance of this Agreement by will not violate or conflict with any other agreement or instrument to which is a party.

(c) Certain Persons. has not used, and will not use, in any capacity associated with or related to the manufacture of the API, the services of any Persons who have been, or are in the process of being, (i) debarred under 21 U.S.C. § 335a(a) or (b) or any comparable Legal Requirements, or (ii) excluded from participation in the Medicare program, any state Medicaid program or any other health care program. Furthermore, neither nor any of its officers, employees or consultants has been convicted of an offense under

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(x) either a federal or state law that is cited in 21 U.S.C. § 335(a) as a ground for debarment, denial of approval or suspension, (y) any other law cited in any comparable Legal Requirements as a ground for debarment, denial of approval or suspension. shall notify immediately upon learning of any circumstance that would cause this certification under this Section 10.1(c) to become false or inaccurate.

(d) Regulatory Consents. has or will have all Consents necessary to timely perform its obligations hereunder and to manufacture the API used in Product for commercial sale.

(e) Maintenance of Facility. During the Term of this Agreement, shall maintain the Facility, required local licenses, the equipment used to manufacture the API, Intellectual Property and any applicable contracts necessary to manufacture the API in accordance with the API Specifications, Legal Requirements, cGMPs, the Quality Agreement and ’s standard operating procedures.

(f) Negative Pledge. The transfer of the API by to is and shall be rightful and free and clear of any liens or encumbrances.

(g) Security Measures. shall maintain reasonable security policies at the Facility and shall use commercially reasonable efforts to have security measures in place to protect the integrity of the API, Third Party Materials, data and works-in-process at the Facility.

(h) Non-Infringement. To ’s best knowledge, ’s performance of its obligations under this Agreement will not infringe upon, nor cause ’s use of the API to infringe upon, the Intellectual Property rights of any Third Party.

10.2 Representations and Warranties of . represents and warrants that:

(a) Status; Enforceability. is a validly existing corporation in good standing under the laws of the jurisdiction of its incorporation; the execution, delivery and performance of this Agreement by has been duly authorized by all requisite corporate action; this Agreement constitutes the legal, valid and binding obligation of , enforceable against in accordance with the terms hereof; and the execution, delivery and performance of this Agreement by will not violate or conflict with any other agreement or instrument to which is a party.

(b) Certain Persons. has not used, and will not use, in any capacity associated with or related to the Product, the services of any Persons who have been, or are in the process of being, (i) debarred under 21 U.S.C. § 335a(a) or (b) or any comparable Legal Requirements, or (ii) excluded from participation in the Medicare program, any state Medicaid program or any other health care program. Furthermore, neither nor any of its officers, employees or consultants has been convicted of an offense under (x) either a federal or state law that is cited in 21 U.S.C. § 335(a) as a ground for debarment, denial of approval or suspension, (y) any other law cited in any comparable Legal Requirements as a ground for debarment, denial of approval or suspension. shall notify immediately upon learning of any circumstance that would cause this certification under this Section 10.2(b) to become false or inaccurate.

(c) Regulatory Consents. has all Consents necessary to perform its obligations hereunder and will, prior to commercial sale of Product, have all Consents necessary for the commercial sale of Product once Product is approved by FDA or any other Governmental Body.

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(d) Non-infringement. To ’s best knowledge, ’s commercial sale of Product will not infringe upon the Intellectual Property rights of any Third Party.

10.3 Disclaimer. OTHER THAN AS EXPRESSLY PROVIDED FOR IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTIES, EITHER EXPRESS OR IMPLIED, AND THE PARTIES EXPRESSLY DISCLAIM ALL IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE AND NONINFRINGEMENT.

Article XI

Liability and Indemnification

11.1 Indemnity by . shall defend, indemnify and hold harmless and ’s Affiliates and licensees and distributors and its and their respective directors, officers, employees and agents from and against all Losses to the extent arising out of or resulting from (a) any breach, nonperformance or failure to comply with any of ’s covenants, agreements, obligations, representations or warranties under this Agreement or the terms of this Agreement; or (b) negligence, recklessness, gross negligence or wrongful intentional acts or omissions by, or strict liability of, or Affiliates, their respective directors, officers, employees, agents or Subcontractors.

