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): August 16, 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))

Item 1.01 Entry into a Material Definitive Agreement

Effective December 15, 2012, Supernus Pharmaceuticals, Inc. ("Supernus" or the "Company") entered into a Commercial Supply Agreement with Catalent Pharma Solutions, LLC (the "Agreement") that defines each party's responsibilities with respect to the manufacture, formulation, development and supply of commercial-grade quantities of topiramate, the active pharmaceutical ingredient required for the finished drug product, Trokendi XRTM (the "Product"). The Company entered into the Agreement in anticipation of final approval by the U.S. Food and Drug Administration (the "FDA") of the Product, which was received on August 16, 2013, and the commercial launch of the Product, which will occur during the next few weeks.

Under the Agreement, the parties agreed that Catalent Pharma Solutions, LLC 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 Catalent Pharma Solutions, LLC, the active pharmaceutical ingredient and any other materials required in connection with the manufacture of the Product, and Catalent Pharma Solutions, LLC 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 August 19, 2013, the Company issued a press release to announce the receipt of final approval from the FDA for Trokendi XR TM, a novel once-daily extended release formulation of topiramate for the treatment of epilepsy. The approval letter states that the FDA completed its review of the application and that Trokendi XR is approved effective August 16, 2013 for use as recommended in the agreed-upon labeling. The FDA granted a waiver for certain pediatric study requirements and a deferral for submission of post-marketing pediatric pharmacokinetic assessments that are due in 2019 followed by clinical assessments in 2025. The company expects to launch the product and for it to be available in pharmacies over the next few weeks. 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 furnished as an Exhibit pursuant to Item 1.01 hereof:

Exhibit 10.1* – Commercial Supply Agreement, dated December 15, 2012, by and among Catalent Pharma Solutions, LLC and the Company. (Filed herewith)

The following documents are furnished as an Exhibit pursuant to Item 8.01 hereof:

Exhibit 99.1 – Press Release dated August 19,2013 of the Company announcing the final approval of Trokendi XR.

^{*}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: August 21, 2013 By: /s/ Gregory S. Patrick
Gregory S. Patrick
Vice-President and Chief Financial Officer

EXHIBIT INDEX

Number	<u>Description</u>	
10.1*	Commercial Supply Agreement, dated December 15, 2012, by and among Catalent Pharma Solutions, LLC and the Company. (Filed herewith)	Attached
99.1	Press Release dated August 19, 2013.	Attached

^{*}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.

EXECUTION COPY

Catalent Pharma Solutions, LLC and Supernus Pharmaceuticals, Inc. Terms and Conditions

Exhibit 10.1

COMMERCIAL SUPPLY AGREEMENT

This Commercial Supply Agreement ("Agreement"), effective as of December 15, 2012 (the "Effective Date"), is made by and between Catalent Pharma Solutions, LLC, having its principal offices at 14 Schoolhouse Road, Somerset, New Jersey 08873, USA (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 <u>Definitions</u>: 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 3.2.
- 1.2 <u>"API Credit Value"</u> means the value of the API for certain purposes of this Agreement, as set forth on Schedule A.
- 1.3 "Affiliate(s)" with respect to Supernus or any third party, any corporation, firm, partnership or other entity that controls, is controlled by or is under common control with such entity; and with respect to Supplier, Catalent Pharma Solutions, Inc. and any corporation, firm, partnership or other entity controlled by it. For the purposes of this definition, "control" means the ownership of at least 50% of the voting share capital of an entity or any other comparable equity or ownership interest.
- 1.4 "Agreement" has the meaning set forth in the introductory paragraph, and includes all its attachments 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.
- 1.5 "API" means the generic compound Topiramate, as further described in the Specifications, which has been released by Supernus, its Affiliate or subcontractor and provided to Supplier.
- 1.6 "Applicable Law" means, in relation to any person, transaction or event, all relevant laws, statutes, regulations and orders of all governmental bodies in the

Territory having jurisdiction (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.

- 1.7 "<u>cGMP</u>" means current good manufacturing practices for the methods and processes used in, and the facilities and controls used for, the manufacture of the Products, all as set forth from time to time by the applicable Regulatory Authority.
- 1.8 "CMC Submission" means a dossier containing all chemistry, manufacturing and controls information filed by Supernus or its sub-licensees to the FDA and other Regulatory Authority to support a filing for Regulatory Approval, as set forth in 21 C.F.R. § 314.50.
- 1.9 "Facilities" means Supplier's facilities located at Winchester, Kentucky, and Decatur Road, Philadelphia, Pennsylvania, or such other Supplier facility as mutually agreed in writing by the Parties from time to time.
- 1.10 "FDA" means the United States Food and Drug Administration or any successor entity thereto.
- 1.11 "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).
- "Latent Defect" means any defect that was not, and could not be reasonably expected to have been found during physical or chemical acceptance testing by Supernus such as, but not limited to, the presence of a contaminant introduced during the Manufacturing or Supplier's failure to comply with the Applicable Laws. For the sake of clarity, the term "Defective Product" defined in Section 6.2 shall include Products that contain a Latent Defect.
- "Launch Date" means the date of first commercial sale of Product 1.13 by Supernus to a third party in the Territory.
- "Manufacturing" means the activities relating to the manufacture of the Product in accordance with the Specifications from Materials supplied by Supplier or Supernus Supplied Materials or Supernus's vendors or subcontractors hereunder spanning the sourcing, receipt, testing and storage of Materials or Supernus Supplied Materials through the processing, manufacturing, packaging and labeling of the Product into finished Product form that is finished product, ready for use in clinical trials, or sale to customers in finished, final packaged form. The terms "manufacture" and "manufactured" refer to the act of manufacturing.
- 1.15 "Manufacturing Date" means the day on which the first batch record entry of Manufacturing is scheduled to occur, as identified in an Acknowledgement.
- "Materials" means raw materials (other than the ** and Supernus 1 16 Supplied Materials), excipients, and all packaging materials (including, without limitation, containers, packaging and labeling) as the foregoing are required in connection with the

