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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**

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

Date of Report (Date of earliest event reported): **February 1, 2013**

**Supernus Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
Incorporation)

**0-50440**

(Commission File Number)

**20-2590184**

(IRS Employer Identification No.)

**1550 East Gude Drive, Rockville MD**

(Address of principal executive offices)

**20850**

(Zip Code)

Registrant's telephone number, including area code: **(301) 838-2500**

**Not Applicable**

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 1.01 Entry into a Material Definitive Agreement**

Effective August 23, 2012, Supernus Pharmaceuticals, Inc. (“Supernus” or the “Company”) entered into a Commercial Supply Agreement with Patheon, Inc. (the “Agreement”) that defines each party’s responsibilities with respect to the manufacture, formulation, development and supply of commercial-grade quantities of oxcarbazepine, the active pharmaceutical ingredient required for the finished drug product, Oxtellar XR™ (the “Product”). The Company entered into the Agreement in anticipation of final approval by the U.S. Food and Drug Administration of the Product, which was received on October 19, 2012, and the commercial launch of the Product, which occurred on February 4, 2013.

Under the Agreement, the parties agreed that Patheon, Inc. will manufacture at its facility, in accordance with mutually agreed upon specifications and current good manufacturing practices, commercial quantities of the Product for the United States. Supernus will be responsible for providing, at no cost to Patheon, Inc., the active pharmaceutical ingredient and any other materials required in connection with the manufacture of the Product, and Patheon, Inc. will be responsible for the manufacture, including processing, packaging and labeling, of the Product in accordance with the specifications.

The foregoing description of this Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Agreement, a copy of which is attached hereto as Exhibit 10.1 and is incorporated herein by reference.

**Item 8.01 Other Events**

On February 1, 2013, Supernus issued a press release regarding the commercial launch of Oxtellar XR tablets in the US as a novel once-daily extended release antiepileptic drug indicated for adjunctive therapy in the treatment of partial seizures in adults and in children 6 to 17 years of age. The Company also announced that its sales force of approximately 75 sales representatives would start promoting the product on February 4, 2013. A copy of this press release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

The following documents are filed as Exhibits pursuant to Item 9.01 hereof:

Exhibit 10.1\* — Commercial Supply Agreement, dated August 23, 2012, by and among Patheon, Inc. and the Company.

Exhibit 99.1 — Press Release dated February 1, 2013 of the Company announcing the commercial launch of Oxtellar XR tablets in the US.

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\*Portions of this exhibit have been redacted and are subject to a confidential treatment request filed with the Secretary of the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities and Exchange Act of 1934, as amended.

**SIGNATURES**

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

SUPERNUS PHARMACEUTICALS, INC.

DATED: February 7, 2013

By: /s/ Gregory S. Patrick  
Gregory S. Patrick  
Vice-President and Chief Financial Officer

**EXHIBIT INDEX**

<b><u>Number</u></b>	<b><u>Description</u></b>	
10.1*	Commercial Supply Agreement, dated August 23, 2012, by and among Patheon, Inc. and the Company.	Attached
99.1	Press Release dated February 1, 2013.	Attached

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\*Portions of this exhibit have been redacted and are subject to a confidential treatment request filed with the Secretary of the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities and Exchange Act of 1934, as amended.

**CONFIDENTIAL MATERIALS OMITTED  
AND FILED SEPARATELY WITH THE  
SECURITIES AND EXCHANGE COMMISSION.  
ASTERISKS DENOTE OMISSIONS.**

**COMMERCIAL SUPPLY AGREEMENT**

This Commercial Supply Agreement, effective as of 8/23, 2012 (the "Effective Date"), is made by and between Patheon Inc., having its principal offices at 2100 Syntex Court, Mississauga, Ontario, L5N 7K9 Canada, (hereinafter "Supplier") and Supernus Pharmaceuticals, Inc., having its principal offices at 1550 East Gude Drive, Rockville, MD 20850 (hereinafter "Supernus") (each of Supplier and Supernus being a "Party" and collectively the "Parties").

Supernus is in the business of developing branded pharmaceutical products and desires to have Supplier manufacture certain of its commercial-grade products for Supernus' use. Supplier is engaged in the business of commercial manufacturing, formulating and developing pharmaceutical products in finished dosage form. The Parties wish to enter into this Agreement to have Supplier manufacture the Product according to the terms and conditions of this Agreement.

**NOW, THEREFORE**, in view of this foregoing premise and in consideration of the foregoing premises and in consideration of the mutual covenants set forth below, the Parties agree as follows:

1. **Definitions:** For the purposes of this Agreement, the following terms shall have the following respective meanings:
  - 1.1 "Acknowledgement" has the meaning set forth in Section 6.2.2.
  - 1.2 "Active Materials Credit Value" means the value of the API for certain purposes of this Agreement, as set forth on Schedule D.
  - 1.3 "Affiliate" means
    - 1.3.1 a business entity which owns, directly or indirectly, a controlling interest in a Party to this Agreement, by stock ownership or otherwise; or
    - 1.3.2 a business entity which is controlled by a Party to this Agreement, either directly or indirectly, by stock ownership or otherwise; or
    - 1.3.3 a business entity, the controlling interest of which is directly or indirectly common to the majority ownership of a Party to this Agreement;

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

- 1.4 "Agreement" has the meaning set forth in the introductory paragraph, and includes all its attachments, schedules and other appendices (all of which are incorporated herein by reference) and any amendments to any of the foregoing made as provided herein or therein.
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- 1.5 “Annual Quantity” means the minimum volume of Product to be manufactured in any Year of this Agreement as set forth in Schedule B.
- 1.6 “API” means Oxcarbazepine which is the active pharmaceutical ingredient required for the Product. The term “Active Materials” may be used interchangeably with the term “API” and shall have the same meaning.
- 1.7 “Applicable Law” means, in relation to any person, transaction or event, all relevant laws, statutes, regulations and orders of all governmental bodies having jurisdiction in the Territory (whether administrative, legislative, executive or otherwise), and all judgments, orders and decrees of all courts, arbitrators, commissions or bodies exercising similar functions having jurisdiction over the person, transaction or event in question.
- 1.8 “Bill Back Items” means the expenses for all third party supplier fees for the purchase of columns, standards, tooling, RFID tags (where applicable), and supporting equipment, and other project specific items necessary for Supplier to perform the Manufacturing Services, and which are not included as Materials.
- 1.9 “Business Day” means a day other than a Saturday, Sunday, or a day that is a statutory holiday in the Province of Ontario, Canada.
- 1.10 “cGMPs” means current good manufacturing practices as described in:
- 1.10.1 Division 2 of Part C of the Food and Drug Regulations (Canada); and
- 1.10.2 Parts 210 and 211 of Title 21 of the United States’ Code of Federal Regulations;
- together with any amendments thereto as may occur from time to time.
- 1.11 “CMC Section” means a dossier containing all Chemistry, Manufacturing and Controls documents in a form acceptable for filing with and approval by FDA and other Regulatory Authorities for inclusion by Supemus or its sub-licensees in their regulatory filings.
- 1.12 “Confidential Information” shall mean information of a confidential nature as described in the Confidentiality Agreement.
- 1.13 “Confidentiality Agreement” means the agreement about the non-disclosure of confidential information between Supplier and Supemus dated November 7, 2011.
- 1.14 “Delivery Date” has the meaning set forth in Section 6.2.2.
- 1.15 “DMF” means a Drug Master File as described in Chapter 21 of the United States Code of Federal Regulations, Section 314.420.

- 1.16 “Facility” shall mean Supplier’s facility located at 111 Consumers Drive, Whitby, Ontario, Canada, or such other Supplier facility as mutually agreed in writing by the Parties from time to time.
- 1.17 “FDA” means the United States Food and Drug Administration or any successor entity thereto.
- 1.18 “FDC Act” means the Federal Food, Drug and Cosmetic Act, USC Section 301, et seq., as amended from time to time, and the rules and regulations promulgated thereunder (including specifically, Title 21, parts 210 and 211 of the Code of Federal Regulations of the United States, as amended from time to time).
- 1.19 “Firm Commitment” has the meaning set forth in Section 6.2.1.
- 1.20 “Formulation” shall mean the approved formulation, manufacturing process and stability protocols, batch records and all other pertinent manufacturing information contained in the then-current Specifications.
- 1.21 “Initial Set Exchange Rate” means 1:1 as of the Effective Date of the Agreement being the initial exchange rate to convert one unit of Supplier facility local currency to one unit of the billing currency, calculated as the average interbank exchange rate for conversion of one unit of Supplier facility local currency to one unit of the billing currency during the 90 day period immediately preceding the Effective Date as published by OANDA.com “The Currency Site” under the heading “FxHistory: historical currency exchange rates” at [www.OANDA.com/convert/fxhistory](http://www.OANDA.com/convert/fxhistory).
- 1.22 “Intellectual Property” has the meaning set forth in Section 22.1.
- 1.23 “Inventory” means all inventories of Materials and work-in-process produced or held by Supplier for the manufacture of the Products but, for greater certainty, does not include the API.
- 1.24 “Late Delivery” has the meaning set forth in Section 7.4.2.
- 1.25 “Latent Defect” means any defect that was not, and could not be reasonably expected to have been found during physical or chemical acceptance testing such as, but not limited to, the presence of a contaminant introduced in a raw material, API or other component, during the Manufacturing or a party’s or supplier’s failure to comply with Applicable Laws. For the sake of clarity, the term “Defective Product” defined in Section 9.5.1 shall include Products that contain a Latent Defect.
- 1.26 “Launch Date” shall mean the first date of commercial Product launch in the Territory, which date Supernus shall document and confirm in writing to Supplier.

- 1.27 “Manufacturing” or “Manufacturing Services” means the activities relating to the manufacture of the Product in accordance with the Specifications, from the Materials, Bill Back Items, and API that are either supplied by Supplier or supplied or caused to be supplied to Supplier by Supernus or its subcontractors hereunder, spanning the sourcing, receipt, testing and/or storage of Materials, Bill Back Items, and API through the processing, manufacturing, packaging and labeling of the Product into finished Product form that is bulk finished product, ready for sale to consumers in finished, final packaged form, in addition to the quality control, quality assurance, any agreed stability testing and related services required to manufacture Product and set forth in this Agreement. The terms “manufacture” and “manufactured” refer to the act of manufacturing.
- 1.28 “Manufacturing Date” means the day on which the first batch record entry of Manufacturing is scheduled to occur, as identified in an Acknowledgement.
- 1.29 “Materials” shall mean raw materials, excipients, and all packaging materials (including, without limitation, containers, packaging and labeling) as the foregoing are required in connection with the manufacture of the Product, or set forth in the applicable Purchase Order, in accordance with the applicable Specifications; for greater certainty, the term “Materials” does not include API (or any other Supernus-Supplied Materials) or Bill Back Items.
- 1.30 “Minimum Ordering Quantity” means the minimum number of batches of a Product to be produced during the same cycle of manufacturing as set forth in Schedule B.
- 1.31 “OTIF” means On Time Delivery in Full.
- 1.32 “Oxcarbazepine” means (a) 10,11-Dihydro-10-oxo-5H dibenz[b,f]azepine-5- carboxamide; and (ii) any derivatives, isomers, salts, solvates, hydrates, or polymorphs, of the foregoing.
- 1.33 “PPI” means the Producer Price Index for pharmaceutical preparations (PCU2834) available on the U.S. Bureau of Labor Statistics website (<http://stats.bls.gov>).
- 1.34 “Price” means the price measured in U.S. dollars to be charged by Supplier for performing the Manufacturing Services, as initially set forth in Schedule B, with respect to the supply of Product, and as contemplated by Schedule C, with respect to the cost of any agreed annual stability testing, and includes certain cost items as specified in Schedule B as well as the cost of Materials.
- 1.35 “Product” means a finished drug product containing commercially available API manufactured in final finished dosage form and packaged by Supplier to meet cGMP requirements and Specifications as listed on Schedule A and for sale by Supernus or its sublicensees.

- 1.36 “Product Forecast” has the meaning set forth in Section 6.2.1.
- 1.37 “Purchase Order” means the written purchase orders delivered to Supplier by Supernus as Firm Commitments, which, upon acceptance by Supplier, are binding, and shall be substantially in the form of Schedule 6.2 attached hereto.
- 1.38 “Quality Agreement” means the commercial quality agreement attached hereto as Schedule F.
- 1.39 “Regulatory Approval” means all necessary approvals of the Regulatory Authority to manufacture the Product and to market, distribute and sell the Product.
- 1.40 “Regulatory Authority” means, in the United States, the FDA, and, in any other country, any agency or agencies having comparable authority.
- 1.41 “Regulatory Scheme” means any regulatory scheme applicable to the Products in any country, as such statutes, regulations, interpretations and guidelines or regulatory schemes that may be amended from time to time, including, without limitation, the statutes, regulations, interpretations, and guidelines administered by the FDA.
- 1.42 “Set Exchange Rate” means the exchange rate to convert one unit of Supplier Facility local currency to one unit of the billing currency for each Year, calculated as the average interbank exchange rate for conversion of one unit of Supplier Facility local currency to one unit of the billing currency during the full year period (October 1st [preceding year] to September 30th) preceding the Reset Date as published by OANDA.com “The Currency Site” under the heading “FxHistory: historical currency exchange rates” at [www.OANDA.com/convert/fxhistory](http://www.OANDA.com/convert/fxhistory).
- 1.43 Singular Terms.  
Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa.
- 1.44 “Specifications” means those protocols and standard operating procedures, including without limitation, formulations, processes, quality control, compression, labeling, packaging, finishing, storage and release requirements and/or procedures and all requisite analyses and tests conducted in connection with any of the foregoing, in each instance conforming to cGMP, utilized in the course of the manufacture of the Products as the same are specified, and mutually agreed to, in writing by Supernus and Supplier and to be amended from time to time in writing as an exhibit to the Quality Agreement and/or Purchase Order.
- 1.45 “Supernus-Supplied Materials” has the meaning set forth in Section 7.1.5.

- 1.46 “Term”, “Initial Term”, and “Renewal Term” have the meaning set forth in Section 5.1.
- 1.47 “Territory” means the geographic area of the United States, or such expanded geographic area which may be established by the Parties from time to time via written amendment to this Agreement.
- 1.48 “Third Party Rights” means the Intellectual Property of any third party.
- 1.49 “United States” shall mean the United States of America, its territories, possessions and the Commonwealth of Puerto Rico.
- 1.50 “Year” means in the first year of this Agreement the period from the Effective Date up to and including December 31 of the same calendar year and thereafter will mean a calendar year.

2. **Currency.**

Unless otherwise indicated, all monetary amounts are expressed in this Agreement in the lawful currency of the United States of America.

3. **Sections and Headings.**

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

4. **Schedules.**

The following Schedules are attached to, incorporated in, and form part of this Agreement:

- Schedule A - Product List and Specifications
- Schedule B - Minimum Ordering Quantity, Annual Quantity, and Price
- Schedule C - Annual Stability Testing
- Schedule D - API, Active Materials Credit Value, and Maximum Credit Value
- Schedule E - Technical Dispute Resolution
- Schedule F - Commercial Quality Agreement
- Schedule G - Form of Shipping Logistics Protocol
- Schedule H - Quarterly API Inventory Report
- Schedule I - Report of Annual API Inventory Reconciliation and Calculation of Actual Annual Yield
- Schedule J - Example of Price Adjustment due to Currency Fluctuation

Schedule K	-	Cycle Time Gantt Chart
Schedule 6.2	-	Form of Purchase Order
Schedule 7.6	-	Validation Services
Schedule 7.7	-	Costs Included & Excluded in Unit Price

5. **Term & Termination.**

5.1 **Term.** Unless earlier terminated as provided herein, the term of this Agreement shall commence on the Effective Date and shall expire \*\* years from the Launch Date (the “Initial Term”). On the \*\* anniversary of the Effective Date, Supemus and the Supplier shall conduct a review, following which the Parties, each within its sole discretion, will decide whether to extend this Agreement beyond the Initial Term and, if so, for how long and whether such extension will automatically renew (each such extension referred to as a “Renewal Term”). Provided the Parties have agreed to a Renewal Term that either is automatically renewing successively or is at least twenty four (24) months in duration, either Party may terminate this Agreement with effect after the Initial Term by providing, at any time, written notice indicating an effective date of termination that is after the Initial Term and not less than twenty four (24) months following the date of such termination notice. The Initial Term, in whole or part, and all Renewal Terms, shall be considered the “Term” of this Agreement.

5.2 **Termination.**

5.2.1 In the event either Party materially breaches the terms of this Agreement, the other Party may terminate this Agreement by giving the breaching Party written notice of election to terminate, effective no less than thirty (30) days from the date of such notice. In the case of material breaches related to monetary obligations, such obligations have to be undisputed and the time period shall be reduced to ten (10) days. If the other Party fails to cure such breach prior to the stated date of termination, this Agreement shall be terminated on such date, provided that, except for breaches related to monetary obligations, if the breaching Party is making continuous and diligent efforts to cure the breach, the thirty (30)-day cure period shall be extended for an additional period of not more than sixty (60) days.

5.2.2 Either Party may terminate this Agreement at any time upon written notice to the other Party in the event that such other Party makes an assignment for the benefit of its creditors, files an action or petition for relief under applicable bankruptcy or insolvency laws, has filed against it an involuntary petition to have it declared bankrupt in which it acquiesces or which is not dismissed within sixty (60) days from the date of such filing, or in the event of the appointment of a receiver for its business.

5.2.3 Supemus may terminate this Agreement at any time upon written notice to Supplier in the event:

(a) Supplier fails, except as a result of a force majeure event (within the meaning of Section 27.6), on \*\* or more occasions during any rolling \*\* period to make deliveries of Product within \*\* following the date on which such delivery is due in accordance with the Acknowledgement, which failure is not cured within a

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\*\* This portion has been redacted pursuant to a confidential treatment request.

period of fifteen (15) days after receipt of written notice of non-delivery from Supemus, and provided that, following the initial Late Delivery in such \*\* period, Supplier and Supemus shall have first discussed and agreed upon a remediation plan;

(b) the Product manufactured by Supplier hereunder is subject to a product recall on more than one occasion by reason of the failure of the Product to meet any of the Specifications, requirements of a Regulatory Authority or Regulatory Approval, or other requirements of law;

(c) Regulatory Approval for Supplier to manufacture the Product under the terms of this Agreement is revoked or withdrawn by the Regulatory Authority due to acts of commission or omission of or by Supplier and such Regulatory Approval has not been reinstated within sixty (60) days following notice of revocation or withdrawal;

(d) Supplier, without the direction or consent of Supemus, sells or otherwise diverts the Product to any person other than Supemus or a designee of Supemus, in United States of America (USA) or in other countries; or

(e) Supplier is unable or unwilling to supply all of the Purchase Orders for Product for which Supplier has issued an acceptance Acknowledgement in accordance with the provisions of Section 6 hereof for a period of greater than 90 days due to a force majeure condition described in Section 27.6 of this Agreement.

5.2.4 Supemus will give at least six months' advance notice if it intends to no longer order Manufacturing Services for a Product due to this Product's discontinuance in the market.

5.2.5 Notwithstanding any provision of this Agreement to the contrary, no competitor of Supplier will be permitted access to the Facility unless necessitated by Supemus' need to qualify an alternate supplier of the Product due to Supplier's actions under Section 5.2.3 or as part of a potential corporate merger or acquisition. Except as stated in the preceding sentence, no provision of this Agreement will preclude any sublicensee, partner, acquirer, consultant or agent of Supemus that is under applicable obligations of confidentiality from having reasonable access to the Facility.