11.2 Indemnity by . shall defend, indemnify and hold harmless and ’s Affiliates and its and their respective directors, officers, employees and agents from and against all Losses to the extent arising out of or resulting from (a) any breach, nonperformance or failure to comply with any of ’s covenants, agreements, obligations, representations or warranties under this Agreement or the terms of this Agreement; or (b) negligence, recklessness, gross negligence or wrongful intentional acts or omissions by, or strict liability of, or Affiliates, their respective directors, officers, employees, agents or contractors.

11.3 Procedures. Any person that may be entitled to indemnification under this Agreement (an “Indemnified Party”) shall give written notice to the Person obligated to indemnify it (an “Indemnifying Party”) with reasonable promptness upon becoming aware of any claim or other facts upon which a claim for indemnification will be based. The notice shall set forth such information with respect thereto as is then reasonably available to the Indemnified Party. The Indemnifying Party shall have the right to undertake the defense of any such claim with counsel reasonably satisfactory to the Indemnified Party, and the Indemnified Party shall cooperate in such defense and make available all records, materials and witnesses reasonably requested by the Indemnifying Party at the Indemnifying Party’s expense. If the Indemnifying Party shall have assumed the defense of the claim with counsel reasonably satisfactory to the Indemnified Party, the Indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by the Indemnified Party in connection with the defense thereof. The Indemnifying Party shall not be liable for any claim settled without its Consent, which Consent shall not be unreasonably withheld. The Indemnifying Party shall obtain the written Consent of the Indemnified Party, which shall not be unreasonably withheld, prior to ceasing to defend, settling or otherwise disposing of any claim if, as a result thereof, the Indemnified Party would become subject to injunctive or other equitable relief or if the Indemnified Party may reasonably object to such disposition of such claim based on a continuing adverse effect on the Indemnified Party.

11.4 Special Indemnity. In the event this Agreement is terminated by pursuant to Section 15.5(a), shall pay to the amount of [\*\*\*], which shall be ’s sole and exclusive remedy with respect thereto, and in the event this Agreement is terminated by pursuant to Section 15.5(g), shall pay to the amount of [\*\*\*], which shall be ’s sole and exclusive remedy with respect thereto.

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11.5 Limitation of Liability. Subject to Section 11.6, in no event, regardless of the form of the claim or cause of action, whether based on contract, warranty, infringement, tort, strict liability or otherwise, shall a Party’s cumulative liability for claims under or relating to this Agreement, including, but not limited to, liquidated damages for delay in delivery or Nonconformity, exceed the aggregate amount of [\*\*\*].

11.6 No Special Damages. Notwithstanding anything to the contrary contained herein, except for breaches of confidentiality obligations, the Parties shall not be liable to each other for any special, indirect, incidental or consequential damages (including for lost profits).

Article XII

Insurance

12.1 Coverage Requirements. Each Party shall maintain in full force and effect beginning no later than [\*\*\*] and during the remaining Term of this Agreement and for a period of [\*\*\*] after expiration or termination of this Agreement, worker’s compensation, property, general liability and product liability insurance coverage in such amounts and with such scope of coverages as are adequate to cover such Party’s obligations under this Agreement and as are customary in the industry for companies of like size and activities and taking into account the nature of the API to be manufactured under this Agreement and the Product. Without limiting any of the foregoing, (a) each Party’s product liability insurance coverage limits shall be no less than [\*\*\*]; (b) ’s insurance shall include coverage for [\*\*\*]; and (c) ’s policy(ies) shall include [\*\*\*]. Each Party shall provide evidence of such insurance to the other Party and ensure that the other Party will receive no less than [\*\*\*] notice of any cancellation, non-renewal or material change in the policy(ies).