This portion has been redacted pursuant to a confidential treatment request. Page 2 of 41

manufacture of the Product, or set forth in the applicable Purchase Order, in accordance with the applicable Specifications.

- 1.17 "PPI" means the Producer Price Index for pharmaceutical preparations (PCU 06-3 8) available on the U.S. Bureau of Labor Statistics website (http://stats.bls.gov).
- 1.18 "Product" as used herein and identified on a Purchase Order means a finished drug product containing API conforming to the Specifications, and manufactured and packaged to meet cGMP requirements and that meets the Specifications.
- 1.19 "<u>Purchase Order</u>" means the binding, written purchase orders delivered to Supplier by Supernus in accordance with in Section 3.2 of this Agreement.
- 1.20 "Regulatory Approval" means all necessary approvals of the Regulatory Authority to manufacture the Product and to market, distribute and sell the Product.
- 1.21 "Regulatory Authority" means, in the United States, the FDA, and, in any other country in the Territory, any agency or agencies having comparable authority.
- 1.22 "Regulatory Scheme" means any regulatory scheme promulgated by a Regulatory Authority applicable to the Products in any country in the Territory, 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.
- 1.23 "Specifications" means those protocols and standard operating procedures, including without limitation, formulations, processes, quality control, encapsulation, 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.
- $1.24 \qquad \text{``Supernus Supplied Materials''} \text{ means API and any other materials} \text{ as may be supplied to Supplier by Supernus.}$
- ** means the ** procured by Supplier on behalf of Supernus and as more specifically defined in the Specifications.
- 1.26 "Tailings" means residual beads from an uncoated or coated batch which are not of sufficient volume to be utilized in a subsequent batch and therefore are considered waste. For example purposes, the current tailings are known by the following designations: **.
- "Territory" means the United States, and any other country that 1.27 the parties agree in writing to add to this definition of Territory in an amendment to this Agreement.

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- "Topiramate" means (a) 2,3:4,5-Bis-O-(1-methylethylidene)-beta-1.28 D-fructopyranose sulfamate, (b) any isomers, salts, solvates, hydrates, or polymorphs, of the foregoing.
- 1 29 "United States" means the United States of America, its territories, possessions and the Commonwealth of Puerto Rico.

Term & Termination. 2

Term. Unless earlier terminated as provided herein, the term of 2.1 this Agreement shall be ** years from the Effective Date (the "Initial Term"). Upon expiration of the Initial Term or any Renewal Term (as defined below), this Agreement shall automatically renew for successive ** year periods (each, a "Renewal Term"; the Initial Term, together with the Renewal Terms, if any, shall be referred to herein as the "Term"), unless and until either party gives the other party at least ** months prior written notice of its desire to terminate as of the end of the then-current Term.

2.2 Termination.

- 2.2.1 Each Renewal Term shall be subject, after its commencement, to early termination by either party upon at least ** months prior written notice to the other party.
- 2.2.2 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, in the event such obligations are undisputed 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. At the end of the sixty (60) day period the other party retains the right to terminate the Agreement if the breach is not fully cured. In the event that disputed monetary obligations remain unresolved after sixty (60) days, the Party to whom the money is owed may terminate this agreement at that time.
- 2.2.3 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.
- 2.2.4 Supernus may terminate this Agreement at any time upon written notice to Supplier in the event of:
- failure of Supplier (other than due to a force majeure condition described in Section 24.6 of this Agreement) on more than ** occasions during any

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rolling ** period to make deliveries of Product within ** following the date on which such delivery is due, which failure is not cured within a period of ** days after receipt of written notice of non-delivery from Supernus;

- the Product manufactured by Supplier hereunder during the Term of the Agreement 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;
- 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;
- Supplier sells or otherwise diverts (d) Supplier sells or otherwise diverts the Product to any person other than Supernus or a designee of Supernus in United States of America (USA), or in other country.
- Supemus may terminate this Agreement at any time upon written notice to Supplier in the event 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 3 hereof for a period of greater than 90 days due to a force majeure condition described in Section 24.6 of this Agreement.