5.2.6 Obligations on Termination.

If this Agreement is completed, expires, or is terminated in whole or in part for any reason, then:

- (a) Supemus will take delivery of and pay for all undelivered Product that are manufactured and/or packaged under a Purchase Order that has been or is tested and meets Specifications, at the Price in effect at the time the Purchase Order was placed;
- (b) Supemus will purchase, at Supplier's cost (including all costs incurred by Supplier for the purchase and handling of the Inventory), the Inventory applicable to the Products which was purchased, produced or maintained by Supplier in

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\*\* This portion has been redacted pursuant to a confidential treatment request.

contemplation of filling Purchase Orders or in accordance with Section 6.3 and that cannot be used otherwise by Supplier or its customers;

- (c) Supemus will satisfy the purchase price payable under Supplier's orders with suppliers of Materials if the orders were made by Supplier in reliance on Purchase Orders or in accordance with Section 6.3;
- (d) Supplier will return to Supemus all unused API (with shipping and related expenses, if any, to be borne by Supemus); and
- (e) Supemus will make commercially reasonable efforts, at its own expense, to remove from Supplier site(s), within forty-five (45) Business Days, all of Supemus' Inventory and Materials (whether current or obsolete), supplies, undelivered Product, chattels, equipment or other moveable property owned by Supemus, related to the Agreement and located at a Supplier site or that is otherwise under Supplier's care and control ("Supemus, Property"). If Supemus fails to remove the Supemus Property within forty-five (45) Business Days following the completion, termination, or expiration of the Agreement, Supemus will pay Supplier \*\* per pallet, per month, one pallet minimum (\*\* per pallet, per month, one pallet minimum, for any of the Supemus Property that contains controlled substances or requires refrigeration) thereafter for storing the Supemus Property, and Supemus will assume any third party storage charges invoiced to Supplier regarding the Supemus Property. Supplier will invoice Supemus for all such storage charges in accordance with Section 12.6 of this Agreement.

5.2.7 Termination of this Agreement shall not relieve either Party of its obligations incurred prior to the date of termination. The obligations under Sections 5.2.6, 5.2.8, 5.2.9, Articles 7, 8, 10, 11, 12, 14, 16, 17, 18, 19, 20, 21, 22, 23, 24, and Sections 27.2 and 27.9 hereof shall survive expiration or termination of this Agreement or of any extensions thereof.

5.2.8 Notwithstanding anything in this Agreement to the contrary, termination of this Agreement shall not affect the rights and obligations under any Purchase Order that have accrued prior to termination, nor any rights or obligations of either Party that are intended by the Parties to survive termination. If Supplier is in the process of manufacturing Product for Supemus on the day this Agreement terminates, such amount of Product that is in the process of manufacturing and that represents firm Purchase Orders shall be carried through until completion and the Product resulting therefrom shall be delivered to Supemus or its sublicensees by Supplier and shall be paid for by Supemus in accordance with the terms hereof, and the Parties hereto hereby agree that this Agreement shall be extended for such purposes.

5.2.9 Subject to Section 5.2.6, in the event of termination of this Agreement by Supemus under Section 5.2.1 or Section 5.2.3, Supplier, at its own expense, will provide the suitable quality and scientific support for the appropriate technical transfers of the manufacturing process and analytical method to transfer the Manufacturing of the Product from the Facility to another site that Supemus intends to utilize for Manufacturing the

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\*\* This portion has been redacted pursuant to a confidential treatment request.

Product. Such assistance may include, but not be limited to, all appropriate documentation, know-how and technical level “man in the plant” from and to the receiving manufacturer. Supplier understands that time will be of the essence.

5.2.9.1 Supplier shall promptly return to Supemus, at Supemus’ expense and direction, any remaining Inventory of Product, API or materials supplied by Supemus or paid for by Supemus; *provided*, that all outstanding and undisputed invoices have been paid in full.

5.2.9.2 Supemus shall pay Supplier for all costs and expenses incurred and undisputed, and all non-cancellable commitments made and undisputed, in connection with Supplier’s performance of this Agreement, so long as such costs, expenses or commitments were made by Supplier consistent with Supemus’ most recent Firm Commitment and the vendor’s minimum purchase obligations.

6. **Manufacture, Forecasts, Firm Commitments, Acknowledgements and Delivery**

6.1 **Manufacture of Product.** Subject to the terms and conditions of this Agreement, and at Supemus’ request in accordance with the terms hereof, Supplier shall manufacture at the Facility in accordance with the Specifications and in compliance with the Regulatory Scheme, including cGMP, and deliver Product to Supemus in the amounts and on the dates specified by Purchase Orders and confirmed by Acknowledgements hereunder. Supplier shall use commercially reasonable efforts to meet Supemus’ demand for Product ordered in accordance with the terms hereof.

6.2 **Forecasts and Firm Commitment.**

6.2.1 **Rolling 18 Month Forecast.** Within sixty (60) days following the Effective Date of this Agreement, Supemus shall give Supplier a non-binding 18 month forecast of the volume of Product that Supemus expects to order in the first 18 months of commercial manufacture of the Product including the expected monthly delivery schedule. Thereafter on or before the 10th calendar day of each month Supemus shall provide Supplier with a 12 month non-binding, good faith estimate of the quantities of Product including validation batches it foresees it will order during such period (the “Product Forecast”). The most recent 12 month Product Forecast will supercede all other forecasts. Within ten (10) days of receipt of the Product Forecast from Supemus, Supplier shall deliver to Supemus a forecast of Supplier’s requirements for API, including agreed upon safety stock for each of the following twelve (12) months as well as the current inventory of excipients plus agreed upon safety stocks. In addition, Supplier shall provide each API lot number, date of manufacture and expiration/retest date. The first two (2) quarters of the Product Forecast shall constitute a binding obligation of Supemus to accept and purchase, and Supplier to manufacture and timely deliver, Product (each quarter, a “Firm Commitment”) to the following extent:

6.2.1.1       \*\* per cent \*\* of Firm Commitment of Product (plus any additional quantities which Supernus may have ordered and which Supplier may have accepted as additional quantities) in the first 3 months of the period and

6.2.1.2       \*\* per cent \*\* of Firm Commitment of Product for the second three months of the period.

6.2.2    Purchase Orders and Acknowledgement. The Parties shall agree upon a form of Purchase Order to be used by Supernus in ordering Product hereunder. Supernus shall from time to time place Purchase Orders with Supplier for manufacture and delivery of quantities of Product (to the extent indicated in Section 6.2.1) to be delivered within \*\* (the "Lead Time") from the first date of Purchase Order submission (the "Delivery Date"). Concurrently with the submission of each Product Forecast, Supernus shall submit a Purchase Order. The parties agree to meet and discuss in good faith whether any change to a Purchase Order should be made. Promptly but not more than three (3) business days following receipt of a Purchase Order, Supplier shall issue a written acknowledgement ("Acknowledgement") of the Purchase Order, provided the Purchase Order is not for a quantity of Product that exceeds the extent of quantity indicated in Section 6.2.1. Each Acknowledgement shall set forth a scheduled Manufacturing Date (or new Manufacturing Date if one had been indicated in the Purchase Order), confirm that adequate Materials and API are in-house to fulfill the Purchase Order, and confirm the delivery date set forth in the Purchase Order. Supplier shall deliver Product against each accepted Purchase Order in accordance with this Agreement. Supernus shall purchase all such Product ordered and delivered by the delivery date specified in an Acknowledgement, provided that such Product meets the Specifications and the Regulatory Scheme, including, without limitation, cGMP. Supplier shall use commercially reasonable efforts to supply quantities of Product ordered in the aggregate that are up to \*\* in excess of the batch quantity in the Firm Commitment, subject to availability of API and Materials.

6.2.3    Conflicts between Purchase Orders and this Agreement. Other than terms respecting quantity, delivery date(s), method of shipment, and destination(s), the terms and conditions of any Purchase Order submitted by Supernus, or written Acknowledgement thereof by Supplier, shall be of no force and effect, whether or not objected to by Supplier or Supernus, and nothing in any such Purchase Order or written Acknowledgement shall supersede the terms and conditions of this Agreement.

6.2.4    Three Year Forecast. On or before the 10th day of June of each Year, Supernus will give Supplier a written non-binding three-year forecast, broken down by quarters for the second and third years of the forecast, of the volume and delivery schedule of each Product Supernus then anticipates will be required to be manufactured and delivered to Supernus during the three-year period.

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\*\*       This portion has been redacted pursuant to a confidential treatment request.

### 6.3 Reliance by Supplier

6.3.1 Supemus understands and acknowledges that Supplier will rely on the firm Purchase Orders and Product Forecasts submitted under Section 6.2 in ordering Unique Materials (as defined below), if any, required to meet the firm Purchase Orders. For greater certainty, as at the Effective Date, no Unique Materials are contemplated by the Parties; however, this Section 6.3 is included in the Agreement in case there are Unique Materials to be addressed in the future. Supemus understands that, to ensure an orderly supply of the Unique Materials, Supplier may want to purchase the Unique Materials in sufficient volumes to meet the production requirements for Products during part or all of the forecasted periods referred to in Section 6.2 or to meet the production requirements of any longer period agreed to by Supplier and Supemus. Accordingly, Supemus authorizes Supplier to purchase Materials unique to Supemus' Products or otherwise specified and agreed to in writing by the Parties as potentially limited in availability ("Unique Materials") to satisfy the Manufacturing Services requirements for Products for the first \*\* months contemplated in the most recent Product Forecast. Supplier may make other purchases of Unique Materials to meet Manufacturing Services requirements for longer periods if agreed to in writing by the Parties. Supemus will give Supplier written authorization to order Unique Materials for any launch quantities of Product requested by Supemus which will be considered a firm order when accepted by Supplier. If Unique Materials ordered by Supplier under firm Purchase Orders or otherwise ordered under this Section are not included in finished Products manufactured for Supemus within \*\* after the forecasted month for which the purchases have been made (or for a longer period as the Parties may agree), or if the Unique Materials have expired during the period, then Supemus will pay to Supplier its costs therefore (including all costs incurred by Supplier for the purchase and handling of the Unique Materials). But if these Unique Materials are used in Products subsequently manufactured for Supemus or in third party products manufactured by Supplier, Supemus will receive credit for any costs of those Unique Materials previously paid to Supplier by Supemus.

6.3.2 If Supemus fails to take possession or arrange for the destruction of (i) Unique Materials, within 12 months of purchase, or (ii) finished Product, within three months of manufacture, then Supemus will pay Supplier \*\* per pallet, per month thereafter for storing the Unique Materials or finished Product. Storage fees for Unique Materials or Product which contain controlled substances or require refrigeration will be charged at \*\* per pallet, per month. Storage fees are subject to a one pallet minimum charge per month. Supplier may ship released Product held by it longer than 3 months to Supemus or its designated location, at Supemus' expense, on 14 days written notice to Supemus.

### 6.4 Minimum Orders.

Supemus may only order Manufacturing Services for batches of Products in multiples of the Minimum Ordering Quantities as set out in Schedule B.

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\*\* This portion has been redacted pursuant to a confidential treatment request.

7. **Manufacture of Product.**

7.1 **Manufacturing Services.**

Supplier will perform the Manufacturing Services for the Territory for the fees specified in Schedules B and C to manufacture Products for Supemus or its designee(s), which fees shall be paid by Supemus and are subject to adjustment in accordance with the terms and conditions of this Agreement. Schedule B sets forth a list of cost items that are included in the Price for Products; all cost items that are not included in this list are excluded from the Price and are subject to additional fees to be paid by Supemus. Supplier may change the Facility for the Products, at its cost, only with the prior written consent of Supemus, this consent not to be unreasonably withheld. If Validation or Manufacturing Services have not started within 12 months of the Effective Date of this Agreement, Supplier may amend the fees set out in Schedules B and C. During the initial \*\* years following Launch Date in the US, Supemus shall procure not less than \*\* of its Product requirements for the United States from Supplier, and not less than \*\* of its Product requirements for the United States from Supplier during the remainder of the Initial Term. During any Renewal Term, Supemus shall procure not less than \*\* of its Product requirements for the United States from Supplier.

7.1.1 Conversion of API and Materials. Supplier will convert API and Materials into Products.

7.1.2 **Quality Control and Quality Assurance of Materials.** Supplier will perform the quality control and quality assurance testing on the API, Materials, and in-process samples as specified in the Quality Agreement. Lot review and release of the API, Materials, and in process samples to Supemus will be the responsibility of Supplier's quality assurance group. Supplier will perform its lot review and release responsibilities in accordance with Supplier's standard operating procedures. Each time Supplier releases a lot of API or Materials, it will give Supemus a certificate of analysis and certificate of compliance including a statement that the lots were tested in accordance with and meet Specifications and cGMPs. Supemus will have sole responsibility for the release of Products to the market in the Territory. The form and style of batch documents, including, but not limited to, batch production records, lot packaging records, equipment set up control, operating parameters, and data printouts, raw material data, and laboratory notebooks are the exclusive property of Supplier and Supplier hereby grants Supemus the right to use said batch documents to fulfill its obligations to sublicensees, partners, and regulatory authorities as the case may be. Specific Product related information contained in those batch documents is Supemus property.

7.1.3 **Materials.** Supplier will purchase and test all Materials (with the exception of Supemus-Supplied Materials) at Supplier's expense and as required by the Specifications and to meet the Firm Commitment. Except as set forth in the Quality Agreement, Supplier shall not alter or change vendor without the prior

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written notice to and approval of Supernus, which may be withheld or granted in its sole and absolute discretion.

7.1.4 Packaging. Supplier will procure all package components required for the Product and as set forth in the Specifications and to meet the Firm Commitment. Supplier will package the Products as set out in the Specifications and in accordance with the Quality Agreement. Supernus will provide, approve and be responsible for the cost of artwork development. Such artwork, advertising, and labelling information shall remain the exclusive property of Supernus and Supernus shall be solely responsible for the content thereof. Such artwork, advertising and labelling information and reproductions thereof may not be used by Supplier in any manner other than to perform its obligations hereunder. Supplier will determine and imprint the batch numbers and expiration dates for each Product shipped. The batch numbers and expiration dates will be affixed on the Products and on the shipping carton of each Product as outlined in the Specifications and as required by cGMPs. Supernus may, in its sole discretion, make changes to labels, product inserts, and other packaging for the Products. Those changes will be submitted by Supernus to all applicable governmental agencies and other third parties responsible for the approval of the Products. Supernus will be responsible for the cost of labelling obsolescence (if applicable) when changes occur, as contemplated in Section 12.4. Supplier's name will not appear on the label or anywhere else on the Products unless: (i) required by Applicable Law; or (ii) Supplier consents in writing to the use of its name.

7.1.5 Supply of API and any Materials to be Provided by Supernus.

7.1.5.1 At least ninety (90) days prior to the requested delivery date of the Product to Supernus, Supernus or its subcontractor will provide Supplier with the Materials to be supplied by Supernus in addition to providing the API (collectively, "Supernus-Supplied Materials"), at no cost to Supplier, all in sufficient quantity to enable Supplier to perform the manufacturing activities and supply Product to Supernus. Upon receipt of the Supernus-Supplied Materials, Supplier shall test the Supernus-Supplied Materials against the Specifications. In the event the Supernus-Supplied Materials do not meet Specifications, Supplier shall not be liable for any related delays thereof and Supernus will arrange for replacement supply of Supernus-Supplied Materials. Supernus acknowledges that Supplier shall have no liability whatsoever in case of Late Delivery of the Product due to late delivery by Supernus of the Supernus-Supplied Materials. If applicable, Supplier and Supernus will cooperate and provide such assistance to each other as may be reasonably necessary to permit the import of the Supernus-Supplied Materials for the purpose of manufacturing the Product under this Agreement.

7.1.5.2 In accordance with Section 6.2.2 herein, at least ninety (90) days prior to the requested Delivery Date of the Product to Supernus, Supplier, at no cost to Supernus, shall confirm via the Acknowledgement that it has sufficient quantity of all API and Materials in stock to perform the manufacturing activities and

supply Product to Supernus on or before the Delivery Date. Upon receipt of such API and Materials, Supplier shall test against the certificate of analysis and Specifications in accordance with the Quality Agreement. In the event the API or Materials do not meet Specifications, Supplier shall use commercially reasonable efforts to obtain replacement supply of failed API or Materials as the case may be. If applicable, Supplier and Supernus will cooperate and provide such assistance to each other as may be reasonably necessary to permit the import of the API or Materials for the purpose of manufacturing the Product under this Agreement. Notwithstanding any provision of this Agreement to the contrary, under no circumstances will Supplier be liable in any way for, and the provisions of Section 5.2.3(a) shall not apply in respect of, any delay or Late Delivery in connection with a need under this Section 7.1.5.2 to obtain replacement supply of failed API unless the failure is solely attributable to an activity performed by Supplier.

7.2 Changes in Manufacture. In accordance with the Quality Agreement, Supplier will notify and obtain written approval from Supernus of any and all proposed changes in its manufacture and testing of the Product and will obtain Supernus' written approval prior to implementation for any such change that would impact the manufacturing process or the Specifications and constitute a reportable change or modification pursuant to any applicable Regulatory Scheme (e.g., Title 21 United States Code of Federal Regulations Section 211 and 314.70).

7.3 Shipments. Shipments of Products will be made EXW (Incoterms 2010) Supplier's shipping point at the Facility unless otherwise mutually agreed in writing. Risk of loss of or damage to Products, in addition to title to Products, will remain with Supplier until Supplier loads the Products onto the carrier's vehicle for shipment at the shipping point, at which time risk of loss or damage, in addition to title to Product, will transfer to Supernus, and at which time Supplier will be deemed to have duly delivered the Product to Supernus hereunder. Supplier will, in accordance with Supernus' instructions and as agent for Supernus, (i) arrange for shipping to be paid by Supernus and (ii) at Supernus' risk and expense, obtain any export licence or other official authorization necessary to export the Products. Supernus will arrange for insurance and will select the freight carrier used by Supplier to ship Products and may monitor Supplier's shipping and freight practices as they pertain to this Agreement. Products will be transported in accordance with the Specifications.

7.4 On Time Delivery.

7.4.1 Supernus and Supplier understand that there may be uncertainties and necessary adjustments in production schedules during the first six (6) months of manufacturing following the Launch (such period being the "Initial Manufacturing Period").

7.4.2 Subject to Section 7.4.3 below, if after the Initial Manufacturing Period, (i) Supplier is unable to deliver the quantity of Product ordered under a Firm

Commitment within \*\* of the Delivery Date due to an act or omission by Supplier (a “Late Delivery”) and (ii) such Late Delivery is the second Late Delivery to have occurred during the previous \*\*, then Supemus will receive a credit from Supplier for the Late Delivery that will be applied against the purchase Price under the next Purchase Order. The credit will be \*\* percent \*\* of the Price of the quantity of Product not delivered by Supplier under the Purchase Order on the Delivery Date (i.e., Supemus Credit = \*\*).

7.4.3 For clarity, a Late Delivery will not be a material breach of this Agreement by Supplier for the purposes of Section 5.2. For clarity, a Late Delivery will not include any delay in shipment of Product caused by events outside of Supplier’s reasonable control, such as: (i) a force majeure event (within the meaning of Section 27.6), (ii) API availability, (iii) a delay in delivery of Supemus-Supplied Materials, (iv) a delay in Product release approval from Supemus, (v) inaccurate forecasts of Supemus, (vi) receipt of non-conforming Supemus-Supplied Materials, (vii) any market-driven delays in deliveries from approved vendors, or (viii) any delays in US FDA customs clearance of shipments to Supemus or its designee.

7.5 Quality Agreement. The Parties will negotiate in good faith the Quality Agreement to address the roles and responsibilities of the Parties hereto with respect to the manufacture of the Product and quality issues. The Quality Agreement will be executed prior to the manufacturing of the first commercial batch. The Quality Agreement shall in no way determine liability or financial responsibility of the Parties for the responsibilities set forth herein. At the reasonable request of either Party, the Parties shall negotiate, in good faith, amendment(s) or supplement(s) to the Quality Agreement (a) to address matters specific to the manufacture of Product for sale and use outside the United States, and (b) to address regulatory concerns raised by any Regulatory Authority or reasonably raised by either Party and (c) as the Parties otherwise mutually agree in writing. In the event that the terms of the Quality Agreement are inconsistent with the terms of this Agreement, the Quality Agreement shall control for quality related issues and this Agreement shall control for all other issues, unless otherwise explicitly agreed to in writing by the Parties.

7.6 Validation Services. If applicable, Supplier shall perform the Product qualification and validation services described in [Schedule 7.6] (the “Validation Services”) for the fees referenced therein, taking into consideration the per-batch pricing in Schedule B.

7.7 Product Maintenance Services. Supemus will receive the following product maintenance services at no additional cost to Supemus (the “Product Maintenance Services”): one annual audit; regulatory audits; one annual Product review (within the meaning of 21 CFR § 221,180); drug master file updates for the Territory, if applicable; access to document library over and above the Quality Agreement; assistance in preparing Regulatory Documentation as needed; Product document and sample storage relating to cGMP requirements; maintenance, updates and storage of

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\*\* This portion has been redacted pursuant to a confidential treatment request.

master batch records and audit reports; and tooling and filter bag maintenance, as applicable. For avoidance of doubt, the following services and items are not included in Product Maintenance Services: process validation (including cleaning and shipping validation; technology transfer; analytical work not specifically related to testing and release of excipients or in-process testing of Product; stability; replacement HPLC columns and replacement tablet tooling, as applicable. The list of services and items included in and excluded from the unit Price are set forth in Schedule 7.7.