Article XIII

Confidentiality

13.1 Definition of “ Confidential Information”. As used herein, the term “ Confidential Information” shall mean all confidential business and technical communications, documents and other information, in each case not constituting Confidential Information, Intellectual Property or data, whether in written, oral or other form, which or an Affiliate furnishes or discloses to or which otherwise learns in connection with the negotiation or performance of this Agreement (whether relating to , an Affiliate or any Third Party for which has an obligation of confidentiality), including the API Specifications and the terms of this Agreement and any information disclosed by prior to the Effective Date.

13.2 Definition of “ Confidential Information”. As used herein, the term “ Confidential Information” shall mean (a) all confidential business information, and (b) technical communications, documents or other information, in each case not constituting Confidential Information, Intellectual Property or data, whether in written, oral or other form, of or a Affiliate that are disclosed to by or a Affiliate or otherwise learns in connection with the negotiation or performance of this Agreement (whether relating to , a Affiliate or any Third Party for which has an obligation of confidentiality), including the terms of this Agreement and any information disclosed by prior to the Effective Date. The fact that a Party is required by a provision of this Agreement to disclose certain information to the other Party shall not have any effect regarding whether such information is Confidential Information or Confidential Information, as the case may be, and all use

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and disclosure of such Confidential Information is subject to this Article XIII. In responding to such a required disclosure, a Party may redact information relating to Third Parties from any documents deliverable to the other Party that are not relevant to the subject matter of this Agreement.

13.3 Treatment of Confidential Information. Both during the Term of this Agreement and thereafter, Confidential Information and Confidential Information (collectively for this Section 13.3 “Confidential Information”) shall be treated in accordance with the requirements of this Article XIII.

(a) Nondisclosure and Non-Use. A Party receiving Confidential Information of the other Party shall (i) maintain in confidence such Confidential Information to the same extent such Party maintains its own proprietary information of similar kind and value (but at a minimum each Party shall use commercially reasonable efforts to maintain Confidential Information in confidence); (ii) not disclose such Confidential Information to any Third Party without prior written Consent of the disclosing Party, except, in the case of , for disclosures to ’s licensees and commercial partners for the Product who agree to be bound by obligations of non-disclosure and non-use at least as stringent as those contained in this Article XIII; and (iii) not use such Confidential Information for any purpose except those purposes permitted by this Agreement.

(b) Exceptions. Notwithstanding any other provision of this Agreement, the receiving Party may disclose Confidential Information of the disclosing Party to a Third Party: (i) to the extent and to the Persons as required by an applicable Legal Requirements, legal process or court order, or an applicable disclosure requirement of any Governmental Body, the U.S. Securities and Exchange Commission, the Nasdaq market or any other securities exchange or market; or (ii) to the extent necessary to exercise the rights granted to the receiving Party under this Agreement in filing or prosecuting patent applications, prosecuting or defending litigation or otherwise establishing rights or enforcing obligations under this Agreement, or conducting clinical trials or seeking regulatory approval of the Product; provided, however, that the receiving Party shall first have given prompt notice to the disclosing Party to enable the disclosing Party to seek any available exemptions from or limitations on any applicable disclosure requirement and shall reasonably cooperate in such efforts by the disclosing Party. shall reasonably cooperate with in providing prospective commercial partners with access to the Facility during normal business hours and allowing the prospective partners to perform reasonable due diligence related to the manufacture and supply of API hereunder to the extent such access to the Facility or information does not interfere with the daily operation of ’s business, and subject to ’s right to deny access to or disclosure of Confidential Information at ’s sole and absolute discretion. Notwithstanding, the Parties agree that all process information related to the manufacture of API, whether contained in a DMF or otherwise, shall, subject to Section 13.4, constitute Confidential Information and shall not be disclosed to or any prospective commercial partners under any circumstances.