2.3 Consequences of Termination & Survival.

- Termination of this Agreement shall not relieve either Party of its obligations incurred prior to the date of termination. The obligations under Sections 10, 13, 18, 19, 20, 22, 23, and 24 hereof shall survive expiration or termination of this Agreement or of any extensions thereof.
- Notwithstanding anything in this Agreement to the contrary, termination of this Agreement shall not affect the rights and obligations under any Purchase Order pursuant to Section 3.2 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 Supernus 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 Supernus or its sublicensees by Supplier and shall be paid for by Supernus in accordance with the terms hereof, and the Parties hereto hereby agree that this Agreement shall be extended for such purposes.
- In the event Supernus terminates the Agreement due to a material breach by Supplier, then following written notice of termination, Supplier will, at its own expense, reasonably cooperate with and will provide reasonable technical assistance to Supernus in connection with Supernus's efforts to transfer the Manufacturing of the Product from the Facility to another site that Supernus intends to utilize for Manufacturing the Product. Such assistance may include but not be limited to:

This portion has been redacted pursuant to a confidential treatment request. Page 5 of 41

2.3.3 1 assistance including technical personnel to Supernus, supplying reasonable technical

suitable quality and scientific 2332 support for the appropriate technical transfers of the manufacturing process and analytical method

2333 all appropriate and reasonably necessary documentation and technical records, requested by Supernus, know how and technical level "man in the plant" to the receiving manufacturer. Supplier understands that time will be of the essence.

2.3.3.4 Supplier shall promptly return to Supernus, at Supernus' expense and direction, any remaining inventory of Product, API, ** or Supernus Supplied Materials; provided, that all outstanding and undisputed invoices have been paid in full.

2.3.3.5 Supernus shall pay Supplier for all costs and expenses incurred and undisputed, and all noncancellable 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 Supernus' most recent Firm Commitment and the vendor's minimum purchase obligations.

Forecasts, Orders, and Delivery.

- 3.1 <u>Forecasts and Firm Commitment.</u> Within sixty (60) days following the execution of this Agreement, Supernus shall deliver to Supplier for its review a non-binding forecast for the following ** months. The forecast shall be divided into calendar quarterly forecasts and shall include Supernus' anticipated requirements and proposed delivery dates. Thereafter, on or before the 10th day of each calendar month, beginning at least 6 months prior to the anticipated Launch Date, Supemus shall provide Supplier with a rolling ** month nonbinding, good faith estimate of the quantities of Product including validation batches it foresees it will order during such period (each, a "Forecast"). Within ten (10) days of receipt of such Forecast from Supernus, Supplier shall deliver to Supernus a forecast of Supplier's requirements for API, including agreed upon safety stock for each of the following ** months as well as the current inventory (or the amount on order) of ** plus agreed upon safety stocks to meet the Forecast. Supplier will be responsible for ordering, storing and ** on behalf of Supernus as will be calculated from the Forecast provided by Supernus. In addition, Supplier shall provide each ** lot number, date of manufacture and **. The forecasts for Product requirement for the ** quarters shall constitute a hinding obligation of Supernus to purchase and Supplier to account quarters shall constitute a binding obligation of Supernus to purchase and Supplier to accept a "Firm Commitment") as follows:
- ** per cent ** of forecasted quantities (plus any additional quantities which Supernus may have ordered as agreed upon by the Steering Committee) in the first 3 months of the period; and
- ** percent ** of forecasted quantities for the second three months of the period.

This portion has been redacted pursuant to a confidential treatment request. Page 6 of 41

- 3.2 Purchase Orders and Acknowledgment. The Parties shall agree upon a form of Purchase Order to be used by Supernus in ordering Product hereunder. Supernus may from time to time place Purchase Orders with Supplier for quantities of Product at least ** (the "Lead Time") prior to the delivery date requested in each respective Purchase Order. The parties agree to meet and discuss in good faith whether any change to the Lead Time should be made following completion of the validation batches. Promptly but not more than five (5) business days following receipt of a Purchase Order, Supplier shall issue a written acknowledgement ("Acknowledgement") that it accepts the Purchase Order. Each acceptance Acknowledgement shall either confirm the delivery date set forth in the Purchase Order or set forth a reasonable alternative delivery date and shall include the Manufacturing Date. Subject to Section 3.6.2, Supplier may reject any Purchase Order in excess of ** in batch quantity of the Firm Commitment or otherwise not given in accordance with this Agreement. 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 Supernus Supplied Materials, ** and Materials and its manufacturing, packaging and equipment capacity. All Purchase Orders shall be for full batch quantities of Product or integral multiples thereof.
- 3.3 <u>Conflicts between Purchase Orders and this Agreement.</u> 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.
- 3.4 <u>Supplier's Cancellation of Purchase Orders.</u> Notwithstanding Section 3.2, if Supernus refuses or fails to timely supply conforming Supernus Supplied Materials in accordance with Section 4.2, Supplier reserves the right to reschedule that part of a Purchase Order without conforming Supernus Supplied Materials upon written notice to Supernus.
- 3.5 <u>Manufacturing and Delivery.</u> Subject to the terms and conditions of this Agreement, and at Supernus' request in accordance with the terms hereof, Supplier shall Manufacture at the Facilities in accordance with the Specifications and in compliance with the Regulatory Scheme, including cGMP, and deliver (pursuant to Section 4.5) Product to Supernus. Subject to Supernus' prior approval which shall not be unreasonably withheld, Supplier shall have the right to cause any of its Affiliates to perform any of its packaging and quality control obligations hereunder, and Supernus shall accept such performance as if it were performance by Supplier. Supplier shall use its commercially reasonable efforts to meet Supernus' demand for Product ordered in accordance with the terms hereof.

3.6 <u>Long Lead Time Materials.</u>

3.6.1 If Supplier purchases or enters into commitments to purchase any of the Materials specified as long lead time materials, on Schedule A (the "Long Lead Time"

^{**} This portion has been redacted pursuant to a confidential treatment request.