7.8 **Bill Back Items.** Bill Back Items will be charged to Supemus at Supplier's cost plus a \*\* handling fee, subject to Supemus' prior approval in the case of any Bill Back Items costing more than USD \*\* (before the handling fee). There are no Bill Back Items currently identified.

8. **API Yield.**

8.1 **Reporting.** Supplier will give Supemus a monthly inventory report of the API held by Supplier using the inventory report form set out in Schedule H, which will contain the following information for the month:

**Quantity Received:** The total quantity of API that complies with the Specifications and is received at the Facility during the applicable period.

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

**Quantity Converted:** The total amount of API contained in the Products manufactured with the Quantity Dispensed (including any additional Products produced in accordance with Section 9.5.1 or 9.5.2), delivered by Supplier, and not rejected, recalled or returned in accordance with Sections 9.1 to 9.4, inclusive, because of Supplier's failure to perform the Manufacturing Services in accordance with Specifications, cGMPs, and Applicable Laws.

Within 60 days after June 30th each Year, Supplier will prepare a half-Year reconciliation report of API if the Quantity Dispensed for the half-Year exceeds the Quantity Converted for the half-

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Year by more than 20kg. In this case, an “**Actual Half-Year Yield**” for the Product at the Facility will be calculated as a percentage, as follows:

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Within 60 days after the end of each Year, Supplier will prepare an annual reconciliation of API (including all amounts reported on the half-Year reconciliation report, if one was required) on the reconciliation report form set forth in Schedule I including the calculation of the “**Actual Annual Yield**” or “**AAY**” for the Product at the Facility during the Year. AAY is the percentage of the Quantity Dispensed that was converted to Products and is calculated as follows:

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After Supplier has produced a minimum of 10 commercial production batches of Product and has produced commercial production batches for at least six months at the Facility (collectively, the “**Target Yield Determination Batches**”), the Parties will mutually agree on the target yield for the Product at the Facility (the “**Target Yield**”).

8.2 Shortfall Calculation. If the Actual Half-Year Yield falls more than five percent below the Target Yield, then the shortfall for the period January 1 to June 30 (the “**Half-Year Shortfall**”) will be calculated as follows:

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If the Actual Annual Yield falls more than five percent below the Target Yield, then the shortfall for the Year (the “**Annual Shortfall**”) will be calculated as follows:

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8.3 Credit for Shortfall. If there is a Half Year Shortfall for a Product in the first half of a Year, then Supplier will credit Supemus’ account for the amount of the Half-Year Shortfall not later than 60 days after June 30<sup>th</sup>.

If there is an Annual Shortfall for a Product in a Year, then Supplier will credit Supemus’ account for the amount of the Annual Shortfall less, if any, the Half Year Shortfall, which resulting amount shall be credited not later than 60 days after the end of the Year.

Each credit under this Section 8.3 will be summarized on a reconciliation report substantially in the form set forth in Schedule I (to be adjusted accordingly for any half-Year reconciliation report).

Upon expiration or termination of this Agreement, any remaining credit owing under this Section 8 will be paid to Supemus, an Annual Shortfall calculation shall be made (regardless of the time

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of year), and the Annual Shortfall, if any, will be disclosed by Supplier on the reconciliation report form.

8.4 **Maximum Credit.** Supplier's liability for API calculated in accordance with this Section 8 in a Year will not exceed, in the aggregate, the Maximum Credit Value set forth in Schedule D.

8.5 **No Material Breach.** It will not be a material breach of this Agreement by Supplier under Section 5.2.1 if the Actual Half-Year Yield or the Actual Annual Yield is less than the Target Yield.

9. **PRODUCT CLAIMS AND RECALLS**

9.1 **Product Testing Results.** Within 10 business days of Product being released by Supplier and Supemus having received appropriate Product samples and supportive documentation, Supemus will perform its quality control and quality assurance testing of the bulk and final Product. Prior to shipment of Product by Supplier, each time Supemus releases a batch of Product, it will provide Supplier a certificate of analysis and certificate of compliance including a statement that the batch was tested in accordance with and meets Specifications ("Release Notice"). In addition, Supplier shall hold for inspection, or at the request of Supemus deliver to Supemus, retention samples of each lot of Product manufactured by Supplier under this Agreement. Upon receipt of each lot of Product, Supemus shall have the right, but not the obligation, to test such Product in accordance with the terms of the Quality Agreement to determine compliance with the Specifications and/or cGMP. Supemus may also conduct any additional testing or investigation or audit it determines to be of value to determine: (i) compliance of Product with the Specifications; and/or (ii) manufacture of Product pursuant to cGMP, and/or any other standard imposed by law. Product shall be deemed to be acceptable if, upon testing, it meets the Specifications, is documented to be compliant with cGMP, or any additional tests or audits as agreed by the Parties. Supemus shall also have the right to inspect each shipment of Product for conformance with inspection criteria to be agreed upon by Supemus and Supplier. However, Supemus' acceptance of a shipment shall not preclude a subsequent rejection of such shipment or any portion thereof following discovery of any Latent Defect in such shipment. A Deficiency Notice shall include such notice concerning discovery of a Latent Defect. Upon timely receipt of a Deficiency Notice from Supemus Supplier shall conduct an appropriate investigation in its discretion to determine whether or not it agrees with Supemus that Product is Defective Product and to determine the cause of any nonconformity. Subject to Section 9.3, Supplier will have ten (10) days to advise Supemus by notice in writing that it disagrees with the contents of the Deficiency Notice. If Supplier agrees that Product is Defective Product and determines that the cause of nonconformity is attributable to Supplier's failure to Manufacture in accordance with the Specifications, cGMPs, Applicable Laws, or any other assignable cause ("Supplier Defective Manufacturing"), then Section 9.5.1 shall apply. Rejection of any shipment that, in whole or part, fails to meet Specifications or to comply with cGMP or Applicable Laws (a "Deficiency Notice"), will be issued within twenty (20) Business Days ("Review Period") of receipt of Product from Supplier.

9.2 Acceptance or Rejection. Supplier will have no liability for any deviations for which it has not received a Deficiency Notice. Supplier retains the right of appeal to an independent laboratory as provided in Section 9.3 hereof.

9.3 Independent Laboratory Testing. Upon receipt of a Deficiency Notice, Supplier will have ten (10) days to advise Supernus by notice in writing that it disagrees with the contents of the Deficiency Notice. In the event of any disagreement between Supplier and Supernus relating to Product conformance with Specifications, the Parties will use good faith efforts to reach an amicable resolution of such disagreement. In the event that resolution cannot be reached, a mutually agreed upon, neutral, independent third-party laboratory shall be brought in to resolve the disagreement upon the request of either Party. This evaluation will be binding on the Parties. If the evaluation certifies that any Products deviate from the Specifications, cGMPs, or Applicable Laws, Supernus may reject those Products in the manner contemplated in this Section 9.3, and Supplier will be responsible for the cost of the evaluation. If the evaluation does not so certify for any of the Products, then Supernus will be deemed to have accepted delivery of the Products on the 40th day after delivery (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, on the 40th day after discovery thereof by Supernus, but not after the expiration date of the Product), and Supernus will be responsible for the cost of the evaluation.

9.4 Product Recalls and Returns.

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

9.4.2 Recalls. If (i) any governmental or Regulatory Authority issues a directive, order or, following the issuance of a safety warning or alert about a Product, a written request that any Product be Recalled, (ii) a court of competent jurisdiction orders a Recall, or (iii) Supernus determines that any Product should be Recalled or that a “Dear Doctor” letter is required relating to the restrictions on

the use of any Product, Supplier will co-operate as reasonably required by Supernus, having regard to all applicable laws and regulations.

9.4.3 **Product Returns.** Supernus will have the responsibility for handling customer returns of the Products. Supplier will give Supernus any assistance that Supernus may reasonably require to handle the returns.

9.5 **Supplier's Responsibility for Defective and Recalled Products.**

9.5.1 **Defective Product.** If Supernus rejects Products under Sections 9.1 to 9.3, inclusive, and the deviation is determined to have arisen from Supplier's failure to provide the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws or for any negligence, fault, error or omission assignable to Supplier ("Defective Product"), Supplier will credit Supernus' account for Supplier's invoice Price for all amounts paid by Supernus to Supplier for the Defective Products. If Supernus previously paid for the Defective Products, Supplier will promptly, at Supernus' election, either: (i) refund all amounts paid by Supernus for the defective Products; (ii) offset the amount paid against other amounts due to Supplier hereunder; or (iii) replace the Defective Products with conforming Products without Supernus being liable for payment therefore under Section 7.1, contingent upon the receipt from Supernus of all Supernus-Supplied Materials required for the manufacture of the replacement Products. For greater certainty, Supplier's responsibility for any loss of Supernus-Supplied Materials in Defective Product will be captured and calculated in the API Yield under Section 8. If Supernus rejects Product under Section 9 and the non-conformance is not determined to have arisen from any negligence, fault, error or omission of Supplier then Supernus shall remain liable to pay the invoice price therefore and shall reimburse Supplier for all costs and expenses associated with the investigation, additional testing and disposal of the Product. It is understood that causes of non-conformity may not be immediately determined. If subsequent data, inspection or other finding leads to a determination Defective Product was due to the negligence, fault error or omission of the Supplier, then a full credit for the non-saleable, non conforming batch, plus the costs of the initial investigation will be issued or fully reimbursed as the case may be.

9.5.2 **Recalled Product.** If a Recall or return results from, or arises out of, a failure by Supplier to perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws, Supplier will be responsible for the documented out-of-pocket expenses of the Recall or return and will use its commercially reasonable efforts to replace the Recalled or returned Products with new Products, contingent upon the receipt from Supernus of all Supernus- Supplied Materials required for the manufacture of the replacement Products. For greater certainty, Supplier's responsibility for any loss of Supernus-Supplied Materials in Recalled Product will be captured and calculated in the API Yield under Section 8. If Supplier is unable to replace the Recalled or returned Products (except where this inability results from a failure to receive the required

Supernus-Supplied Materials), then Supernus, subject to Sections 9.4.2 and 9.4.3, may request Supplier to reimburse Supernus for the Price that Supernus paid to Supplier for Manufacturing Services for the affected Products. In all other circumstances, recalls, returns, or other corrective actions will be made at Supernus' cost and expense.

9.5.3 Except as set forth in Sections 9.5.1 and 9.5.2 above, Supplier will not be liable to Supernus nor have any responsibility to Supernus for any deficiencies in, or other liabilities associated with, any Product manufactured by it, (collectively, "**Product Claims**"). For greater certainty, Supplier will have no obligation for any Product Claims to the extent the Product Claim (i) is caused by deficiencies in the Specifications, the safety, efficacy, or marketability of the Product or any distribution thereof, (ii) results from a defect in a Supplier-sourced Material that is not discoverable by customary industry practice by Supplier using the test methods set forth in the Specifications, (iii) results from a defect in the API or Materials supplied by Supernus that is not discoverable by customary industry practice by Supplier using the test methods set forth in the Specifications, (iv) is caused by actions of third parties occurring after the Product is shipped by Supplier under Section 7.3, (v) is due to packaging design or labelling defects or omissions for which Supplier has no responsibility, or (vi) is due to any other breach by Supernus of its obligations under this Agreement.

10. **Inspections and Notification of Visits**

10.1 **Inspection**. Subject to the Quality Agreement, Supernus, its sublicensees, partners and consultants may enter Supplier's premises upon reasonable notice during Supplier's normal business hours for the purpose of inspecting the Facility, procedures and any relevant records relating to the manufacture and testing of Product (including but not limited to, all batch sheets and records for all manufacturing steps), during the Term of this Agreement. Each Party shall be responsible for its costs associated with such inspections. In addition, Supernus and/or its Affiliates, subcontractors, or sublicensees shall have the right to be present during the manufacture of Product, upon at least five (5) Business Days' advance notice to Supplier. No such inspection shall diminish or increase Supplier's obligations hereunder. Supernus may conduct an audit at no cost under this Section once during any 12-month period; *provided*, that additional inspections may be conducted in the event there is a material quality or compliance issue concerning Product or its Manufacturing. Supernus shall indemnify and hold harmless Supplier for any action or activity of its representatives while on Supplier's premises.

10.2 **Notification of Regulatory Visits**. In the event that any Facility of Supplier used in the manufacturing of Product hereunder is inspected by representatives of any Regulatory Authority or any other U.S. federal, state or local regulatory agency in connection with Supplier's manufacture of the Product, Supplier shall notify Supernus immediately by telephone and follow up in writing, upon learning of such inspection, and shall supply Supernus with copies of any reports or responses including, but not limited to any Form 483s or Establishment Inspection Reports (EIRs) prepared by the agency or Supplier relating to such inspection to the extent that

such report relates to Product, within ten (10) days of Supplier's receipt of such report. Supemus acknowledges that it may not direct the manner in which Supplier fulfills its obligations to permit inspection by and to communicate with Regulatory Authorities unless specific or significant to Supemus' Product. Supemus may send representatives to such Facility and Supemus may participate fully in any portion of such inspection relating to the Product. Supemus shall have the right to review and comment on any responses to such reports or other correspondence prior to submission to the applicable Regulatory Authority and Supplier shall incorporate Supemus' comments into any such responses.

11. **Manufacturing Records.**

11.1 **Maintenance and Retention of Records.** Supplier will keep records of the manufacture, testing, and shipping of the Product, and retain samples of the Product as are necessary to comply with manufacturing regulatory requirements applicable to Supplier, as well as to assist with resolving Product complaints and other similar investigations. Copies of the records and samples will be retained for a period of one year following the date of Product expiry, or longer if required by law, at which time Supemus will be contacted concerning the delivery and destruction of the documents and/or samples of Product. Under no circumstances shall Supplier destroy any records pertaining to the Product without giving Supemus a fifteen (15) day prior written notice. Supemus is responsible for retaining samples of the Product necessary to comply with the legal/regulatory requirements applicable to Supemus.

11.2 **Access to Records.** Upon request by Supemus or in accordance with the Quality Agreement, Supplier shall provide copies of the process and the individual and master batch records used by Supplier for any step in the manufacture of Product. Supemus may use the information in such batch records in regulatory submissions in order to gain or maintain Regulatory Approval. Supemus, or its nominee, shall be entitled to take copies or extracts from the records pertaining to the Product during such review or audit. Supplier will provide all reasonably necessary assistance to Supemus, at no cost to Supplier, in support of Supemus' efforts to obtain or maintain such Regulatory Approval.

11.3 **Records; Regulatory Submissions.** During the Term of this Agreement, Supplier will assist Supemus with all regulatory matters relating to the Product manufacturing. Supplier shall be responsible for: (i) updating the Supplier DMF as required by Regulatory Authorities and, if applicable, preparing suitable manufacturing instructions, manufacturing controls and manufacturing documentation in a timely manner for inclusion in any CMC Submission, as far as required by Regulatory Authorities; (ii) providing Supemus and the appropriate Regulatory Authorities with letters of authorization for access to Supplier's DMF, if applicable, and all information, process validation data, batch documents, annual distribution data, and other data required to support the CMC Submission and obtain regulatory approvals, including any investigations of any deviations from the manufacturing or testing processes; (iii) conducting material contact and cleaning validation studies, shipping validation studies, and other studies in a timely manner to comply with cGMP, and to develop data required to pass a Regulatory Authority's inspections and to support the manufacture of Product in the Facility; (iv) permitting Supemus to conduct all necessary cGMP and quality assurance reviews of Supplier's documentation supporting the supply of Product to Supemus; (v) obtaining and maintaining at its

expense any facility or other licenses, permits, registration and any regulatory approvals necessary for the manufacture of Product hereunder; and (vi) permitting Regulatory Authorities to conduct inspections and to permit Supernus to attend such inspections.

11.4 Deviations. Supplier agrees that its quality assurance function shall review the manufacturing records for all steps and all lots of Product it manufactures hereunder. Upon discovery of any deviation from cGMP or from any warranty hereunder Supplier shall conduct promptly an appropriate investigation to determine the cause of such deviation and take appropriate action at its expense to avoid recurrence. Supplier shall provide a copy of any such investigation report to Supernus for approval.

11.5 Operations Team and Reports.

11.5.1 The Parties will form an operations team as a decision making forum for Supernus and Supplier to address and resolve whatever issues might arise during the course of this Agreement ("Operations Team"). The Operations Team will:

- a) establish metrics to include but not be limited to: On Time Delivery in Full (OTIF %), forecasting effectiveness, technical stockouts, actual stockouts, vendor improvement programs, client improvement programs, cycle time improvements and quality standards;
- b) oversee the timing and implementation of relevant phases of manufacture and packaging as it pertains to Supernus' product;
- c) monitor arrangements for the procurement of Supernus-Supplied Materials; and
- d) review the operation of this Agreement and the Quality Agreement. This will include volume forecasts, supply plans, technical and pricing issues, and agreed upon performance measures including on time in full deliveries, on time in full payments and quality standards.

Supernus and Supplier shall appoint as members of the Operations Team a reasonable number of suitably qualified and experienced representatives of each of the parties and shall each designate one member appointed by it to be the principal contact in relation to the day to day management of the administration of this Agreement. Each Party may appoint no more than four (4) persons to the Operations Team.

The Operations Team shall meet at regular intervals on such dates and such locations as may be agreed upon by the Parties, by video or teleconference or directly. In particular, the Operations Team shall strive to meet at least once per quarter but in any event shall meet no less than three times per year. The Operations Team may also meet upon ten (10) days of written request therefore by either party should circumstances necessitate such a meeting. A quorum shall consist of no fewer than two representatives from each Party.

The members of the Operations Team shall endeavor to decide matters that come before it on a unanimous basis. In the event that a unanimous decision cannot be reached on any material matter, the matter at issue shall be referred to the senior operations executive of each party as designated and who together shall review and determine agreement and communicate their decision to the Operations Team.

11.5.2 Supplier will supply on an annual basis all Product data in its control, including release test results, complaint test results, and all investigations (in manufacturing, testing, and storage), that Supemus reasonably requires in order to complete any filing under any applicable regulatory regime, including information needed for Supemus to file their Annual Report with the FDA. At Supemus' request, Supplier will provide a copy of the Annual Product Review Report to Supemus at no additional cost. Any additional report requested by Supemus beyond the scope of cGMPs and customary FDA requirements will be subject to an additional fee to be agreed upon between Supplier and Supemus. For the purposes of this provision, "Annual Report" means the annual report to the FDA prepared by Supemus regarding the Product as described in Title 21 of the United States Code of Federal Regulations, Section 314.81(b)(2). Also for the purposes of this provision, "Annual Product Review Report" means the annual product review report prepared by Supplier as described in Title 21 of the United States Code of Federal Regulations, Section 211.180(e).

11.6 FDA Filings.

11.6.1 Regulatory Authority. Supemus will have the sole responsibility for filing all documents with all Regulatory Authorities and taking any other actions that may be required for the receipt and/or maintenance of Regulatory Authority approval for the commercial manufacture of the Products. Supplier will assist Supemus, to the extent consistent with Supplier's obligations under this Agreement, to obtain Regulatory Authority approval for the commercial manufacture of all Products as quickly as reasonably possible.

11.6.2 Verification of Data. Prior to Supemus filing (after the Effective Date) any documents with any Regulatory Authority that incorporate data generated by Supplier, Supemus will make available the relevant sections of the documents incorporating this data to give Supplier the opportunity to verify the accuracy and regulatory validity of those sections as they relate to Supplier generated data. Supplier's review of relevant sections and written feedback to Supemus shall not extend beyond ten days from time of receipt by Supplier.

Verification of CMC. Prior to Supemus filing with any Regulatory Authority any documentation which is or is equivalent to the FDA's Chemistry and Manufacturing Controls ("CMC") related to any Marketing Authorization, such as

a New Drug Application or Abbreviated New Drug Application, Supernus will make available that part of the CMC relating to batch records.

11.6.3 Deficiencies. If, in Supplier's sole discretion, acting reasonably, Supplier determines that any of the information given by Supernus under Section 11.6.2 is inaccurate or deficient in any manner whatsoever (the "Deficiencies"), Supplier will notify Supernus in writing of the Deficiencies within five days of initial receipt of said information. The Parties will work together to have the Deficiencies resolved prior to any pre-approval inspection.