(c) Terms of Agreement. The Parties agree that the existence of and the material terms of this Agreement shall be considered Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth below in this Section 13.3(c) (in lieu of the authorized disclosure provisions set forth in Section 13.3(b), to the extent of any conflict) and without limiting the generality of the definition of Confidential Information set forth in Sections 13.1 and 13.2. If either Party desires to make a public announcement concerning this Agreement or the terms hereof, such Party shall give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and approval. A Party shall not be required to seek the permission of the other Party to repeat any information as to the existence

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and terms of this Agreement that has already been publicly disclosed by such Party in accordance with the foregoing or by the other Party. Either Party may disclose the terms of this Agreement to such Party’s existing investors, directors and professional advisors and to potential investors, acquirors or merger partners and their professional advisors who are bound by written or professional obligations of non disclosure and non-use that are at least as stringent as those contained in this Article XIII or are customary for such purpose. acknowledges that or its Affiliates may be obligated to file a copy of this Agreement with the U.S. Securities and Exchange Commission with its next quarterly report on Form 10-Q, annual report on Form 10-K or current report on Form 8-K or with any registration statement filed with the U.S. Securities and Exchange Commission pursuant to the Securities Act of 1933, as amended, and shall be entitled to make such filings.

13.4 Excluded Information. Notwithstanding any provision herein to the contrary, the requirements of this Article XIII shall not apply to any information of either Party which:

(a) at the time of disclosure hereunder is generally available to the public;

(b) after disclosure hereunder becomes generally available to the public, except through breach of this Article XIII by the receiving Party or its Affiliates;

(c) was not acquired directly or indirectly from the disclosing Party or its Affiliates and which the receiving Party lawfully had in its possession prior to disclosure by the disclosing Party without confidentiality, nondisclosure and non-use obligations;

(d) is independently developed by employees or agents of the receiving Party without the use of the Confidential Information of the disclosing Party; or

(e) becomes available to the receiving Party from a Third Party that is not legally prohibited from disclosing such Confidential Information, provided such information was not acquired by such Third Party directly or indirectly from the disclosing Party or its Affiliates.

13.5 Return of Confidential Information. At any time upon the request of the other Party, to the extent such Confidential Information is not reasonably necessary to enable a Party to perform its obligations under this Agreement, or upon expiration or termination of this Agreement, the Party receiving Confidential Information will cease its use and, upon request, within thirty (30) days either return or destroy (and certify as to such destruction) all Confidential Information of the other Party, including any copies or other embodiments thereof, except that the receiving Party may retain a copy for archive purposes. The return and/or destruction of such Confidential Information as provided above shall not relieve the receiving Party of its other obligations under this Article XIII.

13.6 Redaction of Confidential Information. Notwithstanding ’s right to redact or limit Confidential Information from deliveries of or access to data, reports or any other information, may not redact or limit any Confidential Information that is reasonably necessary for to comply with all Legal Requirements. In this regard, the Parties agree that all process information related to the manufacture of API, whether contained in a DMF or otherwise, shall, subject to Section 13.4, constitute Confidential Information and shall not be disclosed to under any circumstances, notwithstanding anything herein to the contrary; provided, however, shall provide any relevant Governmental Body with all information necessary to support ’s Drug Application filings in a timely manner. Furthermore, for the avoidance of doubt, subject to Section 13.4, all information provided to under this Agreement is Confidential Information and nothing in this Agreement shall be construed as giving any right to use or disclose (A) any Intellectual Property (except as may be permitted by any express license from ), or (B) any Confidential Information (except as may be expressly permitted under this Agreement).

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Article XIV

Force Majeure Event

14.1 General. Except for any obligation to pay money, neither Party shall be held liable or responsible to the other Party nor be deemed to be in default under, or in breach of any provision of, this Agreement for failure or delay in fulfilling or performing any obligation of this Agreement when such failure or delay is due to a Force Majeure Event, and without the fault or negligence of the Party so failing or delaying. For purposes of this Agreement, a “Force Majeure Event” is defined as: acts of God; war; civil commotion; destruction of production facilities or materials by fire, flood, earthquake, explosion or storm; labor disturbances; epidemic; failure of public utilities and similar events which are beyond the reasonable control of the Party affected. In the event of a Force Majeure Event, or , as the case may be, shall immediately notify the other Party of such inability and of the period for which such inability is expected to continue. The Party giving such notice shall thereupon be excused from such of its obligations under this Agreement as it is thereby disabled from performing for so long as it is so disabled. To the extent possible, each Party shall use reasonable efforts to minimize the duration of any Force Majeure Event.