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Materials"), based on Supernus' forecast for a specified month, and the binding Firm Commitment for such specified month is less than •• of the volumes forecasted for such month at the time when such Long Lead Time Materials were purchased or committed to, then Supplier shall notify Supernus within three (3) working days of the discrepancy. Supplier shall manage its inventory so as to minimize its quantities of unusable Long Lead Time Materials and use commercially reasonable efforts to exhaust existing stocks of Long Lead Time Materials promptly. To the extent Long Lead Time Materials purchased by Supplier based on a Supernus forecast for a Product cannot be used by Supplier for Products or for other Supplier business within 6 months of the specified month for which those Long Lead Time Materials were purchased, Supernus shall pay Supplier for those Long Lead Time Materials at the actual documented cost paid by Supplier for such Long Lead Time Materials.

3.6.2 If the binding Firm Commitment for a given month is more than ** greater than then forecast provided by Supernus ** prior to the time at which the forecast becomes a binding Firm Commitment for that month, and in reliance on the earlier forecast Supplier did not purchase or enter into a commitment to purchase sufficient amounts of Long Lead Time Materials to timely meet that binding Firm Commitment, then Supplier shall inform Supernus within three (3) working days upon discovery of its inability to meet the binding Firm Commitment as a result of insufficient inventories of the Long Lead Time Materials. Supplier shall continue to use its reasonable commercial efforts to obtain the Long Lead Time Materials after compliance with its obligations under this Section 3.5, then Supernus shall cooperate with Supplier in order to extend the delivery dates for such binding Firm Commitment to the extent such extension is required due to such inadequate inventories of Long Lead Time Materials.

4 Materials. Manufacture and Delivery of Product.

4.1 Materials. Except as provided in Section 4.2, Supplier shall provide all Materials required by Supplier to manufacture the quantity of Product necessary to meet the Firm Commitment, unless otherwise agreed to in writing by the parties. At all times during the first 12 months following the Effective Date, Supplier shall establish and maintain a stock of Materials sufficient to meet ** of the Firm Commitment. Supplier shall use commercially reasonable efforts to promptly notify Supernus in the event that an impairment to Supplier's credit or any other financial issue has, or is reasonably likely to have, a material negative impact on Supplier's ability to purchase the Materials in a timely manner.

In the event that any Material (other than API) becomes subject to purchase lead times beyond the Firm Commitment time frame, Supplier shall notify Supernus and such Material shall be considered Long Lead Time Materials. Supplier shall purchase and store on behalf of Supernus the ** and Supernus shall reimburse Supplier for Supplier's cost to do so within ** following receipt of ** by Supplier and invoice to Supernus. Except as set forth in the Quality Agreement, Supplier shall not alter or change the vendors of such Materials without prior written notice to and approval of Supernus, which may be withheld or granted in its sole and absolute discretion. In certain instances, Supernus may require a specific supplier, manufacturer or vendor (collectively the "Vendor" or "Vendors") to be used for Materials. In such an event, (i) such Vendor will be identified in the Specifications and (ii) the Materials from such Vendor shall be deemed Supernus Supplied Materials for purposes of this Agreement. If the cost of the Material from any such Vendor is greater than Supplier's costs for the same raw material of equal quality from other vendors, Supplier shall add the difference between

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

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Supplier's cost of the Material and the Vendor's cost of the Material to the Unit Pricing. Supernus will be responsible for all reasonable costs associated with qualification of any such Vendor who has not been previously qualified by Supplier. Supplier shall provide a good faith estimate of qualification costs to Supernus in advance. In the event of (i) a Specification change for any reason, (ii) obsolescence of any Material or (iii) termination or expiration of this Agreement, Supernus shall bear the cost of any such Materials (including packaging at cost plus **) that are unused, so long as Supplier purchased such Materials in quantities consistent with Supernus' most recent Firm Commitment and the Vendor's minimum purchase obligations and such Material cannot be used by Supplier or its customers for any other purpose. Supernus shall provide or approve, prior to the procurement of applicable Material, all artwork, advertising and labeling information necessary for Manufacturing, Such artwork, advertising and labeling information is and shall remain the exclusive property of Supernus and Supernus shall be solely responsible for the content thereof. Such artwork, advertising and labeling information or any reproduction thereof may not be used by Supplier in any manner other than performing its obligations hereunder.

4.2 Supernus Supplied Materials.

4.2.1 Supernus or its subcontractor will provide Supernus Supplied Materials, together with associated certificates of analysis, at no cost to Supplier, in sufficient quantity to enable Supplier to perform the manufacturing activities and supply Product to Supernus. Supernus or its subcontractor will deliver such items to the Facility no later than 30 days prior to the Manufacturing Date. Supernus, its subcontractor, vendors or other suppliers shall be responsible at its expense for securing any necessary export or import clearances or permits required in respect of such supply. Supplier shall use such items solely for Manufacturing. Upon receipt of the Supernus Supplied Materials by Supplier, Supplier shall inspect or test as the case may be such items to verify its identity. Unless otherwise expressly required by the Specifications, Supplier shall have no obligation to test such items to confirm that they meet the associated specifications or certificate of analysis or otherwise; but in the event that Supplier detects a nonconformity with Specifications, Supplier shall give Supernus immediate notice of such nonconformity. Supplier shall follow Supernus' reasonable written instructions in respect of return or disposal of defective Supernus Supplied Materials, at Supernus' cost. In the event the Supernus Supplied Materials do not meet Specifications Supplier shall not be liable for any defects in Product or related delays thereof and Supernus will supplier shall not be liable for any defects in Product or related delays thereof and Supernus will supplier shall not be liable for any defects in Product or related delays thereof and Supernus will supplier shall supplied to the supernus Supplier shall supplied to the supernus supplied Materials. Supernus acknowledges that 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 of the Supernus Supplied Materials by Supernus or the **.