11.6.4 Supernus Responsibility. For clarity, the Parties agree that, in reviewing the documents referred to in Section 11.6.2, Supplier's role will be limited to verifying the accuracy of the description of the work undertaken or to be undertaken by Supplier. Subject to the foregoing, Supplier will not assume any responsibility for the accuracy of any application for receipt of an approval by a Regulatory Authority. Supernus has sole responsibility for the preparation and filing of the application for approval by the Regulatory Authorities and any relevant costs will be borne by Supernus.

11.6.5 Inspection by Regulatory Authorities. If Supernus does not give Supplier the documents requested under Section 11.6.2, and if Supplier reasonably believes that Supplier's standing with a Regulatory Authority may be jeopardized, Supplier may, in its sole discretion, delay or postpone any inspection by the Regulatory Authority until Supplier has reviewed the requested documents and is satisfied with their contents.

11.6.6 Regulatory Communications. Each Party will promptly notify the other Party of, and provide the other Party with copies of, any correspondence and/or other documentation received or prepared by the Party in connection with (1) receipt of any warning letter or other regulatory correspondence from an applicable Regulatory Authority in connection with the manufacture of the Product; or (2) any recall of the Product; provided that Supplier may redact from such communications portions thereof which Supplier is required to keep confidential pursuant to binding agreements with third parties.

## 12. **Price and Payment**

### 12.1. Pricing

The tiered Price listed in Schedule B for the Products shall be adjusted following process validation and the initial commercial manufacturing campaign ("Final Pricing"). The Final Pricing will then be reflected as a revision to Schedule B and will thereafter remain fixed until December 31, 2013. Price will be subject to annual review and adjustments set forth in Sections 12.2 and 12.3. The tiered Pricing is based on the cycle time gantt chart attached hereto as Schedule K.

12.2 Price Adjustments - Subsequent Years' Pricing

After December 31, 2013, Supplier may adjust the Price effective January 1<sup>st</sup> of each Year thereafter as follows:

12.2.1 Manufacturing Costs. After December 31, 2013, Supplier may adjust the Price for inflation, based upon the preliminary number for any adjustment in the Producer Price Index pcu325412325412 for Pharmaceutical Preparation Manufacturing ("PPI") published by the United States Department of Labor, Bureau of Labor Statistics in August of the preceding Year compared to the final number for the same month of the Year prior to that, unless the Parties otherwise agree in writing provided that Supplier will have notified Supemus of such Pricing adjustment at least ninety (90) days in advance and any annual price increase does not exceed \*\* percent. The Price may also be adjusted for other reasons related to increased or decreased efficiency in the manufacturing process or any other manufacturing change that impacts the cost of manufacturing by greater than \*\*. On or about November 1<sup>st</sup> of each Year, Supplier will give Supemus a statement setting forth the calculation for the inflation adjustment to be applied in calculating the Price for the next Year. The Parties will also conduct the annual review prior to implementation of any Price adjustment.

12.2.2 Costs of Materials. After December 31, 2013, Supplier may adjust the Price due to changes in Material costs. On or about November 1<sup>st</sup> of each Year thereafter, Supplier will give Supemus information about the increase or decrease in Material costs which will be applied to the calculation of the Price for the next Year to reasonably demonstrate that the Price increase or decrease is justified. But Supplier will not be required to give information to Supemus that is subject to obligations of confidentiality between Supplier and its suppliers.

12.2.3 Pricing Basis. After December 31, 2013, Supemus acknowledges that the Price in any Year thereafter is quoted based upon the Minimum Ordering Quantity and the Price tiers specified in Schedule B. The Price is subject to change if the specified Minimum Ordering Quantity changes or if the minimum Annual Quantity in the lowest tier is not ordered in a Year. For greater certainty, if Supplier and Supemus agree that the Minimum Ordering Quantity will be reduced or the minimum Annual Quantity in the lowest tier will not be ordered in a Year whether as a result of a decrease in estimated annual volume or otherwise and, as a result of the reduction, Supplier demonstrates to Supemus that its costs to perform the Manufacturing Services and to acquire the Materials for the Product will increase on a per unit basis (including the amount of the increase), then Supplier may increase the Price by an amount sufficient to absorb the documented increased costs. This cost increase shall exclude the cost associated with unused manufacturing capacity. On or about November 1<sup>st</sup> of each Year, Supplier will give Supemus a statement setting forth the information to be applied in calculating those cost increases for the next Year. But Supplier will not be

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\*\* This portion has been redacted pursuant to a confidential treatment request.

required to give information to Supemus that is subject to obligations of confidentiality between Supplier and its suppliers.

12.2.4 Adjustments Due to Currency Fluctuations. Supplier will adjust the Price for all Product that is manufactured outside the United States or Puerto Rico to reflect currency fluctuations. The adjustment will be calculated after all other annual Price adjustments under this Section 12.2 have been made. The adjustment will proportionately reflect the increase or decrease, if any, in the Set Exchange Rate compared to the Set Exchange Rate established for the prior Year or the Initial Set Exchange Rate, as the case may be. An example of the calculation of the Price adjustment is set forth in Schedule J.

For all Price adjustments under this Section 12.2, Supplier will deliver to Supemus on or about November 1<sup>st</sup> of each Year a revised Schedule B to be effective for the next Year.

12.3. Price Adjustments - Current Year's Pricing

During any Year of this Agreement, the Prices set out in Schedule B will be adjusted as follows:

12.3.1 Extraordinary Increases or Decreases in Costs of Materials. If, at any time, market conditions result in Supplier's cost of Materials being materially greater or less than normal forecasted increases or decreases, then Supplier or Supemus, as the case may be, will be entitled to an adjustment to the Price for any affected Product to compensate it for the increased or decreased Material costs. Changes materially greater or less than normal forecasted increases or decreases will have occurred if, (i) the cost of a Material increases or decreases by \*\* of the cost for that Material upon which the most recent fee quote was based; or (ii) the aggregate cost for all Materials required to manufacture a Product increases or decreases by \*\* of the total Material costs for the Product upon which the most recent fee quote was based. If Material costs have been previously adjusted to reflect an increase or decrease in the cost of one or more Materials, the adjustments set out in (i) and (ii) above will operate based on the last cost adjustment for the Materials.

For a Price adjustment under this Section 12.3.1, Supplier will deliver to Supemus a revised Schedule B and budgetary pricing information, adjusted Material costs or other documents reasonably sufficient to demonstrate that a Price adjustment is justified. Supplier will have no obligation to deliver any supporting documents that are subject to obligations of confidentiality between Supplier and its suppliers. The revised Price will be effective for any Product delivered on or after the first day of the month following Supemus' receipt of the revised Schedule B and that were manufactured using those higher cost materials, and only after existing inventories of lower cost materials have been exhausted.

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\*\* This portion has been redacted pursuant to a confidential treatment request.

12.4 Adjustments Due to Technical Changes. Amendments to the Specifications or the Quality Agreement requested by Supemus will only be implemented following a technical and good faith cost review by Supplier and are subject to Supemus and Supplier reaching agreement on Price changes required because of the amendment. Amendments to the Specifications, the Quality Agreement or the Facility requested by Supplier will only be implemented following the written approval of Supemus, the approval not to be unreasonably withheld. If Supemus accepts a proposed Price change, the proposed change in the Specifications will be implemented, and the Price change will become effective, only for those orders of Products that are manufactured under the revised Specifications. In addition, Supemus agrees to purchase, at Supplier's cost (including all costs incurred by Supplier for the purchase and handling of the Inventory), (i) all Inventory of Materials used under the "old" Specifications and purchased or maintained by Supplier in order to fill firm Purchase Orders or under Section 6.3, if such Inventory can no longer be used under the revised Specifications, and (ii) all other Inventory used under the "old" Specifications and purchased or maintained by Supplier in order to fill Firm Commitments or under Section 6.3, if such Inventory can neither be used under the revised Specifications nor, within four (4) months of implementation of the proposed change in the Specifications, in any third party products manufactured by Supplier (whether the reason such Inventory cannot be used in third party products within said timeline is that the Inventory is not suitable for such products or has expired). Open purchase orders for Materials no longer required under any revised Specifications that were placed by Supplier with suppliers in order to fill Firm Commitments or under Section 6.3 will be cancelled where possible, and if the orders may not be cancelled without penalty, will be assigned to and satisfied by Supemus.

12.5 Multi-Country Packaging Requirements. If Supemus decides to have Supplier perform Manufacturing Services for the Product for countries outside the Territory, then Supemus will inform Supplier of the packaging requirements for each new country and Supplier will prepare a quotation for consideration by Supemus of any additional Material costs and the change over fees for the Product destined for each new country. The agreed additional packaging requirements and related packaging costs and change over fees will be set out in a written amendment to this Agreement.

12.6 Payment Terms. Unless otherwise specified in the applicable Purchase Order, payment shall be made within thirty (30) days from the date of invoice so long as the date of invoice is the same date as the fax and email transmission to Supemus. Supplier will forward each invoice both via fax to the fax number given by Supemus to Supplier in writing and via electronic mail to the email address "accounting@supemus.com", which email address may be changed from time to time, to ensure Supemus has the full thirty (30) days to process payment. Supplier is entitled to charge Supemus, and Supemus shall pay, interest at the rate of \*\* percent \*\* per month on any outstanding but undisputed payments that are not made within such thirty (30) day period. Invoices will be sent when the Product is manufactured and released by Supplier. Supplier will include in said invoices the applicable amount(s), or will send Supemus separate invoices, covering any Inventory or Materials which are to be purchased by Supemus under Section 6.3. The Late Delivery credit set forth in Section 7.4.1 is only available to Supemus if all outstanding undisputed invoices have been paid in full or are within 45 days outstanding from the invoice date when the Late Delivery arose. Any disputed invoices will be subject to the process described in Section 12.6 herein.

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\*\* This portion has been redacted pursuant to a confidential treatment request.

13. **Regulatory Approvals.** Supemus shall have responsibility for obtaining and maintaining such approvals by the FDA, and other regulatory agencies, as are necessary to process and manufacture finished Products at the Facility for sale in the United States and other countries by Supemus or its sublicensees. Supplier shall permit each Regulatory Authority to inspect the Facility and cooperate fully in support of regulatory filings, registrations and/or licensing activities. Supplier shall provide Supemus with such available information as Supemus may reasonably request in order for Supemus to comply with the requirements of the Regulatory Authority and governmental formularies and agencies in regard to the Product. The Parties further agree that, within the context of providing available information, Supplier will use commercially reasonable efforts to cooperate in any registration process outside the United States.

14. **Trademarks.** Supemus, in its sole discretion, shall determine the trademarks and trade names owned or licensed by Supemus to be used in connection with Product and which trademarks and trade names will appear on the labels, labeling, and any promotional materials for the Products. Supemus shall advise Supplier as to the trademarks and trade names Supemus or its sublicensees has selected for the Product. Supplier shall use these trademarks and trade names and no other trademarks and trade names on the labels and labeling for the Product. Supplier shall have no right to use said trademarks and trade names other than in connection with its manufacturing Products for sale to Supemus or its sublicensees under this Agreement. Upon expiration or termination of this Agreement, Supplier shall not use any of these trademarks or trade names, whether or not said trademarks or trade names have been registered with the United States Patent and Trademark Office (“PTO”) or other equivalent agencies for territories outside the United States. Upon the request of Supemus, Supplier shall give Supemus all reasonable assistance in securing or maintaining registration of any trademarks, copyright, or trade names used in connection with the Products with the PTO. Supemus shall have the right to change trademarks and trade names and will reimburse Supplier for any costs incurred for labels or labeling bearing a trademark or trade name that Supemus has determined it no longer wants to use.

15. **Restrictions; Ability to Subcontract.**

15.1 **Non-solicitation.** During the Term of this Agreement and for a period of two (2) years thereafter, regardless of the reason for such termination, neither Party will, directly or indirectly, solicit, as an employee or independent contractor, any person who is, or was at any time, employed by or under contract with the other Party, unless at the time of the solicitation at least two (2) years shall have elapsed since the person was last employed by or under contract with the other Party.

15.2 **Subcontracts.** Supplier shall be permitted to subcontract some portions of the work contemplated by this Agreement to a third party upon receiving prior written approval from Supemus; provided that such third party agrees in writing to be bound by the Quality Agreement, regulatory obligations, and the terms regarding treatment of Confidential Information, protection and ownership of Intellectual Property, and the performance of services in accordance with Applicable Laws that are not less stringent than those of this Agreement. Notwithstanding the

preceding sentence, Supplier shall remain wholly responsible for executing and monitoring the work performed by such subcontractors pursuant to the terms of this Agreement.

16. **Safety Data.** Supemus will provide Supplier with data on the chemical and physical properties, toxicity, and handling, storing, and shipping information for any Materials supplied to Supplier by Supemus and the Product (MSDS or equivalent) and any other information available to Supemus that is necessary for the safe conduct of the manufacturing of the Product by Supplier. Supemus shall supply Supplier with pertinent information relating to Materials supplied to Supplier by Supemus or the Product regarding health or safety hazards to Supplier's workers. Supemus shall update all of such information provided to Supplier as such information becomes available to Supemus.

17. **Representations and Warranties of Supplier.** Supplier represents and warrants to Supemus that:

- 17.1 Neither it nor any of its employees or consultants engaged in performing the services hereunder have been "debarred" by the United States Food and Drug Administration (the "FDA"), nor have any such debarment proceedings against it or any such employees or consultants been commenced. Supplier will immediately notify Supemus in writing if any such proceedings have commenced or if a respective representative is debarred by the FDA.
- 17.2 Supplier will comply with Specifications, cGMPs, and Applicable Laws in the performance of work under this Agreement. Without limitation, Supplier shall be responsible for obtaining all necessary permissions and manufacturing licenses for the manufacture of Product, in accordance with the applicable laws, statutes, rules, and regulations, and, as of the Effective Date and to the best of Supplier's knowledge, any Supplier Intellectual Property used by Supplier to perform the Manufacturing Services (i) is Supplier's or its Affiliate's unencumbered property, (ii) may be lawfully used by Supplier, and (iii) does not infringe any Third Party Rights.
- 17.3 Supplier will not release any batch of Product if the required certificates of conformance indicate that Product does not comply with the Specifications or if Supplier does not hold all necessary approvals to Manufacture the Product.
- 17.4 Supplier, to the best of its knowledge as of the Effective Date, has all necessary authority to use and the permit to use pursuant to this Agreement all Intellectual Property related to Product or Supplier-supplied Materials (including artwork), and the Manufacturing of Product, including any copyrights, trademarks, trade secrets, patents, inventions and developments.
- 17.5 Supplier has (a) a written quality assurance program; (b) planned periodic audits of such quality assurance program; and (c) availability of adequate personnel and facilities to comply with such requirements.

- 17.6 Supplier will not cause the Product to be adulterated or misbranded within the meaning of the FDC Act prior to the delivery of the Product in accordance with Section 7.3 above.
- 17.7 To the best of Supplier's knowledge, it or its subcontractors has not and will not use the services of any persons debarred under 21 U.S.C. § 335(a) or (b) in any capacity associated with or related to the manufacture of the Product. Supplier also warrants that it does not currently employ and covenants that it will not hire, as an officer or an employee, any person who has been convicted of a felony under the U.S. federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product, new drug application or abbreviated new drug application and neither Supplier nor any of its officers or employees has been convicted of a felony under the U.S. federal law for conduct relating to the regulation of any product under the FDC Act.
18. **Representations and Warranties of Supernus.** Supernus covenants, represents, and warrants to Supplier that:
- 18.1 the Specifications for each of the Products are its or its Affiliate's property and that Supernus may lawfully disclose the Specifications to Supplier;
- 18.2 as of the Effective Date and to the best of its knowledge, any Supernus Intellectual Property used by Supplier in performing the Manufacturing Services according to the Specifications (A) is Supernus' or its Affiliate's unencumbered property, (B) may be lawfully used as directed by Supernus, and (C) does not infringe any Third Party Rights;
- 18.3 the performance of the Manufacturing Services by Supplier for any Product under this Agreement or the use or other disposition of any Product by Supplier as may be required to perform its obligations under this Agreement does not infringe any Third Party Rights;
- 18.4 there are no actions or other legal proceedings, concerning the infringement of Third Party Rights related to any of the Specifications, or any of the API and the Materials, or the sale, use, or other disposition of any Product made in accordance with the Specifications;
- 18.5 the Specifications for all Products conform to Applicable Laws, including all applicable cGMPs;
- 18.6 the Products, if labelled and manufactured in accordance with the Specifications and in compliance with applicable cGMPs and Applicable Laws, (i) may be lawfully sold and distributed in every jurisdiction in which Supernus markets the Product, (ii) will be fit for the purpose intended, and (iii) will be safe for human consumption; and

18.7 on the date of shipment, the API will conform to the specifications for the API that Supemus has given to Supplier, and that the API will be adequately contained, packaged, and labelled and will conform to the affirmations of fact on the container.

19. **No Other Warranties**

**EXCEPT AS SPECIFICALLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY EXPRESS OR IMPLIED WARRANTIES, CONDITIONS, OR COVENANTS, STATUTORY OR OTHERWISE, CONCERNING THE PRODUCT MANUFACTURED OR THIS AGREEMENT. WITHOUT LIMITING THE FOREGOING, NEITHER PARTY MAKES ANY IMPLIED WARRANTY OR CONDITION OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE REGARDING THE PRODUCT MANUFACTURED HEREUNDER.**

Without limiting the foregoing, Supplier shall not be responsible for the stability of the Product manufactured and retained in accordance with the Specifications and the Quality Agreement.

20. **Waste Disposal.** Supplier shall dispose of all wastes from the manufacturing process by incineration thereof in accordance with all applicable rules and regulations.

21. **Confidential Information.** The Confidentiality Agreement will apply to all confidential information disclosed by the parties under this Agreement. If the Confidentiality Agreement expires or is terminated prior to the expiration or termination of this Agreement, the terms of the Confidentiality Agreement will continue to govern the parties' obligations of confidentiality for any confidential or proprietary information disclosed by the parties hereunder, for the term of this Agreement, as though the Confidentiality Agreement remained in full force and effect.

22. **Developed Technology.**

22.1 The term "Intellectual Property" means all forms of intellectual property, including, without limitation, rights in patents, patent applications, formulae, methods, trademarks, trade-mark applications, trade-names, trade secrets, inventions, copyright, industrial designs, know how, and improvements thereof.

22.2 For the Term, Supemus hereby grants to Supplier, a non-exclusive, paid-up, royalty-free, non-transferable terminable license of Supemus' Intellectual Property which Supplier must use in order to perform the services hereunder but shall not be used for any other reason whatsoever.

22.3 All inventions, ideas, discoveries, developments, methods, processes, data, information, improvements and biological or chemical materials, (whether or not reduced to practice and whether or not it can be protected under state, federal, or foreign patent, copyright, trade secrecy or similar laws) ("Inventions") which are specific to or dependent on the Product or

based on or derived from Supemus' Confidential Information and conceived, created or developed by Supplier or Supemus (whether alone or with others) in the course of performing the services hereunder are and shall remain the exclusive property of Supemus, and Supemus may use or pursue them without restriction or additional compensation. Supplier shall promptly and fully disclose, in writing, to Supemus any and all such inventions. Supplier shall maintain complete written records of all such Inventions and of all related work or investigations done or carried out by Supplier at all stages of this research project.

22.4 Supplier hereby assigns and agrees to assign to Supemus all of Supplier's right, title and interest in and to any such Inventions. Supplier agrees to cooperate fully in obtaining patent, copyright or other proprietary protection for such Inventions, all in the name of Supemus and at Supemus' cost and expense, and shall execute and deliver all requested applications, assignments and other documents, and take such other measures as Supemus shall reasonably request in order to perfect and enforce Supemus' rights in the Inventions (including transfer of possession to Supemus of all Inventions embodied in tangible materials). And hereby appoints Supemus' attorney to execute and deliver any such documents on its behalf in the event Supplier fails or refuses to do so; provided that Supemus shall give Supplier sixty (60) days notice prior to executing any documents pursuant to such appointment.

22.5 All Intellectual Property generated or derived by Supplier in the course of performing the Services which are not specific to or dependent upon, the Product or are not based on or derived from Supemus' Confidential Information and which have application to manufacturing processes of drug products shall be the exclusive property of Supplier. Supplier hereby grants to Supemus, a non-exclusive, paid-up, royalty-free, transferable license of such Intellectual Property which Supemus may use for the manufacture of the Product.