14.2 Termination Due to Event of Force Majeure; Transition. If, as a result of the conditions referred to in Section 14.1, a Party is unable to fully perform its obligations for a period of [\*\*\*], the other Party shall have the right to terminate this Agreement upon [\*\*\*] prior notice to the non-performing Party.

Article XV

Term; Termination; Remedies

15.1 Term. This Agreement shall commence on the Effective Date and, unless earlier terminated by either Party in accordance with this Article XV, will continue until the seventh (7 ) anniversary of the approval of the

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Drug Application by the FDA (the “Initial Term”) and shall renew automatically for successive five (5) year renewal terms unless either Party notifies the other Party of its intent to not renew by providing written notice to the other Party no less than two (2) years prior to the expiration of the Initial Term or applicable renewal term. The Initial Term together with any renewal term(s) is the “Term.”

15.2 Termination for Breach. This Agreement may be terminated by either Party in the event of the material breach by the other Party of the terms and conditions hereof; provided, however, the other Party shall first give to the breaching Party written notice of the proposed termination or cancellation of this Agreement, specifying the grounds therefor. Upon receipt of such notice, the breaching Party shall have sixty (60) days to respond by curing such breach. If the breaching Party does not cure such breach within such cure period, then (a) if is the breaching Party, (i) shall have the right to terminate this Agreement and (ii) shall have the remedies set forth in Section 15.6; or (b) if is the breaching Party, shall (i) have the right to terminate this Agreement and (ii) shall have the remedies set forth in Section 15.8.

15.3 Insolvency; Bankruptcy. To the extent permitted by Legal Requirements, each Party will have the right to terminate this Agreement immediately upon notice to the other Party, if any of the following occurs: (a) such other Party is declared bankrupt or insolvent, (b) such other Party generally fails to pay its debts as they become due, (c) there is an assignment for the benefit of such other Party’s creditors, (d) a receiver is appointed or there is a voluntary or involuntary petition filed or an action or proceeding commenced for bankruptcy, reorganization, dissolution or winding up of such other Party that is not dismissed within sixty (60) days, or (e) there is a foreclosure or sale of a material part of such other Party’s assets by or for the benefit of any creditor or governmental agency.

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15.4 Discontinuance or Suspension of Product Program. may terminate this Agreement upon thirty (30) days’ written notice to if , in its sole and absolute discretion, discontinues or indefinitely suspends the development and/or commercialization of the Product. Upon the termination of this Agreement pursuant to this Section 15.4, ’s sole obligation shall be for it to reimburse for all documented direct costs and expenses properly and reasonably incurred by pursuant to this Agreement up to the effective date of such termination in connection with ’s then-outstanding obligation to purchase quantities of API forecasted with respect to the binding portion of an applicable [\*\*\*] Forecast; provided, however, that shall use commercially reasonable efforts to mitigate such costs and expenses by cancelling any cancelable orders for Third Party Materials, returning returnable Third Party Materials, and/or using non-returnable Third Party Materials for its own or its other customers’ behalf. For avoidance of doubt, if terminates this Agreement pursuant to this Section 15.4, shall be obligated to purchase the quantities set forth in any Purchase Orders and quantities set forth in any binding portion of a [\*\*\*] Forecast, but not obligated to purchase any minimum purchase requirements set forth in Section 2.2.

15.5 Termination by . Without limiting any other Section of this Article XV, may terminate this Agreement upon thirty (30) days’ written notice to upon the occurrence of any of the following:

(a) Failure to Validate Manufacturing Process. fails to complete the Validation of the Initial Manufacturing Process on or before the Expansion completion date set forth in Section 4.1.

(b) Failure to Achieve Acceptance of Pre-Approval Inspection. (i) receives at any time correspondence from FDA indicating that the Facility or facility of a Third Party Supplier is not approved for the manufacture of API, or (ii) fails to obtain official correspondence from FDA stating that the Facility has been approved for the manufacture of API on or before the [\*\*\*] after the first FDA inspection of the Facility relating to the Expansion.