At the time of the Acknowledgement, Supplier, at no cost to Supernus, shall confirm that it has sufficient quantity of all Materials, ** Supernus Supplied Materials in stock or on order to perform the manufacturing activities, supply Product to Supernus, and to meet the agreed upon delivery date. Upon receipt of the Materials, Supplier shall test against the certificate of analysis and Specifications. In the event the Materials does not meet Specifications, Supplier will arrange for replacement supply of failed Material at no additional cost to Supernus. If applicable, Supplier and Supernus will cooperate and provide such assistance to each as may be reasonably necessary to permit the import of the Materials for the purpose of manufacturing the Product under this Agreement.

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- $\frac{4.3}{\text{with the provisions of Section 3.5 above.}} \underline{\text{Manufacture}}. \text{ Supplier will manufacture Product in accordance}$
- 4.4 <u>Changes in Manufacture</u>. 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 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
- 4.5 <u>Delivery, Title, and Risk of Loss</u>. Supplier will deliver or arrange for the delivery of Product in shippable corrugated boxes to a destination point designated by Supernus or its sublicensee, at the expense of Supernus, Ex Works (Incoterms 2010), Supplier's loading dock, at the Philadelphia, PA packaging Facility. Title to Product will pass to Supernus or its sublicensee upon leaving Supplier's loading dock, whereupon Supernus or its sublicensee will assume all risk of loss or damage barring a conflict as to quality and whether an individual batch can be released. If Supernus fails to take delivery of any Product on any scheduled delivery date, Supplier shall store such Product and Supernus shall be invoiced on the first day of each month following such scheduled delivery for reasonable administration and storage costs.

4.6 On Time Delivery.

- 4.6.1. Supernus and Supplier understand that there may be uncertainties and necessary adjustments in production schedules during the •• of Manufacturing following the Launch (such period being the "Initial Manufacturing Period").
- 4.6.2 Subject to Section 4.6.3 below, if, after the Initial Manufacturing Period, (i) Supplier is unable to deliver the quantity of Product ordered under a Firm Order within ** of the agreed upon delivery date due to an act or omission by Supplier (a "Late Delivery"), and (ii) such Late Delivery is the ** Late Delivery to have occurred during the previous **, then Supernus will receive a credit from Supplier for such Late Delivery that will be applied against the purchase price under the next Firm Order. The credit will be ** of the Unit Price of the quantities of Product subject to such Late Delivery. If not rectified by ** of the agreed upon Delivery Date credit shall increase to **.
- 4.6.3. 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, (ii) availability of Supernus Supplied Materials or **, (iii) US FDA customs clearance of shipment to Supernus or its designee, (iv) the suspension of production by either Party following a report of nonconformity, or (v) any extensions agreed upon pursuant to Section 3.6.2 with respect to Long Lead Time Materials.
- 4.6.4 A Late Delivery will not include any quantities in excess of the Firm Commitment.
 - 4.6.5 A Late Delivery will not be a material breach of

this Agreement.

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

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- 4.7 Quality Agreement. Within thirty 30 days following the Effective Date and in any event prior to the first Manufacturing of Product hereunder, the Parties shall negotiate in good faith and execute a quality agreement ("Quality Agreement"). The Quality Agreement shall in no way determine liability or financial responsibilities for the responsibilities set forth therein. 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, if applicable, 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.
- 4.9 <u>Product Maintenance Services.</u> Supernus will receive the following product maintenance services at no additional cost to Supernus (the "Product Maintenance Services"): one annual audit (as further described in Section 8); regulatory audits (as further described in Section 10); one annual Product review (within the meaning of 21 CFR § 211.180); Product document and sample storage relating to eGMP requirements; maintenance, updates and storage of master batch records and audit reports.
- 4.10 <u>Other Related Services</u>. Supplier shall provide such Product-related services, other than Validation Services, Manufacturing or Product Maintenance Services, as agreed to in writing by the parties from time to time. Such writing shall include the scope and fees for any such services and be appended to this Agreement. The terms and conditions of this Agreement shall govern and apply to such services.

5 API Yield.

- 5.1 <u>Reporting.</u> Supplier will give Supernus a monthly inventory report of the API held by Supplier using the inventory report form set out in Schedule B, which will contain the following information for the month:
- 5.2 Quantity Received: The total quantity of API that complies with the Specifications and is received at the Facility during the applicable period.
- 5.3 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), (iv) API that is converted into Tailings, (v) API contained in Defective Product where the cause of the nonconformity is not Supplier Defective Manufacturing, (vi) API used in in process weigh samples, (vii) residual amounts of API

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remaining in the drum which is impractical to use due to volume, (viii) API contained in Product which needs to be, and can be consistent with cGMP, re-blister packed, if Supernus does not permit such Product to be re-blister packed, or (ix) API received or dispensed in technical transfer activities or development activities during the applicable period, including without limitation, any regulatory, stability, validation, development or test batches manufactured during the applicable period.