23. **Liability and Indemnification.**

23.1 **Consequential Damages**

Under no circumstances whatsoever will either Party be liable to the other in contract, tort, negligence, breach of statutory duty, or otherwise for (i) any (direct or indirect) loss of profits, of production, of anticipated savings, of business, or goodwill or (ii) for any other liability, damage, costs, or expense of any kind incurred by the other Party of an indirect or consequential nature, regardless of any notice of the possibility of these damages.

23.2 **Supemus Indemnity.** Supemus agrees to indemnify, defend and hold harmless Supplier and Supplier's Affiliates, and its and their directors, officers, employees and agents, from and against any and all claims, losses, liabilities, lawsuits, proceedings, costs and expenses, including, without limitation, reasonable attorneys' fees (but not including the cost of recalls), arising out of or in connection with:

23.2.1 injuries and/or death to humans resulting from the use of any Product (including all finished Products or materials resulting from the provision of Supplier's services hereunder), including, without limitation, claims based on

negligence, warranty, strict liability or any other theory of product liability or a violation of applicable laws or regulations, except to the extent that such injuries or violations are the result of Supplier's negligence or willful misconduct in performing the services hereunder or breach of any covenant or agreement hereunder,

23.2.2 the negligence or willful misconduct of Supemus, or the negligence or willful misconduct in advertising, labeling, improper handling, or storage of Product by any person other than Supplier,

23.2.3 any misrepresentation by Supemus or breach by Supemus of any representation, warranty, covenant or agreement hereunder, or

23.2.4 infringement relating to any Product or API of Supemus and that is not attributable to Supplier Intellectual Property.

23.3 Supplier Indemnity. Supplier shall indemnify, defend and hold harmless Supemus and Supemus' affiliates, and its and their directors, officers, employees and agents, from and against any and all claims, losses, liabilities, lawsuits, proceedings, costs and expenses, including, without limitation, reasonable attorneys' fees (but not including the cost of recalls), arising out of or in connection with:

23.3.1 any negligence or willful misconduct of Supplier and/or Supplier's agents in performing the services hereunder,

23.3.2 any misrepresentation by Supplier or breach by Supplier of any representation, warranty, covenant or agreement hereunder, or

23.3.3 infringement by the Product relating to any Supplier Intellectual Property.

23.4 In the event that either Party seeks indemnification (an "Indemnified Party") under the terms of this Section 23, it shall inform the other Party (an "Indemnifying Party") of the claim as soon as reasonably practicable after it receives notice thereof, shall permit the Indemnifying Party, at the Indemnifying Party's cost, to assume direction and control of the defense of the claim, and shall co-operate as requested (at the expense of the Indemnifying Party), in the defense of the claim. The Indemnified Party shall cooperate with the Indemnifying Party in the defense, conduct, prosecution or termination of any claim at the Indemnifying Party's request and at the Indemnifying Party's cost and expense. The Indemnified Party shall not settle or otherwise compromise any claim or suit without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld.

23.5 In the event that the negligence or willful misconduct of both Supplier and Supemus contribute to any such loss, claim, injury, damage, cost or expense, Supplier and Supemus will each indemnify and hold harmless the other with respect to that

portion of the loss, claim, injury, damage, cost or expense attributable to its negligence or willful misconduct.

23.6 Limitation of Liability.

- (a) API. Except as expressly set forth in Section 8, under no circumstances will Supplier be responsible for any loss of or damage to the API unless due to the negligence or wilful misconduct of the Supplier. Supplier's maximum responsibility for loss of or damage to the API will not exceed the Maximum Credit Value set forth in Schedule D.
- (b) Maximum Liability. Supplier's maximum liability to Supernus under this Agreement for any reason whatsoever, including, without limitation, any liability arising under Section 9 or Section 23.3, or resulting from any and all breaches of its representations, warranties, or any other obligations under this Agreement, will not exceed the greater of \*\* dollars \*\* or \*\* percent \*\* of revenues per Year to Supplier under this Agreement, up to a maximum of \*\* dollars \*\* in the aggregate per Year.

24. Insurance.

Each party shall, at its own cost and expense, obtain and maintain in full force and effect during the Term the following: (A) Commercial General Liability Insurance with a limit of liability of not less than \*\* per occurrence and a \*\* aggregate; (B) Products and Completed Operations Liability Insurance with a per occurrence limit of liability of not less than \*\* and aggregate (C) Workers' Compensation Insurance at state statutory limits and Employers Liability Insurance with limits of not less than \*\* each accident; and (D) "All Risk" Property insurance for their individual property and property of others in their care, custody and control. Customer shall be responsible for In Transit/Warehouse Insurance in an amount equal to the full replacement value of its property while in, or in transit to or from, the Supplier facility as required under this Agreement. Each required insurance policy shall be obtained from an insurance carrier with an A.M. Best rating of at least A- VII. If any of the required policies of insurance are written on a claims made basis, such policies shall be maintained throughout the Term and for a period of at least \*\* thereafter. Each party shall obtain a waiver of subrogation clause from its property insurance carriers in favor of the other party. Each party shall be named as an additional insured within the other party's products liability insurance policies; provided, that such additional insured status will apply solely to the extent of the insured party's insurable indemnity obligations with regard to tort negligence under this Agreement. Upon the other party's written request from time to time, each party shall promptly furnish to the other party a certificate of insurance or other evidence of the required insurance.

25. Exclusivity. Provided that Supernus purchases not less than the minimum Product requirements from Supplier each year as set forth in Section 7.1, during the Term of this Agreement, Supplier agrees that it will not work on or perform any service on any product

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\*\* This portion has been redacted pursuant to a confidential treatment request.

containing Oxcarbazepine as an active ingredient in a controlled release formulation (controlled release includes, but is not limited to, sustained release, extended release, delayed or pulsed release) for any party other than Supernus for the duration of this Agreement; provided that this Section 25 shall expire on December 31, 2013 if the Product has not been approved by the FDA for commercial sale in the United States of America prior to that date. For the purposes of this Section 25, Oxcarbazepine means (i) 10, 11 - Dihydro-10-oxo-SH-dibenz(b,f)axepine-5-carboxamide; (ii) any isomers, salts, solvates, hydrates, or polymorphs, of (i).

26. **Notices.**

26.1 Any notice or other communication (except as provided in Section 10.2) shall be sufficiently made or given on the date of mailing if sent to such Party by facsimile on such date, with paper copy being sent by next day express delivery service, addressed to it at its address below (or such address as it shall designate by written notice given to the other Party).

26.2 Duly authorized Purchase Orders and forecasts required pursuant to Section 6 may be transmitted by facsimile machine or via email to the persons named on the Purchase Order, and such facsimile copy shall be deemed an original if signed by duly authorized representatives of both of the Parties or if receipt is otherwise confirmed. Such facsimiles or emails shall constitute valid, binding documents and shall be regarded as such upon receipt and confirmation. The original of the document sent by facsimile shall be promptly sent overnight courier or first class mail to the receiving Party so that accurate files may be maintained. Failure to send timely any original document shall not affect the validity or binding nature of such document.

For Supernus:

Supernus Pharmaceuticals, Inc  
1550 East Gude Drive  
Rockville, Maryland 20850  
Fax: 301.838.1385  
Email address: jbozick@supernus.com

For Supplier:

Patheon Inc.  
2100 Syntex Court  
Mississauga, Ontario L5N 7K9  
Canada  
Attention: Law Department  
Telecopier No.: 905.812.6613  
Email address: Joanne.Varao@patheon.com

***Fill in information above***

With a copy to:

Supernus Pharmaceuticals, Inc  
1550 East Gude Drive  
Rockville, Maryland 20850  
Fax: 301.838.1385  
Email address: gpatrick@supernus.com

With a copy to:

Patheon Inc.  
4721 Emperor Boulevard  
Research Triangle Park,  
NC 27703  
Attention: General Counsel  
Telecopier No.: 919-474-2269  
Email address:  
Michael.Lytton@patheon.com

*Fill in information above*

27. **General Terms and Conditions.**

27.1 **Disputes.** Supplier and Supernus agree to attempt to resolve promptly any dispute by negotiation between their respective executives who have authority to settle such dispute. If any dispute cannot be settled by negotiation then, at the request of either Supplier or Supernus, the dispute shall be submitted to mediation with a mediator chosen jointly by mutual agreement of the Parties. If the dispute cannot be resolved within a reasonable time through mediation, then either Party shall be free to institute action in federal court as set forth below. Notwithstanding any provision contained in this Section 21 to the contrary, the foregoing agreement to submit to mediation any dispute or controversy arising under this Agreement shall not preclude either Party from seeking injunctive or similar relief to avoid irreparable harm while the Parties attempt to resolve the dispute or controversy through mediation.

27.2 Applicable Law/Jurisdiction.

27.2.1 This Agreement is governed by and construed in accordance with the laws of the State of Delaware without giving effect to the principles of conflict of law thereof.

27.2.2 Each Party hereby irrevocably and unconditionally submits, for itself and its property, to the non-exclusive jurisdiction of any Delaware State or Federal court and any appellate court from any thereof; in any suit, action, or proceeding arising out of or relating to this Agreement, or for recognition or enforcement of any judgment, and each Party hereby irrevocably and unconditionally agrees that all claims in respect of any such action or proceeding may be heard and determined in such Delaware State court, or, to the extent permitted by applicable law, in such Federal court. Each Party agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by applicable law. Without limiting the foregoing, each Party agrees that service of process on such Party as provided in this Section 27.2 shall be deemed effective service of process on such Party.

27.2.3 Each Party hereby irrevocably and unconditionally waives, to the fullest extent it may legally and effectively do so, any objection which it may now or hereafter have to the laying of venue of any suit, action or proceeding arising out of or relating to this Agreement in any court referred to herein.

27.2.4 Each Party hereby irrevocably waives, to the fullest extent it may legally and effectively do so, the defense of an inconvenient forum to the maintenance of such suit, action, or proceeding in any such court, and agrees not to plead the same, and agrees that nothing herein will limit the right to sue in any other jurisdiction if a Delaware State or Federal court of competent jurisdiction sitting in New Castle County, Delaware rules or orders that it will not exercise jurisdiction over any such action or proceeding.

27.2.5 To the extent that a Party has or hereafter may acquire any immunity from jurisdiction of any court or from any legal process (whether through service of notice, attachment prior to judgment, attachment in aid of execution or execution, on the ground of sovereignty or otherwise) with respect to itself or its property, it hereby irrevocably waives, to the fullest extent it may legally and effectively do so, such immunity in respect of its obligations under this Agreement.

27.2.6 Each Party hereby acknowledges that a breach of a material covenant herein may cause irreparable harm to the non-breaching Party and that the remedy or remedies at law for any such breach may be inadequate. Each Party hereby agrees that, in the event of any such breach, in addition to all other available remedies hereunder, the non-breaching Party shall have the right to obtain equitable relief to enforce the provisions of this Agreement.

27.2.7 EACH PARTY HEREBY IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

27.3 No Waiver. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party.

27.4 Assignment. Supplier may not assign any of its rights or delegate any of its duties pursuant to this Agreement without the prior written consent of Supernus, which shall not be unreasonably withheld, except no such consent shall be required in the event of any assignment to any third party that assumes ownership or control of the Facility. Supernus may assign this Agreement to its affiliates and parent corporations, or to any third party (a) owning rights or a license under patents covering products containing Product or (b) holding registrations for Product; provided that any such assignment shall not release Supernus from its payment obligations hereunder.

27.5 Severability. If any provision of this Agreement is held to be invalid or unenforceable, all other provisions will continue in full force and effect, and the Parties will substitute for the invalid or unenforceable provision a valid and enforceable provision which conforms as nearly as possible with the original intent of the Parties.

27.6 Force Majeure. Notwithstanding anything to the contrary contained herein, neither Party shall be liable for non-performance, defective or late performance of any of its obligations under this Agreement (other than obligations to pay money) to the extent and for such periods of time as such non-performance, defective or late performance is due to reasons of strike, riots, terrorism, war, act of God, invasion, fire, explosion, floods, delay of carrier, shortage or failure in the supply of materials, acts of government or governmental agencies or instrumentalities and any other contingencies beyond the Parties' reasonable control. The Party affected will give written notice to the other Party of any material delay due to such causes. In the event of one of these contingencies, Supemus shall, in its discretion, first use or direct Supplier to use the Materials and finished Product inventories where possible. If inventories to manufacture are exhausted or unavailable, Supplier's obligation to supply under this Agreement and Supemus' obligation to purchase under this Agreement shall be temporarily suspended until the contingency is removed, but the Agreement shall otherwise remain in full force and effect. In the event a force majeure event prevents a Party's performance under this Agreement for one hundred eighty (180) consecutive days, the other Party may terminate this Agreement upon five (5) days prior written notice to the other Party, but such termination shall not be deemed a breach by the Party affected by the force majeure condition.

27.7 No License. No right or license under any patent or other proprietary right is granted by Supemus under this Agreement, except as specifically and expressly set forth herein.

27.8 Third-Party Beneficiaries. This Agreement is not intended to, and the Parties agree that it does not, bestow any benefit or right upon any third party.

27.9 Use of Names. Both Parties agree not to use or refer to, without the other Party's prior written permission, the existence or contents of this Agreement or the name of the other or any of its affiliates or parent corporations in any public statements, whether oral or written, unless such disclosures are required by law or regulation.

27.10 Independent Contractor. Nothing contained in this Agreement shall be deemed to constitute a partnership between Supemus and Supplier, or to constitute one as the agent of the other. Both Parties shall act solely as independent contractors, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party.

27.11 Headings. Headings in this Agreement are included for ease of reference only and are not to have any legal effect or otherwise be used in connection with the construction of any provision of this Agreement.

27.12 Entire Agreement. This Agreement, which includes all schedules, exhibit and Purchase Orders pursuant hereto, sets forth the entire Agreement and understanding of the Parties as to the subject matter hereof and supersedes any prior understandings, agreements or representations by or between the Parties, written or oral, which may have related to the subject matter hereof in any way. This Agreement may be amended only by a written document signed by authorized representatives of both Parties.

27.13 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument.

*[remainder of page intentionally blank; signatures follow]*

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives.

PATHEON INC.

Date: 8/23/2012

By: /s/ Stuart Grant (SEAL)

Name: Stuart Grant

Title: Chief Financial Officer

SUPERNUS PHARMACEUTICALS, INC.

Date: July 24, 2012

By: /s/ Gregory S. Patrick (SEAL)

Name: Gregory S. Patrick

Title: Chief Financial Officer

**SCHEDULE A**  
**PRODUCT LIST AND SPECIFICATIONS**

**Product List**

TBD

**Specifications**

Prior to the start of commercial manufacturing of Product under this Agreement Supemus will give Supplier the originally executed copies of the FDA approved Specifications. If the Specifications received are subsequently amended, then Supemus will give Supplier the revised and originally executed copies of the revised Specifications. Upon acceptance of the revised Specifications, Supplier will give Supemus a signed and dated receipt indicating Supplier's acceptance of the revised Specifications.

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**SCHEDULE B**  
**MINIMUM ORDERING QUANTITY, ANNUAL QUANTITY, AND PRICE**

**Pricing Tables**

*Manufacturing and Packaging Prices*

Pricing includes the cost of labour, overhead, raw materials, packaging components and QC testing of raw materials. The following price tables are applicable through December 31, 2013.

**150mg Strength - 100's Bottles**

Product	Lots	Annual Quantity (Bottles)	Minimum Ordering Quantity (Bottles)	Price per 100's Bottle		
				Material Price	Conversion Price	Full Service Price
Oxcarbazepine ER Tablets	1	**	**	**	**	**
Oxcarbazepine ER Tablets	3	**	**	**	**	**

**150mg Strength — 1x5 Blister Cards**

Product	Lots	Annual Quantity (Blister Cards)	Minimum Ordering Quantity (Blister Cards)	Price per 1x5 Blister Card		
				Material Price	Conversion Price	Full Service Price
Oxcarbazepine ER Tablets	1	**	**	**	**	**

**150mg Strength — Bulk Tablets**

Product	Lots	Annual Quantity (Tablets)	Minimum Ordering Quantity (Tablets)	Price per 1,000 Tablets		
				Material Price	Conversion Price	Full Service Price
Oxcarbazepine ER Tablets	1	**	**	**	**	**
Oxcarbazepine ER Tablets	3	**	**	**	**	**

\*\* This portion has been redacted pursuant to a confidential treatment request.

**300mg Strength — 100's Bottles**

Product	Lots	Annual Quantity (Bottles)	Minimum Ordering Quantity (Bottles)	Price per 100's Bottle		
				Material Price	Conversion Price	Full Service Price
Oxcarbazepine ER Tablets	1	**	**	**	**	**
Oxcarbazepine ER Tablets	3	**	**	**	**	**

**300mg Strength — 1x5 Blister Cards**

Product	Lots	Annual Quantity (Blister Cards)	Minimum Ordering Quantity (Blister Cards)	Price per 1x5 Blister Card		
				Material Price	Conversion Price	Full Service Price
Oxcarbazepine ER Tablets	1	**	**	**	**	**

**300mg Strength — Bulk Tablets**

Product	Lots	Annual Quantity (Tablets)	Minimum Ordering Quantity (Tablets)	Price per 1,000 Tablets		
				Material Price	Conversion Price	Full Service Price
Oxcarbazepine ER Tablets	1	**	**	**	**	**
Oxcarbazepine ER Tablets	3	**	**	**	**	**

**600mg Strength — 100's Bottles**

Product	Lots	Annual Quantity (Bottles)	Minimum Ordering Quantity (Bottles)	Price per 100's Bottle		
				Material Price	Conversion Price	Full Service Price
Oxcarbazepine ER Tablets	1	**	**	**	**	**
Oxcarbazepine ER Tablets	3	**	**	**	**	**

\*\* This portion has been redacted pursuant to a confidential treatment request.

**600mg Strength — 1x5 Blister Card**

Product	Lots	Annual Quantity (Blister Cards)	Minimum Ordering Quantity (Blister Cards)	Price per 1x5 Blister Card		
				Material Price	Conversion Price	Full Service Price
Oxcarbazepine ER Tablets	1	**	**	**	**	**

**600mg Strength — Bulk Tablets**

Product	Lots	Annual Quantity (Tablets)	Minimum Ordering Quantity (Tablets)	Price per 1,000 Tablets		
				Material Price	Conversion Price	Full Service Price
Oxcarbazepine ER Tablets	1	**	**	**	**	**
Oxcarbazepine ER Tablets	3	**	**	**	**	**

Note: Refer point 2, 'Campaign Assumptions', for additional detail on the manufacturing and packaging batch campaigns assumed in this proposal.

**Key Technical Assumptions**

Below are listed the main assumptions that were utilized by Patheon for quoting this product. Should any of the assumptions change, then the prices will be revised accordingly.

Manufacturing Assumptions

- 1.1 The manufacturing process at Patheon will closely follow the process information provided by Supemus and Patheon's best estimates.
- 1.2 The API, Oxcarbazepine, has been preliminarily evaluated by Patheon as a Toxicity \*\* and can be handled safely using existing equipment and facility.
- 1.3 The core tablet weights and manufacturing batch sizes for each strength proposed by Patheon are summarized in the following table.

Parameter	150mg Tablets	300mg Tablets	600mg Tablets
Tablet weight (mg)	**	**	**
Batch size at Patheon (tablets)	**	**	**
Batch size at Patheon (Kg)	**	**	**

\*\* This portion has been redacted pursuant to a confidential treatment request.

1.4 The following manufacturing equipment train is proposed for Oxcarbazepine Tablets.

Process Step	150mg Tablets	300mg Tablets	600mg Tablets
**	**	**	**
**	**	**	**
**	**	**	**
**	**	**	**
**	**	**	**
**	**	**	**
**	**	**	**

- 1.5 For 150mg and 300mg strengths, there will be \*\* load per batch.
- 1.6 For 600mg strength, there will be \*\* loads per batch that will be combined for final blending in the \*\*.
- 1.7 For 150mg and 300mg strengths, coating will be conducted in a \*\*, assuming \*\* load per batch.
- 1.8 For 600mg strength, coating will be completed in a \*\*, assuming \*\* load per batch.
- 1.9 Printing will be single sided and will be done on the \*\*.
- 1.10 A manufacturing yield of \*\* for all strengths is assumed.

Campaign Assumptions

2.1 The pricing outlined in 'Pricing Table', reflects the campaigns listed below.

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\*\* This portion has been redacted pursuant to a confidential treatment request.