(c) Failure to Supply Unrelated to Force Majeure. In the event of the continued failure of to deliver API to , shall have the right to terminate this Agreement upon thirty (30) days’ prior written notice to . “Continued” for purposes of determining a continued failure to supply shall be a failure to deliver at least [\*\*\*] of the API required to be delivered over a [\*\*\*] period.

(d) Supply of Nonconforming API. delivers Nonconforming API pursuant to [\*\*\*] or more Purchase Orders in any [\*\*\*] period.

(e) Late Shipment. ships API pursuant to [\*\*\*] or more Purchase Orders after the applicable Shipment Date during any [\*\*\*] period.

(f) Failure to Obtain or Maintain Consents. fails to obtain, maintain and comply with all Consents required for the performance of its obligations under this Agreement.

(g) Failure to Ship Commercial Batches. fails to deliver [\*\*\*] batches of API (each batch being [\*\*\*]) to ’s carrier by the Shipment Date(s) specified in the relevant Purchase Order(s), which Shipment Date(s) shall be within [\*\*\*] from the completion date of the Expansion.

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15.6 Effect of Termination by . In the event terminates this Agreement pursuant to Sections 14.2, 15.2, 15.3 or 15.5, (a) shall have the right to terminate, in whole or in part, any Purchase Order issued under this Agreement; (b) shall be relieved of its requirement to purchase quantities of API associated with any binding portion of a [\*\*\*] Forecast; and (c) shall be relieved of its the minimum purchase requirements set forth in Section 2.2.

15.7 Termination by . Without limiting any other Section of this Article XV, may terminate this Agreement upon thirty (30) days’ written notice to upon the occurrence of any of the following:

(a) Failure to Obtain Approval of the Drug Application. ’s failure to obtain approval of the Drug Application for the Product from the FDA by [\*\*\*].

(b) Failure to Place Purchase Orders. ’s failure to place Purchase Orders within [\*\*\*] of the date on which the Approvals are obtained.

(c) Failure to Accept API Unrelated to a Force Majeure Event. ’s continued failure to accept conforming API delivered by unrelated to a Force Majeure Event. “Continued” for purposes of determining a continued failure to accept conforming API shall be a failure to accept at least [\*\*\*] of the API delivered over a [\*\*\*] period.

(d) Failure to Pay. ’s failure to pay invoiced amounts for conforming API (that is not subject to an active investigation of Nonconformity or otherwise disputed in good faith by ) within [\*\*\*] from the applicable due dates for [\*\*\*] consecutive Purchase Orders.

(e) Failure to Order Minimum Quantities. ’s failure to order the relevant minimum annual quantities of API for [\*\*\*] consecutive [\*\*\*]. For purposes of determining the quantities ordered by , (i) all quantities subject to Purchase Orders placed in such Calendar Year, (ii) all quantities of Validation batches of API purchased pursuant to Section 5.4(a) in such Calendar Year, (iii) all quantities ordered from a Secondary Supplier due to ’s failure to supply API hereunder in such Calendar Year and (iv) all quantities ordered from a Secondary Supplier due to a Force Majeure Event in such Calendar Year shall be included in such determination.

15.8 Effect of Termination by . In the event terminates this Agreement pursuant to Sections 14.2, 15.2, 15.3 or 15.7, (a) may, upon [\*\*\*] written notice, require to [\*\*\*] and (b) shall, otherwise, be relieved of any of its obligations to supply any quantities of API under this Agreement.

15.9 Termination of Related Agreement. This Agreement may be terminated by either Party upon written notice to the other Party (notwithstanding the 30-day notice requirement described above) upon the termination of that certain agreement entered into between the Parties on the date of this Agreement related to ’s investment.