5.4 <u>Quantity Converted:</u> The total amount of API contained in the Products manufactured with the Quantity Dispensed, delivered by Supplier, and not rejected or recalled in accordance with Section 6 because of Supplier's failure to perform the Manufacturing Services in accordance with Specifications, cGMPs, and Applicable Laws.

Within 60 days after the end of each calendar year, Supplier will prepare an annual reconciliation of API on the reconciliation report form set forth in Schedule C 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:

For each Product dosage strength, after Supplier has produced a minimum of 10 successful production batches of Product (not counting the validation batches in such dosage strength) (collectively, the "Target Yield Determination Batches"), the Parties will mutually agree on the target yield for the Product (each, a "Target Yield").

Shortfall Calculation. If the Actual Annual Yield falls more than ** below the Target Yield in a calendar year, then the shortfall for such year (the "Shortfall") will be calculated as follows:

5.6 <u>Credit for Shortfall</u>. If there is a Shortfall for a Product in a calendar year, then Supplier will credit Supernus' account for the amount of the Shortfall not later than 60 days after the end of the calendar year using the API Credit Value.

Each credit under this Section 5.6 will be summarized on the reconciliation report form set forth in Schedule C. Upon expiration or termination of this Agreement, any remaining credit owing under this Section 5 will be paid to Supernus. The Annual Shortfall, if any, will be reported by Supplier on the reconciliation report form.

- 5.7 <u>Maximum Credit.</u> Supplier's liability for API calculated in accordance with this Section 5 in a calendar year will not exceed, in the aggregate, the Maximum Credit Value set forth in Schedule A.
- No Material Breach. It will not be a material breach of this Agreement by Supplier, if the Actual Annual Yield is less than the Target Yield.

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- Acceptance and Rejection.
- Review of Testing Results. Supplier shall only deliver Product 6.1 from cGMP compliant production batches for which the corresponding test results meet the requirements of the Specifications, and prior to each shipment hereunder Supplier shall provide to Supernus all appropriate batch record documentation, release protocols, certificates of analysis, and results and such additional production, quality control, quality assurance and other manufacturing documentation as agreed upon by both parties. In addition, Supplier shall hold for inspection, or at the request of Supernus deliver to Supernus, retention samples of each lot of Product manufactured by Supplier under this Agreement. Upon receipt of each lot of Product, Supernus 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. Supernus may also conduct any additional testing or investigation it determines to be of value in accordance with the Quality Agreement to determine: (i) compliance of Product with the Specifications; and/or (ii) manufacture of Product pursuant to cGMP, and/or other standard imposed by Applicable Law. Supernus shall also have the right to inspect each shipment of Product for conformance with inspection criteria to be agreed upon by Supernus and Supplier. Upon request of Supernus, Supplier will at Supernus' cost, in advance of delivery of a particular order of Product ship samples of the applicable lot to Supernus' laboratory for testing.
- 6.2 <u>Acceptance or Rejection.</u> Supernus shall be responsible for final release to the market. Within thirty-five (35) days following delivery of Product samples to Supernus or its designee for final release testing, Supernus shall have the right to give Supplier notice of rejection (a "Rejection Notice") of any shipment that, in whole or part, fails to meet Specifications or to comply with cGMP or Applicable Laws, or which otherwise breaches Supplier's warranties set forth in Section 16.5 of this Agreement ("Defective Product"). Supernus shall at all times supply Supplier with any evidence it has that relates to whether any Product delivered to Supernus by Supplier is nonconforming as contemplated hereunder. Failure by Supernus to give timely notice of rejection shall mean acceptance by it of the shipment to which the notice of rejection would have otherwise applied. However, Supernus' 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. Supernus must notify Supplier in writing within thirty-five (35) days of the date upon which Supernus discovered or should have reasonably known of or discovered such Latent Defect but in no event later than the later of **. The term "Rejection Notice" as defined above shall include such notice concerning discovery of a Latent Defect. Upon timely receipt of a Rejection Notice from Supernus Supplier shall conduct an appropriate investigation in its discretion to determine whether or not it agrees with Supernus that Product is Defective Product and to determine the cause of any nonconformity. If Supplier agrees that Product is Defective Product and determines that the cause of nonconformity is attributable to ** ("Supplier Defective Manufacturing"), then Section 6.5 shall apply. For avoidance of doubt, where the cause of a non-conformity cannot be determined or assigned, it shall not be deemed Supplier Defective Manufacturing.
- Independent Laboratory Testing. In the event of any disagreement between Supplier and Supernus relating to Product conformance with Specifications and/or whether the cause of the nonconformity is Supplier Defective Manufacturing, 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 Parry. The

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independent party's results as to whether or not Product is Defective Product and, if determinable, the cause of any nonconformity shall be final and binding. The cost of such third-party laboratory shall be borne by the Party hereunder determined by the third-party laboratory to be the non-prevailing Party in such disagreement.