**100's Bottles**

<b>Product Description</b>	<b>Manufacturing Campaign (Batches)</b>	<b>Packaging Campaign (Batches)</b>	<b>Bottles per Packaging Campaign</b>
Oxcarbazepine ER Tabs — 150mg, 100's Bottles	1	1	**
Oxcarbazepine ER Tabs — 150mg, 100's Bottles	3	3	**
Oxcarbazepine ER Tabs — 300mg, 100's Bottles	1	1	**
Oxcarbazepine ER Tabs — 300mg, 100's Bottles	3	3	**
Oxcarbazepine ER Tabs — 600mg, 100's Bottles	1	1	**
Oxcarbazepine ER Tabs — 600mg, 100's Bottles	3	3	**

**1x5 Blister Cards**

<b>Product Description</b>	<b>Manufacturing Campaign (Batches)</b>	<b>Packaging Campaign (Batches)</b>	<b>Blister Cards per Packaging Campaign</b>
Oxcarbazepine ER Tabs — 150mg, 1x5 Blister Cards	1	1	**
Oxcarbazepine ER Tabs — 300mg, 1x5 Blister Cards	1	1	**
Oxcarbazepine ER Tabs — 600mg, 1x5 Blister Cards	1	1	**

**Bulk Tablets**

<b>Product Description</b>	<b>Manufacturing Campaign (Batches)</b>	<b>Tablets per Manufacturing Campaign</b>
Oxcarbazepine ER Tabs — 150mg, 1,000's Bulk Tablets	1	**
Oxcarbazepine ER Tabs — 150mg, 1,000's Bulk Tablets	3	**
Oxcarbazepine ER Tabs — 300mg, 1,000's Bulk Tablets	1	**
Oxcarbazepine ER Tabs — 300mg, 1,000's Bulk Tablets	3	**
Oxcarbazepine ER Tabs — 600mg, 1,000's Bulk Tablets	1	**
Oxcarbazepine ER Tabs — 600mg, 1,000's Bulk Tablets	3	**

\*\* This portion has been redacted pursuant to a confidential treatment request.

Packaging Assumptions

3.1 Oxcarbazepine ER tablets will be packaged into the configurations listed in the tables below.

**Oxcarbazepine ER Tablets — 100's Bottles**

150mg	300mg	600mg
100 tablets per 60cc HDPE square bottle	100 tablets per 120cc HDPE square bottle	100 tablets per 215cc HDPE square bottle
**	**	**
**	**	**
**	**	**
** bottle label	** bottle label	** bottle label
** outsert	** outsert	** outsert
1 shipper carton containing 24 bottles	1 shipper carton containing 24 bottles	1 shipper carton containing 24 bottles
60cc bottles packed in shippers with label	120cc bottles packed in shippers with label	215cc bottles packed in shippers with label

**Oxcarbazepine ER Tablets**

1x5 Thermal Form Blister Cards (150mg, 300mg and 600mg)	Bulk Tablets (150mg, 300mg and 600mg)
5 tablets per thermal form blister card	Pails/Lids 15L HDPE White
Shipper 100 x 1 card	Bags, Clear LDPE
Shipper label	Drum Security Seal

3.2 Standard in-house primary packaging components will be used for bulk packaging of tablets.

Testing Assumptions

- 4.1 Testing for raw materials and packaging components are based on information to date at the site.
- 4.2 Micro testing has not been included on the finished product.
- 4.3 Finished product testing is assumed to be performed by Supemus.

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\*\* This portion has been redacted pursuant to a confidential treatment request.

Cleaning Assumptions

5.1 Patheon assumes the current cleaning procedures are adequate and full cleaning occurs after each campaign.

**SCHEDULE C**  
**ANNUAL STABILITY TESTING**

Supplier and Supemus will agree in writing on any stability testing to be performed by Supplier on the Products, if applicable. Such agreement will specify the commercial and Product stability protocols applicable to the stability testing and the fees payable by Supemus for this testing.

**SCHEDULE D**  
**API**

<b><u>API</u></b>	<b><u>Supplier</u></b>
Oxcarbazepine	**

**ACTIVE MATERIALS CREDIT VALUE**

The Active Materials Credit Value will be as follows:

<b><u>PRODUCT</u></b>	<b><u>API</u></b>	<b><u>ACTIVE MATERIALS CREDIT VALUE</u></b>
TBD	Oxcarbazepine	Supernus' actual cost for API not to exceed ** per kilogram

**MAXIMUM CREDIT VALUE**

Supplier's liability for API calculated in accordance with Section 8 of the Agreement for any Product in a Year will not exceed, in the aggregate, the maximum credit value set forth below:

<b><u>PRODUCT</u></b>	<b><u>MAXIMUM CREDIT VALUE</u></b>
TBD	The greater of ** dollars ** or ** percent ** of revenues per Year to Supplier under this Agreement, up to a maximum of ** dollars ** in the aggregate per Year.

\*\* This portion has been redacted pursuant to a confidential treatment request.

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**SCHEDULE E**  
**TECHNICAL DISPUTE RESOLUTION**

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

1. **Appointment of Expert.** Within ten Business Days after a Party requests under Section 12.2 that an expert be appointed to resolve a Technical Dispute, the Parties will jointly appoint a mutually acceptable expert with experience and expertise in the subject matter of the dispute. If the Parties are unable to so agree within the ten Business Day period, or in the event of disclosure of a conflict by an expert under Paragraph 2 hereof which results in the Parties not confirming the appointment of the expert, then an expert (willing to act in that capacity hereunder) will be appointed by an experienced arbitrator on the roster of ADR Chambers who will be a retired judge of the Ontario Superior Court of Justice or on the roster of the American Arbitration Association.
2. **Conflicts of Interest.** Any person appointed as an expert will be entitled to act and continue to act as an expert even if at the time of his appointment or at any time before he gives his determination, he has or may have some interest or duty which conflicts or may conflict with his appointment if before accepting the appointment (or as soon as practicable after he becomes aware of the conflict or potential conflict) he fully discloses the interest or duty and the Parties will, after the disclosure, have confirmed his appointment.
3. **Not Arbitrator.** No expert will be deemed to be an arbitrator and the provisions of the *Arbitration Act* (Ontario) or of any other applicable statute (foreign or domestic) and the law relating to arbitration will not apply to the expert or the expert's determination or the procedure by which the expert reaches his determination under this Schedule E.
4. **Procedure.** Where an expert is appointed:
  - (a) **Timing.** The expert will be so appointed on condition that (i) he promptly fixes a reasonable time and place for receiving representations, submissions or information from the Parties and that he issues the authorizations to the Parties and any relevant third party for the proper conduct of his determination and any hearing and (ii) he renders his decision (with full reasons) within 15 Business Days (or another date as the Parties and the expert may agree) after receipt of all information requested by him under Paragraph 4(b) hereof.
  - (b) **Disclosure of Evidence.** The Parties undertake one to the other to give to any expert all the evidence and information within their respective possession or control as the expert may reasonably consider necessary for determining the matter before him which they will disclose promptly and in any event within five Business Days of a written request from the relevant expert to do so.
  - (c) **Advisors.** Each Party may appoint any counsel, consultants and advisors as it feels appropriate to assist the expert in his determination and so as to present their

respective cases so that at all times the Parties will co-operate and seek to narrow and limit the issues to be determined.

- (d) Appointment of New Expert. If within the time specified in Paragraph 4(a) above the expert will not have rendered a decision in accordance with his appointment, a new expert may (at the request of either Party) be appointed and the appointment of the existing expert will thereupon cease for the purposes of determining the matter at issue between the Parties save this if the existing expert renders his decision with full reasons prior to the appointment of the new expert, then this decision will have effect and the proposed appointment of the new expert will be withdrawn.
- (e) Final and Binding. The determination of the expert will, except for fraud or manifest error, be final and binding upon the Parties.
- (f) Costs. Each Party will bear its own costs for any matter referred to an expert hereunder and, in the absence of express provision in the Agreement to the contrary, the costs and expenses of the expert will be shared equally by the Parties.

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

**SCHEDULE F**  
**COMMERCIAL QUALITY AGREEMENT**

*[to be attached at end of document]*

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**SCHEDULE G**  
**FORM OF SHIPPING LOGISTICS PROTOCOL**

Shipping terms will be EXW (INCOTERMS 2000) Supplier's shipping point at the Facility.

Exports of Products from Canada to the United States

1. Shipping terms will be EXW (INCOTERMS 2000) Supplier's shipping point at the Facility.
2. Supernus, as the importer of record into the United States, will advise Supplier prior to export of the Products from Canada of Supernus' designated customs broker and freight forwarder to enable Supplier to complete all applicable shipping documentation.

**[NOTE TO DRAFT: Use this section if we are exporting outside of North America]**

International Exports of Products from Canada (other than to the United States)

**[NOTE TO DRAFT: Use next 3 clauses if we are exporting EXW to outside of North America. We can only ship EXW to outside of North America if Supernus has a Canadian affiliate that can act as the "exporter of record" from Canada. Many clients do not have Canadian affiliates, in which case export to outside of North America must be FCA.]**

**EX WORKS**

1. Shipping terms will be EXW (INCOTERMS 2000) Supplier's shipping point at the Facility.
2. Supernus will designate its exporter of record from Canada and will advise Supplier of the name and address of that affiliate.
3. Supernus will instruct its Canadian affiliate to advise Supplier prior to export of the Products from Canada of the affiliate's designated customs broker and freight forwarder to enable Supplier to complete all applicable shipping documentation.

**[NOTE TO DRAFT: Use this section if we are exporting outside of North America and if the shipment is not EXW - see prior note to draft. In most cases, we will use FCA so the following 3 clauses will apply rather than the prior 3 clauses.]**

**FCA**

1. Shipping terms will be FCA (INCOTERMS 2000) Supplier's shipping point at the Facility.
  2. Supplier, as the exporter of record from Canada, will carry out all customs formalities necessary to export the Products including declaring the value of the Products being exported from Canada by completing a B-13 Export Declaration form which will be completed showing Supplier as the exporter of record of the Products with a value equivalent to Supplier's selling Price of the Products to Supernus plus assists. The assist value will be calculated in a manner consistent with the method of calculation used in
-

calculating the values provided under Section 2.1(f) of the Agreement and as may be specified in the instructions of Canada Revenue Agency at time of export. For the purposes hereof, "assists" means (a) materials, components, parts, and other goods incorporated in the Products; (b) tools, dies, moulds, and other goods utilised in the production of the Products; (c) any materials consumed in the productions of the Products; (d) engineering, development work, art work, plans and sketches. undertaken by Supplier for the production of the Products.

3. Supplier will report exports directly to Canada Revenue Agency and Statistics Canada at the time of shipment from the Facility.
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[SUPERNUS LETTERHEAD]

Form of Logistics Routing Guide

Patheon Inc.

[INSERT ADDRESS]

Attention: A/M

**1. Routine Routing/Shipping Instructions**

The following lists the recommended agents and procedures for shipments of [PRODUCT NAME] from Supplier's manufacturing site at [INSERT SITE ADDRESS], Ontario, Canada to [INSERT DESTINATION NAME AND ADDRESS].

**AGENTS:**

- Freight forwarder Contact: PH: ( )
- Customs broker Contact: PH: ( )

Questions concerning transport logistics should be directed to [SUPERNUS CONTACT INFO].

The following documents must be provided to the carrier for transport and customs purposes:

- Proforma Invoice
- Bill of Lading ("B/L")
- Applicable Permits/Declarations
- Packing List
- If eligible, NAFTA Certificate of Origin will be provided in blanket form yearly to Supernus Pharmaceuticals, Inc. or its broker.

Upon shipment departure from Supplier, a full set of documents must also be faxed to the following individuals:

- [INSERT SUPERNUS CONTACT FAX OR EMAIL]

**Freight is shipped to:**

[INSERT DESTINATION NAME AND ADDRESS]

**Information to be provided on Proforma Invoice.**

- Net Quantity
- SupplierCode & Lot Number
- Supernus Lot Number/ Purchase Order ("PO")Number
- \$ / Unit Including Assist Value (API Usage) & Toll Manufacturing Charge
- HTS (Harmonize Tariff Schedule)#
- NDC/IND/ANDA
- FDA Product Code
- Ship Date
- Supplier Bill of Lading Number
- Gross Weight
- Number of Pallets

**Assist Values:**

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- [INSERT API NAME] \$/kg.

**Note:** Supernus Pharmaceuticals, Inc. will provide updated values during the first month of each calendar year. If a change occurs throughout the year, Supplier will be notified within 30 days. Method of valuation for API will be provided in writing to Patheon Inc.

**Information to be provided on Bill of Lading:**

- B/L Number
- Carrier
- Origin Point
- Shipper Information
- Consignee
- Consignee Address
- Ship Date
- Number of Pallets
- Gross Weight
- PO Number for each Product/Lot
- Description of Goods Indication PC, Lot Number Quantity
- Seal Number
- Freight Terms (EXW or FCA)
- Carrier Signature

**Information to be provided on Packing List:**

- Ship date
- Bill of Lading Number
- Number of Pallets
- Weight
- Product Description
- SupplierCode Number, if applicable
- SupplierLot Number, if applicable
- Number of Full Cartons (drums if bulk) x Quantity Per Carton
- Number of Partial Cartons (drums if bulk) x Quantity Per Carton
- Total Number of Cartons with Total Quantity Shipped

**2. *Non Routine Routing/Shipping Instructions***

As non-standard shipments are unique, the specific situations are to be discussed and agreed to by both Supplier and Supernus Pharmaceuticals, Inc. prior to shipment. Examples of nonstandard shipments are shipping study samples, clinical/development batches, etc.

Yours truly,

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AUTHORIZED SIGNATORY

Supernus Pharmaceuticals, Inc.

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**SCHEDULE H**  
**QUARTERLY API INVENTORY REPORT**

TO: Supemus Pharmaceuticals, Inc.  
FROM: Patheon Inc.  
RE: API quarterly inventory report under Section 2.2(a) of the Commercial Supply Agreement dated • (the “Agreement”)

Reporting quarter:

API on hand at beginning of quarter: kg (A)

API on hand at end of quarter: kg (B)

Quantity Received during quarter: kg (C)

Quantity Dispensed(1) during quarter: kg  
(A+ C—B)

Quantity Converted during quarter: kg  
(total API in Products produced and not rejected, recalled or returned)

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

PATHEON INC. DATE: \_\_\_\_\_

Per: \_\_\_\_\_  
Name:  
Title:

---

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

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**SCHEDULE I**  
**REPORT OF ANNUAL API INVENTORY RECONCILIATION**  
**AND CALCULATION OF ACTUAL ANNUAL YIELD**

TO: Supemus Pharmaceuticals, Inc.  
 FROM: Patheon Inc.  
 RE: API annual inventory reconciliation report and calculation of Actual Annual Yield under Section 2.2(a) of the Commercial Supply Agreement dated • (the “Agreement”)

Reporting Year ending:

API on hand at beginning of Year: kg (A)

API on hand at end of Year: kg (B)

Quantity Received during Year: kg (C)

Quantity Dispensed(1) during Year: kg (D)  
 (A+C-B)

Quantity Converted during Year: kg (E)  
 (total API in Products produced and not rejected, recalled or returned)

Active Materials Credit Value: \$ / kg (F)

Target Yield: % (G)

Actual Annual Yield: % (H)  
 ((E/D) \* 100)

Shortfall: \$ (I)  
 (((G- 5) - H)/100) \* F \* D  
 (if a negative number, insert zero)

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

---

Based on the foregoing reimbursement calculation Supplier will reimburse Supemus the amount of \$ .

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

DATE: \_\_\_\_\_

PATHEON INC.

Per: \_\_\_\_\_  
Name:  
Title:

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**SCHEDULE J**  
**EXAMPLE OF PRICE ADJUSTMENT DUE TO CURRENCY FLUCTUATION**  
**Section 12.2.4**

Forex Trading	Exchange Rates	Money Transfers	Currency Hedging	About Us	My Account
	<b>OANDA</b>	Currency Converter	Currency Tools	Data Services	
Home	Currency Tools	Historical Exchange Rates			

Historical Exchange Rates: Results

Conversion Table: USD to CAD (Interbank rate)

Time period: 10/01/08 to 09/30/09.

Average (365 days): 1.18007 — “Set Exchange Rate”

---

**SAMPLE EXCHANGE CALCULATION**

Initial Exchange Rate: 1.00000 CAD/USD  
Set Exchange Rate: 1.18007 CAD/USD

Initial Price: \*\*  
Revised Price (FX): \*\* (Material price and PPI adjustments)

Calculation:

$$\begin{aligned} [\text{Revised Price (After FX)}] &= [\text{Revised Price (Before FX)}] \times [\text{Initial Exchange Rate}] / [\text{Set Exchange Rate}] \\ &= ** \times 1.00000 / 1.18007 \\ &= ** \end{aligned}$$

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\*\* This portion has been redacted pursuant to a confidential treatment request.

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**SCHEDULE 6.2**  
**FORM OF PURCHASE ORDER**

PURCHASE ORDER NO. \_\_\_\_\_

This Purchase Order No. \_\_\_\_\_ is agreed upon this \_\_\_\_\_, 20\_\_\_\_ between the Purchase Order Managers identified below of both Supplier and Supernus, pursuant to a Commercial Supply Agreement dated \_\_\_\_\_, 20\_\_\_\_ between such parties and is to be part of such Commercial Supply Agreement.

1. Quantity and Lot Number(s) of API to be Used:
2. Quantity Ordered (by batch and configuration)
3. The Product Specifications are attached hereto.
4. The Product shall be shipped to Supernus or its specified subcontractor or sublicensee at:

5. Estimated Compensation: Supernus shall pay to Supplier the estimated sum of US \$ \_\_\_\_\_ in consideration of the performance of this Purchase Order.

[6. Estimated Delivery Schedule: [XXX]]

PATHEON INC.

SUPERNUS PHARMACEUTICALS, INC.

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_  
Fax: \_\_\_\_\_

By: \_\_\_\_\_ (SEAL)  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_  
Fax: \_\_\_\_\_

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**SCHEDULE 7.6**  
**VALIDATION SERVICES**

Supplier and Supemus will agree in writing on any validation services to be performed by Supplier on the Products, if applicable.

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## SCHEDULE 7.7

### Costs Included in Unit Price Proposal

- Excipients and component QC testing
- Active Pharmaceutical Ingredients (API) identity test
- Raw materials and packaging components costs
- Direct labour
- General factory overheads
- GMP confirmation of the processing operation
- One Supemus audit every twelve-months (and additional audits if for cause) as set forth in Section 0.1
- Regulatory Inspection support as set forth in Section 10.2
- Supplier's retention of records and retained samples as set forth in Section 11.1
- Copies of documents as set forth in Section 11.2
- Manufacturing site DMF and updates as set forth in Section 11.3
- Operations Team Meetings and Reports as Set forth in Section 11.5
- Product data for Annual Report and Annual Product Review Report as set forth in Section 11.5.2
- Data review and verification by Supplier as set forth in Section 11.6

### Costs Not Included in Unit Price Proposal

- Finished product testing (to be performed by Supemus)
  - API to be supplied by Supemus at no cost to Patheon
  - API complete QC testing (to be performed by Supemus or agent of Supemus)
  - API analytical reference standards
  - Technology transfer and registration batches
-

- Process validation, cleaning validation, shipping validation
  - Regulatory support and CMC files updating
  - Routine periodic auditing of component suppliers not currently on Patheon's approved list
  - Post marketing stability testing
  - Any specific visual inspection of the bulk or of the finished products
  - Any specific shipment preparations for specific countries (Japan etc.) which will be quoted when they are defined
  - Replacement HPLC columns and replacement tablet tooling
-

**Quality Agreement  
For  
Commercial Product  
Manufacturing**

Between

Supernus Pharmaceuticals, Inc.  
1550 East Gude Dr.  
Rockville, MD — USA

and

Patheon Inc  
Whitby Operations  
111, Consumers Drive  
Whitby, Ontario  
Canada L1N 5Z5

Review Due Date (maximum 5 years from date of execution): 25 - Oct - 2017

**CONFIDENTIAL**

## **1. Scope**

Under a Commercial Supply Agreement between Supernus Pharmaceuticals, Inc. (hereinafter referred to as “SUPERNUS”) Patheon Inc. (hereinafter referred to as “SUPPLIER”); SUPPLIER agreed to provide manufacturing of product, packaging and labeling services in respect to SUPERNUS drug product (hereinafter referred to as “PRODUCT”).

In the event of any conflict between the terms of this Quality Agreement and the Commercial Supply Agreement, the Commercial Supply Agreement shall take precedence except with respect to any specific quality related issue.