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Article XVI

Miscellaneous

16.1 Notices. In addition to the other specific procedures for notification provided herein, all notices, demands, requests and other communications made hereunder shall be in writing and shall be given either by personal delivery, by facsimile or by internationally recognized overnight courier (with charges prepaid) and shall be deemed to have been given or made: (a) if personally delivered, on the day of such delivery; (b) if sent by facsimile, on the day it is sent or, if not sent on a business day, the next business day; or (c) if sent by overnight courier, on the business day following the date deposited with such overnight courier service, in each case pending the designation of another address, addressed as follows:

16.2 Independent Contractors. Each Party shall be treated as an independent contractor of the other. Neither Party shall be deemed to be a co-venturer, partner, employee or a legal representative of the other Party for any purpose. Neither Party shall have the authority to enter into any contracts in the name of or on behalf of the other Party or incur any charges or expenses for or in the name of the other Party.

16.3 Entire Understanding. The Parties agree, on their own and their respective Affiliates’ behalf, that this Agreement, including Schedules hereto, and any other document identified herein, constitutes the entire agreement between the Parties and their Affiliates relating to the subject matter hereof, and all prior agreements or arrangements, written or oral, between the Parties and their Affiliates relating to the subject matter hereof are hereby superseded and merged with this Agreement.

16.4 Assignment. This Agreement will be binding upon and inure to the benefit of the Parties, their successors and permitted assigns. Neither Party shall delegate, transfer, convey, assign or pledge this Agreement, in whole or in part, or any of its rights or obligations under this Agreement, without the prior written Consent of the other Party in each instance, and any such action without Consent shall be void and have no effect. However, notwithstanding the foregoing, a Change of Control of either Party shall not be deemed to be an assignment of this Agreement and shall not be subject to the other Party’s Consent.

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16.5 Dispute Resolution. If the Parties fail to resolve any claim, dispute or controversy of whatever nature arising out of or relating to this Agreement (other than one relating to the validity, enforceability, infringement or misappropriation of Intellectual Property rights, which shall not be subject to this Section 16.5), the Parties shall refer the dispute, to their respective officers designated below or such other officers as the Parties may designate in writing from time to time, for attempted resolution by good faith negotiations within [\*\*\*] after so submitting the dispute. The designated officers are as follows:

If such dispute is not resolved by the end of the [\*\*\*] period, then either Party shall be entitled to refer the matter to be finally settled by arbitration to be held in accordance with the then-current Rules of Arbitration and Conciliation of the International Chamber of Commerce by three (3) arbitrators to be appointed in accordance with the said Rules. The Parties agree that any such unresolved dispute, and any claim or dispute related to the validity of this arbitration clause, may be resolved solely by binding arbitration under this Section 16.5. The arbitration shall take place in London, England if the claim giving rise to such arbitration is brought by and the arbitration shall take place in Singapore if the claim giving rise to such arbitration is brought by . In each case, the proceedings shall be conducted and all documentation shall be presented in the English language. The award of the arbitrators shall be final and without appeal. Any competent court shall be able to order enforcement of the award. Each Party will bear its own attorneys’ fees and other costs and expenses incurred pursuant to this Section 16.5. For avoidance of doubt, the foregoing shall not prohibit or delay a Party from seeking appropriate injunctive or other equitable relief.

16.6 Subcontractors. may utilize Subcontractors with appropriate expertise and experience in the performance of its obligations under this Agreement; provided, however, that must give its written Consent in each instance prior to the use of Subcontractors by (such Consent not to be unreasonably withheld or delayed). Nothing in this Section 16.6 shall relieve from any obligation under this Agreement.

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16.7 Amendment. This Agreement, including any Schedule hereto, may not be amended or modified in any manner except by an instrument in writing signed by a duly authorized officer of each Party.

16.8 Severability. If and to the extent that any court of competent jurisdiction holds any provision (or any part thereof) of this Agreement to be invalid or unenforceable, such holding shall in no way affect the validity or enforceability of the remainder of this Agreement, and the invalid or unenforceable provision shall be fully severed from this Agreement, and there shall automatically be added in lieu thereof a provision as similar in

terms and intent to such severed provision as may be legal, valid and enforceable.