6.4 Defective Product.

- 6.4.1 If Supemus rejects Products under Section 6 and the non-conformance is determined to have arisen from Supplier Defective Manufacturing, and Supernus has not previously paid for the Defective Product, Supplier will replace the Defective Products contingent upon the receipt from Supernus of all Supernus Supplied Materials required for the manufacture of the replacement Products, and Supernus shall be liable to pay Supplier's invoice price for such replacement Product but shall not be liable to pay Supplier's invoice price for the Defective Product.
- If Supernus rejects Products under Section 6 and 6.4.2 the non-conformance is determined to have arisen from Supplier Defective Manufacturing and Supernus has previously paid for the Defective Products, Supplier will promptly, at Supernus' election, either: (i) refund all amounts paid by Supernus to Supplier for the Defective Products; (ii) offset the amount paid to Supplier against other amounts due to Supplier hereunder; or (iii) replace the Defective Products with conforming Products without Supernus being liable for Supplier's invoice price for such replacement Product, contingent upon the receipt from Supernus of all API and other Supernus-supplied Materials required for the manufacture of the replacement Products.
- 6.4.3 Supplier's responsibility for any loss of API in Defective Product due to Supplier Defective Manufacturing will be captured and calculated in the API Yield under Section 5. Supplier will also reimburse Supernus for all other Supernus Supplied Materials that were incorporated in the Defective Product.
- If Supernus rejects Product under Section 6 and the non-conformance is not determined to have arisen from Supplier Defective Manufacturing 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 of Supplier Defective Manufacturing then a full credit for the non-saleable, non conforming batch, plus the costs of the initial investigation will be retroactive as per section 6.3. Likewise, if subsequent data, inspection or other finding leads to a determination that Defective Product was not attributable to Supplier Defective Manufacturing then Supernus shall 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.
- Recalled Product. If a Recall (as defined in Section 10.6 below) results from, or arises out of, a failure by Supplier to perform the Manufacturing in accordance with the Specifications, cGMPs, and Applicable Laws, Supplier will be responsible for the documented out-of-pocket, administrative expenses of the Recall and will use its commercially reasonable efforts to replace the Recalled Products with new Products contingent upon the receipt from Supernus of all API and other Supernus-supplied Materials required to produce

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new Product. If Supplier is unable to replace the Recalled or returned Products (except where this inability results from a failure to receive the required API, or other Supernus Supplied Materials), then subject to Section 4.6 Supplier will reimburse Supernus for the price that Supernus paid to Supplier for Manufacturing Services for the affected Products including the costs to replace the Supernus API and Supernus Supplied Materials. In all other circumstances, Recalls, returns, or other corrective actions will be made at Supernus' cost and expense. Supplier's responsibility for any loss of Supernus Supplied Materials in a recalled Product will be captured and calculated in the API Yield under Section 5 or reimbursed as the case may be.

6.4.6 <u>Returned Products.</u> Supernus will have the responsibility for handling customer returns of the Products.

6.4.7 Exclusive Remedy. Except as set forth in this Section 6.5 and Section 20 (Indemnification), 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") AND THE OBLIGATIONS SET FORTH IN THIS SECTION 6.5 TOGETHER WITH SUPERNUS' RIGHTS TO INDEMNIFICATION UNDER SECTION 20 (IN EACH CASE, SUBJECT, FOR THE AVOIDANCE OF DOUBT, TO THE LIMITATIONS SET FORTH IN SECTION 22) SHALL BE SUPERNUS' SOLE AND EXCLUSIVE REMEDY UNDER THIS AGREEMENT FOR DEFECTIVE PRODUCT AND IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED. For greater certainty, Supplier will have no obligation for any Product Claims to the extent the Product Claim (i) is caused by the safety, efficacy, or marketability of the Product or any distribution thereof, (ii) Product failure to meet the Specifications due to changes requested by Supernus, (iii) results from a defect in the API 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 Supernus or third parties occurring after the Product is shipped by Supplier under Section 4.5, (v) is due to packaging design or labeling defects or omissions, including without limitation any Product Claim for "failure to warm", (vi) is due to any unascertainable reason, or (vii) is due to any other breach by Supernus of its obligations under this Agreement.

7 Steering Committee. Supernus and Catalent shall within 30 days of the Effective Date of this Agreement, nominate representatives from their respective employees, consultants or Affiliates to a steering committee ("Steering Committee") established with general oversight responsibility for the management of certain aspects of manufacturing, packaging and quality. In particular the Steering Committee shall:

7.1 Oversee the timing and implementation of relevant phases of manufacture and packaging as it pertains to Supernus' product;
7.2 Monitor arrangements for the procurement of

Supernus Supplied Materials; and

7.3 Review and coordinate the operation of this Agreement and the Quality Agreement and progress and resolve any operational issues. This will include volume forecasts and delivery dates, lead times for Long Lead Time Materials, 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.

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Supernus and Catalent shall appoint as members of the Steering Committee 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 Steering Committee.

The Steering Committee shall meet at regular intervals on such dates and such locations as may be agreed upon by the Parties, by video or teleconference or in person. In particular, the Steering Committee shall strive to meet at least once per quarter but in any event shall meet no less than three times per year. The Steering Committee may also meet upon ten (10) days of written request therefore by either party should circumstances necessitate such a meeting.

The members of the Steering Committee 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 Steering Committee. The Steering Committee shall not have the right to amend this Agreement.