## **2. Applicable GMP Standard**

SUPPLIER shall manufacture the PRODUCT in compliance with United States (US) 21 Code of Federal Regulations (CFR) Part 210 and 211 and guidance(s); United States Pharmacopeia (USP) Convention, International Conference on Harmonization, and Division 2 of Part C of the Food and Drug Regulations (Canada) together with the latest Health Canada, FDA and EMA guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time and as interpreted by relevant ICH guidelines.

### **General Considerations**

Any communications about the subject matter of this Agreement will be directed, in the first instance, to the person(s) identified in Section 23.

If any provision of this Agreement should be or found invalid, or unenforceable by law, the rest of the Agreement will remain valid and binding and the parties will negotiate a valid provision which meets as close as possible the objective of the invalid provision.

If this Agreement requires modification such that either party affected cannot be reasonably expected to continue to perform under this Quality Agreement, then the parties will negotiate and revise the Quality Agreement accordingly. Any revision of this Quality Agreement will be made in writing and signed by both parties.

## **3. Duration of Agreement**

This Quality Agreement shall commence on execution thereof by both parties and subject to the following provisions of this clause shall expire or terminate in respect of any Manufacturing Agreement on the expiry or termination of that

agreement. Any section of this Quality Agreement which has a predefined retention, survival or maintenance period, for example batch/lot documentation, raw data storage, PRODUCT complaints and sample retention, shall survive the termination of this contract for the period defined in the appropriate section. This Quality Agreement cannot be modified except with the written approval of all signatory parties of this document. Specifications and master batch records may be modified with written authorization from Quality Assurance representatives of both companies. Appendices may be updated as necessary with written authorization from both parties.

This Agreement will start on the latest signature date in Section 26..

#### **4. Confidentiality**

SUPERNUS and SUPPLIER will treat as confidential all data supplied by the other in connection with the manufacture of the PRODUCT or performance of this Quality Agreement pursuant to the terms of the Confidential Disclosure Agreement between the parties and/or the terms of the Commercial Supply Agreement concerning confidential information.

#### **5. Security**

SUPPLIER has and will maintain controlled access to the Plant through a security card key or similar system. All visitors will be required by SUPPLIER to sign-in and be escorted during any site visit. All Third Party visitors, excluding representatives of Regulatory Authorities, will be required to enter into a confidentiality agreement no less onerous than the terms of the Confidential Disclosure Agreement prior to entering areas being used to manufacture SUPERNUS PRODUCTS.

#### **6. Regulatory Requirements**

##### **6.1 Permits/Licenses**

SUPERNUS will be solely responsible for obtaining or maintaining, any permits or other regulatory approvals in respect of the PRODUCT or its specifications.

SUPPLIER will obtain and maintain the appropriate manufacturing license(s) to allow for the Manufacturing services in accordance with local and federal regulatory requirements.

## **6.2 Regulatory Filing I Registration Change Control**

SUPERNUS will determine whether changes to or related to the PRODUCT will impact a regulatory filing and will apply for and receive approval for any required manufacturing amendment, change or addition to its PRODUCT authorization.

Master Production Records and Specifications will be approved by both SUPERNUS' Quality Assurance and SUPPLIER's Quality Assurance. No changes to the above documents may be implemented without the signed authorization from an authorized member of the SUPERNUS Quality Assurance Department.

All required regulatory approvals must be obtained prior to implementation. Variations to established production procedures may be initiated by either party, but must be agreed to in writing by the authorized members of the Quality Assurance Departments of both companies before implementation. The release status of the finished PRODUCT produced under a variation will be decided as part of the variation approval process. Quality Assurance of the SUPPLIER and SUPERNUS will have the right to reject the batch/lot should they conclude that such action is appropriate.

SUPERNUS is responsible for all communications with Regulatory Authorities related to the PRODUCT, as well as for the approval, maintenance, and updating of approval in a timely manner.

## **7. Regulatory Compliance**

SUPPLIER will ensure that PRODUCT is manufactured and shipped in strict compliance with current US Federal and European Community (EC) regulatory and statutory requirements relating to GMP (US 21 CFR parts 210 and 211 and EU Directive 2003/94/EC for the manufacture of finished medicinal product) as applicable to the manufacture of the PRODUCT, regulatory approvals and local laws and regulations applicable at the site(s) of manufacture and/or testing.

### **7.1 Government Agency Inspections, Communication and Requisitions**

SUPPLIER will permit all relevant inspections by regulatory authorities of premises, procedures, and documentation.

SUPPLIER will notify the head of SUPERNUS Quality Assurance immediately of receipt of any notice of inspection from a regulatory authority pertaining directly to the PRODUCT and within one (1) Business Day (BD) of any regulatory

authority request for PRODUCT samples, batch documentation, or other information related to the PRODUCT.

SUPPLIER will notify the head of SUPERNUS Quality Assurance within one (1) BD of receipt of any major Form 483 observations, warning letter or the like from any regulatory agency that relates directly to the PRODUCT; or if the supply of PRODUCT will be affected, or if the facilities or personnel used to produce, test or package the PRODUCT will be affected.

SUPERNUS' Head of Quality Assurance will be notified within one (1) BD of any inspection by a Regulatory Authority regarding the PRODUCT. SUPPLIER will permit a representative from SUPERNUS Quality Assurance to be present at inspections directly relating to involving SUPERNUS PRODUCTS. SUPPLIER will secure SUPERNUS' agreement prior to making any commitment to a Regulatory Authority regarding the PRODUCT. Should the Regulatory Authority issue a warning letter or any major client-specific observations to SUPPLIER, a copy of these documents will be forwarded to SUPERNUS Quality Assurance within five (5) BD of receipt. Major Client-specific observations would include observations that have potential SUPERNUS PRODUCT safety impact. If necessary, SUPPLIER may redact names of other customers or products to protect confidentiality. Copies of formal response letters from SUPPLIER, including 483 observations or similar, to the Regulatory Authority that may have major SUPERNUS PRODUCT impact will also be forwarded to SUPERNUS Quality Assurance within five (5) BD upon issuance to the Regulatory Authority.

Inspection report responses from SUPPLIER related to the PRODUCT will be reviewed and approved by SUPERNUS Quality Assurance prior to submission to the regulatory agency.

## **7.2 Annual Product Review**

SUPPLIER will provide requested information to SUPERNUS in a timely manner.

SUPPLIER will perform an annual product review on commercial products and will issue a report to SUPERNUS no later than three months after the conclusion of an annual manufacturing cycle. This report will be a review of any changes in the manufacturing, packaging, testing, or validation of the PRODUCT in the previous year; a summary of lots made, released, and rejected. Also, control charting or trend analysis of key PRODUCT parameters will be performed on an annual basis. Any abnormalities will be explained in the annual review. This review will be conducted in accordance with 21 CFR 211.180(e) and any other appropriate regulations.

## **8. Quality Management**

### **8.1 GMP, Health and Safety Compliance**

SUPPLIER will conduct operations in compliance with applicable environmental, occupational health and safety laws, and current GMP regulations.

### **8.2 Organization and Personnel**

SUPPLIER shall have a Quality Assurance unit that have the responsibility for approving and rejecting all procedures or specifications that can impact the identity, strength, quality, and purity of the PRODUCT. SUPPLIER's Quality Assurance unit shall have Standard Operating Procedures (SOP) to fulfill its responsibilities.

SUPPLIER shall have documented evidence of sufficient, appropriate and qualified personnel and/or consultant(s) thru training, education, experience or a combination thereof to perform activities related to the manufacturing and supervision of PRODUCT manufacture.

SUPPLIER shall ensure that all personnel engaged in GMP activities are aware and knowledgeable of their responsibilities.

### **8.3 Audit Rights**

SUPPLIER will permit audits based on reasonable prior written notice, of all relevant premises, procedures and documentation by SUPERNUS representatives; to the extent such audits are related to SUPERNUS' PRODUCT. SUPERNUS audits are limited to one audit per calendar year unless for cause.

SUPERNUS shall have the right to conduct one Manufacturing Audit per year (such annual Manufacturing Audit to be hereinafter referred to as an "Annual MA").

Event MA: In addition to the Annual MA, in the event that SUPPLIER shall receive a "483 Observation" or a "Warning Letter" from the Food and Drug Administration (FDA) or any foreign equivalent outside the USA relating to the manufacture, packaging, testing or labeling of the SUPERNUS PRODUCT by SUPPLIER; or similar notice alleging non-compliance; SUPERNUS has rejected a batch/lot of PRODUCT where it has been agreed or determined that such PRODUCT failed to meet Specifications or cGMP; or SUPERNUS or SUPPLIER have received a series of complaints which are judged to be major from Third Parties within any year relating to the manufacture (individually or collectively, an "Event") SUPERNUS shall have the right to conduct additional Manufacturing Audits according to the terms specified below (such Event Manufacturing Audit(s) to be hereinafter referred to as an "Event MA(s)").

Routine Visits: It is agreed that SUPERNUS may arrange routine observational visits to the facility in which manufacture of SUPERNUS PRODUCT is to be undertaken.

Manufacturing Audit: For purposes of this Agreement, the term “Manufacturing Audit” shall mean an audit of SUPPLIER’s Plant for the PRODUCT by no more than two employees and/or agents of SUPERNUS for purposes of reviewing SUPPLIER’s procedures and processes used in Manufacturing the SUPERNUS PRODUCT. Any such agents shall be qualified to conduct manufacturing audits, shall comply with all SUPPLIER’s facility rules regarding safety and security notified by SUPPLIER to SUPERNUS and its employees and agents and shall execute a written agreement to maintain in confidence all Information obtained during the course of any such audit except for disclosure to SUPERNUS subject to the terms hereof. Each Manufacturing Audit shall be conducted during SUPPLIER’s normal business hours and upon at least fifteen (15) BD prior written notice to SUPPLIER in the case of an Annual MA, or with two (2) BD notice to SUPPLIER in the case of an Event MA. In all cases SUPERNUS shall ensure that its employees or agents will conduct each Manufacturing Audit so as not insofar as is reasonably practicable to interfere with the normal and ordinary operation of SUPPLIER’s Plant. During a Manufacturing Audit, SUPERNUS or its agents will be escorted at all times by SUPPLIER personnel. Upon SUPERNUS’s request, SUPPLIER shall make available for SUPERNUS’ review and inspection all equipment and facilities used in or in relation to the manufacture of the PRODUCT, records and support documents (i.e. manufacturing and analytical) with respect to each Batch/lot of the PRODUCT and other Raw Materials/Chemical Components and packaging components used in the manufacture or packaging of the PRODUCT hereunder. At any such audit, SUPERNUS shall have the right to obtain copies of such batch records with respect to SUPERNUS PRODUCT, provided however, that SUPERNUS pays SUPPLIER for its reasonable costs associated with making such copies. All costs of an Event MA shall be borne by SUPERNUS unless the requirement for audit arises as a result of the negligence of SUPPLIER or the breach of the terms of this Agreement by SUPPLIER, in which case SUPPLIER shall absorb all costs associated with the audit.

Correspondence: Each party shall promptly notify the other party of, and shall provide such other party with copies of, any correspondence and other documentation received or prepared by the notifying party in connection with any of the following events:

- Receipt of a “483 Observation Letter” or “Warning Letter” from the FDA or any other Regulatory Authority or any relevant foreign equivalent outside the USA in connection with the manufacture, packaging, testing, storage or security of the PRODUCT;

- Any field alert, recall, market withdrawal or correction of any Batch/lot of the PRODUCT; or
- Any regulatory comments relating to the manufacture of SUPERNUS PRODUCT requiring a response or action by the notifying party.

Audit Close Out: An exit meeting will be held with representatives from SUPPLIER and SUPERNUS to discuss significant audit observations.

SUPERNUS will provide a written report of all observations within fifteen (15) BD to SUPPLIER.

Within \*\* of audit report receipt, SUPPLIER will provide a written response to all findings that details corrective action to be implemented. SUPPLIER will follow up to ensure that all corrective actions are implemented. SUPERNUS may confirm follow-up action by performing a follow-up audit separate from the Annual MA or Event MA.

#### **8.4 Subcontracting**

SUPPLIER will not subcontract tasks to a third party without SUPERNUS' consent. SUPPLIER may subcontract raw material testing to other SUPPLIER's facilities and to other qualified third party laboratories.

#### **8.5 Self Inspection**

SUPPLIER will perform annual self inspections of its premises, facilities, and processes used to manufacture, package, test, and store SUPERNUS' raw materials, packaging and labeling materials, intermediate, PRODUCT in accordance with SUPPLIER's written standard operating procedures (SOPs) to ensure compliance with current GMPs and this Quality Agreement.

#### **8.6 Material Control**

SUPPLIER shall have procedures in place for the receipt, identification, storage, handling, sampling, dispensing, testing/re-testing, disposition (i.e., approval, rejection, quarantine) and destruction of materials (i.e., excipients, Active Pharmaceutical Ingredient (API), packaging components, labeling components).

Prior to its use in the manufacture of SUPERNUS' PRODUCT, materials provided by SUPPLIER or SUPERNUS will be inspected, tested against current specifications and released by SUPPLIER against the SUPPLIER specification system.

SUPERNUS will provide SUPPLIER with a copy of the API specification.

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\*\* This portion has been redacted pursuant to a confidential treatment request.

### 8.6.1 Material Destruction

SUPPLIER, at SUPERNUS' request, will either return to SUPERNUS or dispose of any outdated or rejected material. If the material is disposed of, disposal will be consistent with the nature of the material and sent to a permitted waste disposal facility. Prior to such disposal:

SUPPLIER will send notice to SUPERNUS about SUPPLIER's intent to dispose of the material. If no direction is received from SUPERNUS, SUPPLIER will dispose of the material no sooner than \*\* after the date of the notice.

The materials will be disposed and destroyed in compliance with local environmental regulations and performed in a secure and legal manner that prevents unauthorized use or diversion.

SUPPLIER will maintain destruction records in accordance with SUPPLIER SOPs.

### 8.7 Vendor Audit Responsibility

SUPPLIER is responsible for vendor quality assessment of SUPPLIER furnished materials (i.e.: raw materials, packaging and labeling components) and SUPPLIER's service providers. SUPPLIER will audit and approve the vendor and ensure cGMP compliance in accordance with SUPPLIER's SOPs. SUPPLIER shall not alter or change vendor without the prior written notice to and approval of SUPERNUS, which may be withheld or granted in its sole and absolute discretion.

#### 8.7.1 SUPERNUS Furnished Materials

SUPERNUS is responsible for vendor quality assessment of SUPERNUS furnished materials (i.e.: Active Pharmaceutical Ingredient "API") and for providing a certificate of analysis upon SUPPLIER receipt of each batch of APL A certificate of compliance confirming the following (when applicable) is provided to SUPPLIER:

- That the materials are compliant with the provisions outlined in the "Note for Guidance on minimizing the risk of transmitting spongiform encephalopathy agents via human and veterinary medicinal products" (EMA/410/01, Rev.2 or update), and
- A residual solvent certificate confirming that there is no potential for specific toxic solvents listed in the EP / USP / ICH residual solvents Class I, Class II or Class III to be present and the material, if tested, will comply with established EP / USP / ICH requirements. If any of the solvents listed in the EP I USP I ICH residual solvents Class I, Class II or Class III are

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\*\* This portion has been redacted pursuant to a confidential treatment request.

used in the manufacture or are generated in the manufacturing process, solvents of concern will be indicated.

#### **8.8 Corrective and Preventive Action (CAPA)**

SUPPLIER will have a system in place to document corrective and preventive actions resulting from but not limited to: deviations, investigations, customer complaints in accordance with SUPPLIER's SOPs and evaluate its effectiveness.

#### **9. Buildings, Facilities, Utilities and Equipment**

All buildings and facilities used in the manufacturing, packaging, testing and storage of any materials and/or PRODUCT will be of suitable size, construction and location to facilitate cleaning, and will be maintained in a good state of repair. Maintenance and cleaning records will be kept in accordance with SUPPLIER's SOPs.

SUPPLIER will provide adequate lightning, ventilation, air filtration, air heating/cooling, plumbing, sewage/refuse, washing/toilet facilities and sanitation in accordance with the GMP operation requirements. Qualification as applicable and maintenance will be performed and kept in accordance with SUPPLIER' SOPs.

#### **9.1 Equipment/Computer System - Qualification, Calibration and Preventive Maintenance**

All equipment used in manufacturing, packaging, testing and storage of any materials and/or PRODUCT will be suitable for its intended use and appropriately located to allow for cleaning and maintenance. Qualification, calibration and maintenance records will be kept according to SUPPLIER' SOPs for all critical equipment. SUPPLIER will calibrate equipment and qualify computer systems used in the manufacturing and testing of the materials and/or PRODUCT in accordance with SUPPLIER's SOPs.

SUPPLIER is responsible for establishing and following a cleaning validation program for all equipment used in the manufacturing process.

#### **9.2 Environmental Monitoring Program**

SUPPLIER will perform and maintain an environmental monitoring program. The collected data will be reviewed and interpreted by the responsible person within SUPPLIER's quality unit. Any out of limit results will be managed appropriately in accordance with SUPPLIER's SOPs.

## **10. Production Controls**

### **10.1 Master Batch Record**

SUPERNUS will provide the manufacturing specifications and in-process controls to SUPPLIER.

SUPPLIER is responsible for preparing the master batch records in accordance with specifications and in-process controls; however, SUPPLIER must obtain written approval from SUPERNUS Quality Assurance for each document version before manufacturing.

SUPPLIER will manufacture the PRODUCT in accordance with the specifications and in-process controls. SUPPLIER is responsible for having procedures for charge in components, calculation of yield, equipment identification, time limitations on production in-process sampling and respective testing control. The PRODUCT shall be manufactured in accordance with the manufacturing and packaging procedures set forth in the Specifications and Master Production Records and additional internal SUPPLIER's site procedures. Such procedures must be made available for scrutiny by authorized personnel of SUPERNUS Quality Assurance.

### **10.2 Standard Operating Procedures**

SUPPLIER is responsible for maintaining any Standard Operating Procedures ("SOPS") required to make the PRODUCT in accordance with cGMPs and as described in SUPERNUS'S NDA, or compendia) documentation as well as any other applicable regulatory requirements.

### **10.3 Manufacturing and Equipment Data**

SUPPLIER is responsible for safe keeping and retention of records of machine usage (previous Products produced in non-dedicated machinery), cleaning, any maintenance/calibration performed, Raw Material/Chemical Component batch/lot numbers and certification, in-process results/parameters, and test results and shall perform all functions in accordance with regulatory requirements.

### **10.4 Re-Processing and Re-work**

Re-process and re-work is not allowed without the written approval of Supernus Quality Assurance. SUPPLIER shall maintain written procedures for re-processing batch(es) that do not conform to standards or specifications and ensure that after reprocess batch(es) will conform .

## **10.5 Personnel Training**

SUPPLIER will provide appropriate training for all employees. Each person engaged in the manufacture, packaging, testing, storage, and shipping of the materials and/or PRODUCT will have the education, training, and experience necessary, consistent with current GMPs and safety training requirements.

## **11. Packaging, Labeling and Printed Materials**

### **11.1 Master Batch Packaging and Labeling Records**

SUPERNUS will provide the packaging, labeling and printing materials specifications to SUPPLIER.

SUPPLIER is responsible for preparing the master batch records in accordance with specifications; however, SUPPLIER must obtain written approval from SUPERNUS Quality Assurance for each document version before first use of such version in manufacturing the PRODUCT.

SUPPLIER is responsible having available written procedures for the adequate control of labels to include: incoming examination, disposition, storage, issuance examination of issued labels, reconciliation and destruction of unused labels.

SUPPLIER shall have a system that controls the lot number and appropriate expiration dates on labels.

SUPPLIER will package and label the PRODUCT in accordance with the specifications.

### **11.2 Printed Material and Artwork**

SUPERNUS will provide artwork, labeling text and specifications for labeling/printed materials to SUPPLIER.

SUPPLIER must obtain written approval from SUPERNUS Quality Assurance for each labeling/printed materials proof version before become effective.

## **12. Exception Reports (Deviations / Investigations)**

### **12.1 Manufacturing Instruction Deviations**

SUPPLIER will document, investigate and resolve deviations from approved manufacturing, packaging and labeling instructions or specifications in accordance with SUPPLIER's SOPs. SUPPLIER will report and obtain approval from SUPERNUS responsible person for any deviation affecting the PRODUCT.