16.9 Waiver. Any failure of a Party to comply with any obligation, covenant, agreement or condition herein contained may be expressly waived, in writing only, by the other Party hereto, and such waiver shall be effective only in the specific instance and for the specific purpose for which made or given.

16.10 Survival. Articles I (to the extent required to enforce other surviving rights or obligations), VIII, IX, X, XI, XII, XIII, XV, XVI and Sections 6.1(b), 6.3, 6.4, 6.5, 6.6, 6.7, 6.8, 6.9, 7.5, 7.7, and 7.9, and any other provision which by its terms specifically shall so state, together with any obligations accrued hereunder at the time of termination or expiration, shall survive the termination or expiration of this Agreement.

16.11 Drafting Ambiguities. Each Party to this Agreement and its counsel have reviewed and revised this Agreement. The rule of construction to the effect that any ambiguities are to be resolved against the drafting Party shall not be employed in the interpretation of this Agreement or any amendment or Schedules hereto.

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16.12 Headings; Schedules; Counterparts.

(a) Headings. The headings of the Sections of this Agreement are for reference purposes only, are not part of this Agreement and shall not in any way affect the meaning or interpretation of this Agreement.

(b) Schedules. All Schedules and Exhibits delivered pursuant to this Agreement shall be deemed part of this Agreement and incorporated herein by reference as if fully set forth herein. In the event that any Schedule conflicts with any of the terms or provisions of this Agreement, the terms and provisions of this Agreement shall prevail.

(c) Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original but all of which together shall constitute one and the same instrument. Facsimile signatures shall be treated as original signatures.

16.13 Governing Law. This Agreement and all matters arising out of or relating to this Agreement shall be governed, construed and enforced in accordance with the laws of the State of New York, USA, without regard to principles of conflicts of law. The Parties agree that the provisions of the United Nations Convention on Contracts for the International Sale of Goods shall not apply.

16.14 Remedies. Unless otherwise expressly provided in this Agreement, none of the remedies set forth in this Agreement are intended to be exclusive, and each Party shall have available to it all remedies available under law or in equity or in any other agreement between the Parties.

16.15 Injunctive Relief. In the event that either or breaches or threatens to breach any provision of Article VIII or Article XIII of this Agreement, the Parties agree that irreparable harm to the other Party should be presumed, and the damages to such Party would probably be very difficult to ascertain and would be inadequate. Accordingly, in the event of such circumstances, each of and agree that, in addition to any other right and remedies available at law or in equity, the other Party shall have the right to seek injunctive relief from any court of competent jurisdiction.

16.16 Standard Forms. In all communications, and may employ their standard forms, but nothing in those forms shall be construed to be in addition to or modify or amend the terms and conditions of this Agreement, and, in the case of any conflict herewith, the terms and conditions of this Agreement shall control.

16.17 Further Assurances. Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

16.18 Counterparts. This Agreement may be executed in two counterparts and by facsimile or PDF signature, each of which shall be deemed an original and which together shall constitute one instrument.

16.19 English Language. The English language version of this Agreement will be controlling on the Parties. All information, documents, reports, notices, writings and communications to be provided by one Party to the other Party hereunder will be provided in the English language.

***[Remainder of page intentionally left blank.]***

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IN WITNESS WHEREOF, each of the Parties hereto has caused this Agreement to be duly executed as of the date first written above.

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**SCHEDULE 3.1**

**PRICING SCHEDULE Price Schedule**

**[\*\*\*]**

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**SCHEDULE 3.1(e)**

**API PRICE ADJUSTMENT [\*\*\*]**

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**SCHEDULE 4.1 EXPANSION PLANS [\*\*\*]**

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**SCHEDULE 4.5**

**SECOND EXPANSION PLANS [\*\*\*]**

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**SCHEDULE5.1**

**APISPECIFICATIONS**

**1**

**[\*\*\*]**

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[\*\*\*]

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**SCHEDULE 6.2**

**FORM OF CERTIFICATE OF ANALYSIS [\*\*\*]**

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