SUPPLIER will provide copies of all deviation reports to SUPERNUS as part of the executed batch record.

## **12.2 General Deviations**

SUPPLIER will document, investigate and resolve all other general deviations in accordance with SUPPLIER's SOPs. SUPPLIER will provide copies of all deviation reports to SUPERNUS as part of the executed batch record where there is a potential to affect PRODUCT quality.

### **12.2.1 Notification of Deviations**

Although no deviation from the approved Master Batch Record should occur, any deviation from the process during manufacture must be carefully explained and documented in the batch/lot records, justified and approved by SUPPLIER'S Quality Assurance and production management, and included in the document package. Notification of any process deviations will be forwarded to SUPERNUS Quality Assurance in writing within two (2) BD of the occurrence. SUPERNUS will be provided with documentation for the evaluation of the deviation and SUPERNUS will determine the final disposition of the batch/lot.

Completed investigations and deviations must be forwarded to SUPERNUS Quality Assurance by SUPPLIER within two (2) BD of completion, unless involving a failure potentially impacting safety, identity, strength, quality or purity in which case they are to be forwarded immediately upon completion.

## **13. Release of Product**

### **13.1 Batch Release**

Individual batch/lot review and disposition will be the responsibility of SUPPLIER's Quality unit who will act in accordance with SUPPLIER's SOPs. SUPPLIER is responsible for ensuring and certifying that the PRODUCT has been manufactured according to cGMPs, specifications, the Master Batch Record, compendia) and other applicable regulatory requirements. This includes a complete and thorough review of the Executed Production Records. Executed Production Records will be reviewed by the Patheon Quality Unit and forwarded to SUPERNUS Quality Assurance by the SUPPLIER within \*\* after its review. If a limited batch/lot review schedule has been agreed upon between SUPERNUS and SUPPLIER, it may be acceptable to send only limited documentation from each Executed Production Record. Unless an investigation is necessary, the batch/lot will be dispositioned by SUPPLIER within \*\* from the completion of packaging.

SUPPLIER will notify SUPERNUS Quality Assurance in writing within one (1) BD of any batch/lot of PRODUCT rejected by SUPPLIER. This communication should be accompanied by a completed investigation with regard to the failure

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\*\* This portion has been redacted pursuant to a confidential treatment request.

and include evaluation of effect of failure on other batch/lot(s). SUPERNUS maintains the right to review all applicable data and determine the final disposition of the batch/lot.

### **13.2 Batch Contamination — Batch Integrity**

Should SUPERNUS become aware of the possible contamination or batch/lot integrity issue of any batch/lot, regardless of the age of the batch/lot, SUPPLIER will allow members of SUPERNUS Technical Services-Quality Assurance access to the facility and all applicable records. SUPERNUS and the SUPPLIER will form a joint task force to investigate the situation, determine the root cause, and implement a correction action to assure that this situation does not happen again. SUPERNUS Quality Assurance will determine the final disposition of the batch/lot.

### **13.3 Certificate of Compliance (CoC)**

For each batch/lot released, SUPPLIER will deliver to SUPERNUS a CoC or similar that will include at a minimum:

- A statement that the PRODUCT and if applicable, its predecessors has been manufactured, packaged, and tested in accordance with cGMP, appropriate regulations, compendia) requirements, Master Batch Record and Specifications.
- The CoC will identify the lot number(s), lot expiry date(s), and quantity (ies). The specific lot number will be the lot number identified on the Executed Batch Record for the PRODUCT.

### **13.4 Product Release for Distribution**

SUPERNUS or its representative(s) will have sole responsibility for release testing of the PRODUCT for distribution.

## **14. Validation**

### **14.1 Cleaning Method**

SUPERNUS will provide to SUPPLIER toxicological information to be used in the development of a cleaning program. SUPPLIER will maintain an appropriate cleaning and cleaning validation program.

### **14.2 Manufacturing Process**

SUPPLIER will generate and provide to SUPERNUS Quality Assurance the Manufacturing Process Validation Protocol (PVP) and will not execute this PVP until it has been approved in writing by SUPERNUS Quality Assurance.

After the PVP has been executed, the SUPPLIER will provide all applicable documentation to SUPERNUS. SUPERNUS Quality Assurance will approve the executed PVP Report in writing.

Any proposed changes after the initial PVP Report is issued, shall be evaluated by SUPPLIER and SUPERNUS Quality Assurance and if deemed necessary appropriate change controls and re-execution of a PVP is required.

## **15. Change Control**

SUPPLIER will notify and obtain written approval from SUPERNUS Quality Assurance before implementing any proposed changes to the process, materials, testing, equipment or premises, where such changes may directly affect the PRODUCT.

For those changes required to comply with applicable laws and regulatory agency requirements, SUPPLIER shall notify SUPERNUS of such requirements after SUPPLIER becomes aware of the need for such change.

SUPERNUS will be responsible for determining whether or not to initiate registration variation procedures and for maintaining adequate control over the commitments made with respect to the PRODUCT to the regulatory authorities.

SUPPLIER will not make changes to any PRODUCT related documentation except through the established SUPPLIER change control system, and all master document revisions must be approved in writing by SUPERNUS' Quality Assurance unit prior to implementation. Any changes made to issued batch records (prior to master revisions) must be reviewed and approved in writing by SUPERNUS' Quality Assurance prior to implementation unless otherwise agreed to in writing.

## **16. Documentation**

### **16.1 Record Retention**

SUPPLIER will maintain all PRODUCT batch/lot records for a minimum of one (1) year following expiration date of PRODUCT and supply all these records to SUPERNUS upon request.

SUPPLIER will maintain records and evidence on the testing of materials and packaging/labeling materials for \*\* after the materials were last used in the manufacture or packaging/labeling of the PRODUCT.

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At the end of the above noted retention period, SUPERNUS will be contacted concerning the future storage or destruction of the documents

## **16.2 Batch Documentation Requisition**

At the request of SUPERNUS, SUPPLIER will provide a copy of any of the executed batch/lot documents relating to PRODUCT to SUPERNUS within five (5) BD of such request.

## **17. Laboratory Controls**

### **17.1 Specifications and Test Methods**

SUPPLIER will test and disposition raw material(s); will perform in-process control testing in accordance with the approved specifications, validated and/or verified analytical methods, and SUPPLIER's SOPs.

### **17.2 Out of Specifications (OOS) / Out of Trend (OOT)**

SUPPLIER will notify SUPERNUS' Quality Assurance unit of confirmed out-of-Specification ("OOS") or out-of-trend ("OOT") results within one (1) BD of the confirmed result. SUPPLIER will generate an OOS or OCT report as per SUPPLIER procedures and obtain written approval of the report from the SUPERNUS's Quality Assurance prior to the disposition of the batch/lot. Each OOS or OOT investigation must be reviewed and approved by SUPPLIER'S designated quality person. SUPPLIER must evaluate if the failure has jeopardized the safety, efficacy or quality of the PRODUCT.

### **17.3 Analytical Method Validation, Verification and Transfer**

SUPPLIER will maintain an appropriate method validation, verification and transfer program in place that follows GMP standard as described in Section 2, as applicable. The accuracy, sensitivity, specificity and reproducibility of analytical methods shall be documented. The suitability of all analytical methods shall be verified under actual conditions of use.

SUPPLIER is responsible for validating and approving non-compendial analytical methods or verifying (if applicable) and approving non-compendial analytical methods, when SUPPLIER is responsible for analytical testing.

SUPERNUS is responsible for validating and approving non-compendial analytical methods or verifying (if applicable) and approving compendia) analytical methods, when SUPERNUS is responsible for analytical testing.

SUPPLIER and SUPERNUS are responsible for performing analytical method transfer when required.

#### **17.4 Stability Program**

SUPERMUS is responsible for the stability program. SUPPLIER will document and provide SUPERMUS with request quantity of samples to be shipped to SUPERMUS or its representatives.

In the situation where SUPPLIER agrees to perform stability testing on behalf of SUPERMUS, this agreement will be in writing.

#### **18. Storage and Shipment**

SUPPLIER will maintain records for storage and shipment of PRODUCT in accordance with the agreed qualified transportation requirements.

##### **18.1 Product Storage and Shipment Changes**

SUPPLIER will communicate any proposed changes to the PRODUCT storage or shipping for SUPERMUS review and approval.

##### **18.2 Product Quarantine**

SUPPLIER will have a system in place for assuring that not released PRODUCT is not shipped unless authorized by the SUPERMUS' Quality Assurance unit.

#### **19. Product Complaints**

##### **19.1 Complaint Investigation**

SUPPLIER will investigate all manufacturing and packaging type PRODUCT complaints related to the manufacturing services provided. SUPERMUS Quality Assurance is responsible for receiving and initially investigating any complaints and will notify SUPPLIER of any complaint that may impact the PRODUCT quality. SUPPLIER will investigate any PRODUCT complaints and provide a report to SUPERMUS within \*\* days. The investigation shall be completed in accordance with all cGMP regulations and any other applicable regulations. In case the investigation could not be finalized within \*\*, SUPPLIER will provide an interim report to SUPERMUS.

SUPERMUS shall have responsibility for reporting all complaints relating to the PRODUCT to the FDA and any other Regulatory Authority, including, but not limited to, complaints relating to the manufacture of the PRODUCT as well as adverse drug experience ("ADE") reports.

SUPERMUS will retrieve complaint sample(s) when applicable and forward them to SUPPLIER in a timely manner to facilitate a complete and comprehensive investigation.

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## **20. Product Recall**

### **20.1 Product Recall Notification**

SUPPLIER will notify SUPERNUS Quality Assurance in one (1) BD after SUPPLIER has confirmed a reason for recall. SUPPLIER will inform SUPERNUS of any serious quality issue that may result in a recall of supplied PRODUCT.

SUPERNUS will notify SUPPLIER about a PRODUCT recall or other regulatory type PRODUCT notification (e.g.: field alert) as soon as possible, but, in any event, prior to informing the appropriate regulatory authorities. SUPERNUS will be responsible for all related recall activities.

### **20.2 Regulatory Agency Notification**

SUPERNUS will perform the PRODUCT recall and will inform the appropriate regulatory authorities. Where legislated, SUPPLIER reserves the right to notify regulatory authorities of PRODUCT quality issues; however SUPPLIER will inform SUPERNUS prior to notification to the regulatory authorities.

## **21. Return and Salvage**

SUPPLIER shall have written procedures for receiving, identifying, holding, testing, re-processing or destroying returned PRODUCT.

Salvage shall not occur, unless SUPPLIER and SUPERNUS Quality Assurance units approve the process.

## **22. Reserve/ Retention Samples**

### **22.1 Raw Materials (API, Excipients)**

SUPPLIER will maintain a representative reserve sample of each lot in each shipment received and used to manufacture the PRODUCT. The reserve sample will consist of at least two (2) times the necessary quantity for all Quality Control tests required to determine whether the raw materials meet required specifications.

The API reserve samples will be stored by SUPPLIER under controlled conditions in accordance with cGMP storage requirements for \*\* beyond the expiration date of the last lot of the PRODUCT containing the API.

All other reserve samples will be stored by SUPPLIER under controlled conditions in accordance with cGMP storage requirements for \*\* beyond the expiration date.

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The reserve samples will be made available by SUPPLIER to SUPERNUS or a regulatory agency, if requested.

**22.2 Product**

SUPPLIER will maintain a representative reserve sample of each lot of PRODUCT manufactured. Reserve sample(s) will be stored by SUPPLIER under controlled conditions in accordance with labeled requirements for \*\* beyond the expiration date of the PRODUCT. The reserve sample will consist of at least two (2) times the necessary quantity for all Quality Control tests required to determine whether the PRODUCT meet required specifications.

SUPPLIER will be responsible for annual visual inspection of reserve samples from representative sample batch/lot selected by acceptable statistical procedures for evidence of deterioration unless visual examination would affect the integrity of the reserve sample per 21 CFR 211.170b. Any evidence of retain sample deterioration must be reported to SUPERNUS Quality Assurance with three (3) BD of discovery and investigated per internal SUPPLIER’s SOPs. The investigation must be forwarded to SUPERNUS Quality Assurance upon completion by SUPPLIER.

**23. Quality Contacts**

	SUPPLIER	SUPERNUS
<b>Responsibility</b>	Quality Assurance	Quality Assurance
<b>Name</b>	**	Maira T. Adzema
<b>Title</b>	Associate Director, Quality Assurance	Sr. Manager Quality Assurance
<b>Phone</b>	**	301 838-2626
<b>Fax</b>	**	301 424-1385
<b>E-mail</b>	**	madzema@supernus.com
<b>Address</b>	111 Consumers Drive Whitby, Ontario, L1N 5Z5	1550 East Gude Drive Rockville, MD 20850 - USA

**24. Attachments**

Attachment I — Responsibility Table

**25. History**

QA-CPRD-804.00 — Initial version

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\*\* This portion has been redacted pursuant to a confidential treatment request.

**26. Approval**

IN WITNESS WHEREOF, the parties have caused their duly authorized officer to execute and deliver this Quality Agreement.

**Patheon Inc.**

/s/ George Elia  
George Elia  
Director, Quality Operations

Date: 25-Oct-2012

**Supernus Pharmaceuticals, Inc.**

/s/ Frank G. Mottola  
Frank G. Mottola  
Executive Director Compliance and Facilities

Date: 25-Oct-2012

**ATTACHMENT 1 - RESPONSIBILITY TABLE**

SUPPLIER will be responsible for all the operations that are marked with “X” in the column titled “SUPPLIER” and SUPERNUS will be responsible for all the operations that are marked with “X” in the column titled “SUPERNUS”. If marked with “(X)”, cooperation is required from the designated party.

Item Number	Subject / Terms	SUPERNUS	SUPPLIER
<b>1.1. Regulatory Requirements</b>			
1.1.1	Permits/Licenses	X	X
1.1.2	Regulatory Filing / Registration Change Control	X	(X)
1.1.3	Regulatory Compliance		X
1.1.4	Government Agency Inspections, Communications and Requisitions	(X)	X
1.1.5	Annual Product Review	(X)	X
<b>1.2. Quality Management</b>			
1.2.1	GMP, Health and Safety Compliance		X
1.2.2	SUPERNUS Audit Rights	X	
1.2.3	Subcontracting	(X)	X
1.2.4	Self-Inspection		X
<b>1.3. Material Control</b>			
1.3.1	API Test Methods and Specifications	X	
1.3.2	Material Destruction	(X)	X
1.3.3	Vendor Audit Responsibility	X	X
1.3.4	SUPERNUS Furnished Materials	X	
1.3.5	In-coming Material Testing	(X)	X
<b>1.4. Building, Facilities, Utilities and Equipment</b>			
1.4.1	General		X
1.4.2	Equipment, Qualification, Calibration and Preventative Maintenance		X
1.4.3	Environmental Monitoring Program		X
<b>1.5. Product Controls</b>			
1.5.1	Master Batch Record	(X)	X
1.5.2	Re-process and re-work	N/A	N/A
1.5.3	Personnel Training		X
<b>1.6. Packaging, Labelling and Printed Materials</b>			
1.6.1	Master Batch Packaging Records	(X)	X
1.6.2	Printed Material and Artwork	X	X
<b>1.7. Exception Reports (Deviations / Investigations)</b>			
1.7.1	Manufacturing Instruction Deviations	(X)	X
1.7.2	General Deviations	(X)	X
1.7.3	Notification of Deviations		X
<b>1.8. Release of Product</b>			
1.8.1	Test Methods and Specifications	X	
1.8.2	Batch Release	X	X
1.8.3	Certificate of Compliance		X
1.8.4	Product Release	X	
<b>1.9. Validation</b>			
1.9.1	Cleaning Method	(X)	X
1.9.2	Analytical Method	X	

<b>Item Number</b>	<b>Subject / Terms</b>	<b>SUPERNUS</b>	<b>SUPPLIER</b>
1.9.3	Manufacturing Process	X	(X)
<b>1.10. Change Control</b>			
1.10.1	General	X	X
<b>1.11. Documentation</b>			
1.11.1	Record Retention		X
1.11.2	Batch/lot Document Requisition		X
<b>1.12. Laboratory Controls</b>			
1.12.1	Specifications and Test Methods	X	X
1.12.2	Out of Specifications (OOS) / Out of Trend (OOT)	(X)	X
<b>1.13. Stability</b>			
1.13.1	Sample Storage		X
1.13.2	Stability Studies and Protocol	X	X
1.13.3	Stability Failures	(X)	X
1.13.4	Termination of Agreement	X	X
<b>1.14. Storage and Distribution</b>			
1.14.1	General		X
1.14.2	Product Storage and Shipment Changes	(X)	X
1.14.3	Product Quarantine		X
<b>1.15. Product Complaints</b>			
1.15.1	Complaint Investigation	X	(X)
<b>1.16. Product Recall</b>			
1.16.1	Product Recall Notification		X
1.16.2	Government Agency Notification		X
<b>1.17. Reserve and Retention Samples</b>			
1.17.1	Raw Material and Active Ingredient Reserve Sample		X
1.17.2	Finished Product Retention Sample	X	X



FOR IMMEDIATE RELEASE

### **Supernus Launches Oxtellar XR™ in the United States**

**Rockville, MD, February 1, 2013** —Supernus Pharmaceuticals, Inc. (NASDAQ: SUPN), a specialty pharmaceutical company, today announced that Oxtellar XR tablets are now available for sale in the US. Oxtellar XR is a novel once-daily extended release antiepileptic drug indicated for adjunctive therapy in the treatment of partial seizures in adults and in children 6 to 17 years of age. The product has been shipped to major wholesalers in the market, and the Company's sales force of approximately 75 sales representatives will start promoting the product on February 4.

"The commercial launch of Oxtellar XR marks the achievement of our vision of becoming a commercial organization marketing its own products in the CNS specialty pharma sector. It also confirms the long standing heritage we have in strong execution against our corporate goals said Jack Khattar, President & CEO, of Supernus. I would like to thank all Supernus employees for their hard work and dedication that allowed us to deliver on our commitment to providing innovative therapeutic options to patients who suffer from epilepsy," added Jack Khattar.

#### **About Oxtellar XR**

Oxtellar XR is a novel once- daily extended release formulation of oxcarbazepine. It is an antiepileptic drug (AED) indicated for adjunctive therapy in the treatment of partial seizures in adults and in children 6 to 17 years of age. The recommended daily dose for adults is 1200 mg to 2400 mg once per day, and for children 6 to 17 years of age is 900 mg to 1800 mg depending on weight. The product is available in 150 mg, 300 mg and 600 mg extended-release tablets.

**For full prescribing and safety information, click here.**

#### **About Supernus Pharmaceuticals, Inc.**

Supernus Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system, or CNS, diseases. The Company has one marketed product for epilepsy, Oxtellar XR (extended-release oxcarbazepine), and one tentatively approved product for epilepsy, Trokendi XR™ (extended-release topiramate). The Company is also developing several product candidates in psychiatry to address large market opportunities in ADHD, including ADHD patients with impulsive aggression. These product candidates include SPN-810 for impulsive aggression in ADHD and SPN-812 for ADHD.

#### **Forward-Looking Statements:**

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements do not convey historical information, but relate to predicted or potential future events that are based upon management's current expectations. These

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statements are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. In addition to the factors mentioned in this press release, such risks and uncertainties include, but are not limited to, the Company's ability to raise sufficient capital to implement its corporate strategy; the implementation of the Company's corporate strategy; the Company's future financial performance and projected expenditures; the Company's product research and development activities, including the timing and progress of the Company's clinical trials, and projected expenditures; the Company's ability to receive, and the timing of any receipt of, regulatory approvals to develop and commercialize the Company's product candidates; the Company's ability to protect its intellectual property and operate its business without infringing upon the intellectual property rights of others; the Company's expectations regarding federal, state and foreign regulatory requirements; the therapeutic benefits, effectiveness and safety of the Company's products and product candidates; the accuracy of the Company's estimates of the size and characteristics of the markets that may be addressed by its products and product candidates; the Company's ability to increase its manufacturing capabilities for its products and product candidates; the Company's projected markets and growth in markets; the Company's staffing needs; and other risk factors set forth from time to time in the Company's periodic reports and other filings made with the Securities and Exchange Commission. The Company undertakes no obligation to update the information in this press release to reflect events or circumstances after the date hereof or to reflect the occurrence of anticipated or unanticipated events.

CONTACTS:

Jack Khattar, President & CEO

Gregory S. Patrick, Vice President and CFO

Supernus Pharmaceuticals, Inc.

Tel: (301) 838-2591

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