- Inspection and Visits. Subject to the Quality Agreement, Supernus may enter Supplier's premises upon reasonable notice during Supplier's normal business hours for the purpose of reviewing the facilities, 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. Supernus may conduct one 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 so long as not due to Supplier negligence. In addition, Supernus, or its Affiliates or sublicensees, shall have the right to send up to 2 representatives to the Facility to be present during the performance of the services related to this Agreement for a maximum of 10 days per calendar year, upon at least five (5) business days' advance notice to Supplier. Supernus sublicensees and representatives that are not employees of Supernus may be required to sign a confidentiality agreement prior to being allowed access to the Facility. No such inspection shall diminish or increase Supplier's obligations hereunder.
- Notification of Regulatory Visits. In the event that any of Supplier's Facilities used in the manufacturing of Product hereunder are 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 on the same day by telephone and follow up in writing in accordance with the Quality Agreement, upon learning of such inspection, and shall supply Supernus with copies of any reports or responses (redacted as appropriate) 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. Supernus acknowledges that it may not direct the manner in which Supplier fulfills its obligations to permit inspection by and to communicate with Regulatory Authorities, If Supplier has been provided advance notice of such inspection, Supernus may send representatives to such Facilities to be available for questions, provided Supernus may be on-site but not directly participate in such inspections. Supernus shall have the right to review and comment on any

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responses, to the extent that such responses relate directly to Product, to such reports or other correspondence prior to submission to the applicable Regulatory Authority and Supplier shall consider in good faith Supernus' comments.

Manufacturing Records.

- 10.1 <u>Maintenance and Retention of Records.</u> During the Term of this Agreement, and for a period of two (2) years after its expiry or termination or as otherwise set forth in the Quality Agreement, Catalent shall, keep at is normal place of business detailed, accurate and up to date record showing any regulatory documentation generated for Supernus in relation to the services provided hereunder (the "Records"). Under no circumstances shall Catalent destroy any Records without giving Supernus a fifteen (15) day prior written notice. Supplier will maintain adequate and accurate books and records with respect to the Product, including but not limited to, manufacturing records and lot traceability records, with respect to each Product lot in accordance with the Quality Agreement. These records will be retained for the period required by Applicable Law or the Quality Agreement.
- 10.2 <u>Access to Records.</u> Upon seven (7) days notice from Supernus or in accordance with the Quality Agreement, Supplier shall provide copies of Records, the process and the individual and master batch records used by Supplier for any step in the manufacture of Product. Supernus may use the information in such batch records in regulatory submissions in order to gain or maintain Regulatory Approval. Supernus, or its nominee, shall be entitled to take copies or extracts from the Records during any such review or audit.
- 10.3 <u>Records; Regulatory Submissions.</u> During the Term, Supplier will assist Supernus with all regulatory matters relating to Manufacturing. Supplier shall be responsible for: (i) if applicable, providing Supernus with suitable manufacturing instructions, manufacturing controls and manufacturing documentation in a timely manner for Sup emus to include in Supernus' CMC Submissions, as far as required by regulatory authorities; (ii) providing Supernus with all information, process validation data, batch documents, and other data generated during the performance of the Manufacturing and 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 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 Supernus to conduct all necessary cGMP and quality assurance reviews of Supplier's documentation supporting the supply of Product to Supernus; and (v) obtaining and maintaining at its expense any licenses, permits, and registration with respect to general Facility operations required by any Regulatory Authority in the jurisdiction in which Supplier Manufactures Product and Supernus shall obtain and maintain all other Regulatory Approvals, including those necessary for Supplier to commence Manufacturing.
- 10.4 <u>Deviations</u>. Supplier agrees that its quality assurance function shall review the manufacturing records for all steps and all lots of Product it manufactures hereunder in accordance with the Quality Agreement. 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 will provide a copy of any such investigation report to Sup emus in accordance with the Quality Agreement.

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- 10.5 <u>Regulatory Communications</u>. 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.
- 10.6 Recall. If Supplier believes a recall, field alert, Product withdrawal or field correction ("Recall") may be necessary with respect to any Product supplied under this Agreement, Supplier shall notify Supernus on the same business day. Supplier will not act to initiate a Recall without the express prior written approval of Supernus, unless otherwise required by Applicable Laws and shall provide all necessary cooperation and assistance to Supernus. Supernus shall provide Supplier with an advance copy of any proposed submission to a Regulatory Authority in respect of any Recall, and shall consider in good faith any comments from Supplier. The cost of any Recall shall be borne as set forth in Section 6.5.5.
- 10.7 <u>Waste Disposal</u>. Supplier shall dispose of all wastes from the manufacturing process by incineration thereof in accordance with all Applicable Laws.

11 Price and Payment.

- 11.1 Payment Terms. Supernus shall make payment within 30 days after receipt of undisputed invoice. Supernus requests that Supplier forward each invoice via mail and to accounting@supernus.com or other email address designated by Supernus in writing to Supplier from time to time to ensure it has the full thirty (30) days to process payment. Supernus agrees, upon the request of Supplier, to pay interest at the rate of ** per month on any outstanding but undisputed payments that are not made within such thirty (30) day period.
- Manufacturing Fees. The price to be paid by Supernus for dosages, quantities, strengths and pack sizes of Product (the "Unit Price") purchased pursuant to this Agreement shall initially be as specified in Schedule D attached hereto. The Unit Prices will be adjusted following process validation and the initial commercial manufacturing campaign in the manner contemplated in Schedule D. Thereafter, except as provided below, the prices **. Thereafter, the prices shall be subject to an annual review and may be adjusted as set forth in this Section. Price adjustments for PPI will not occur more than once in any consecutive ** period, and may be based upon, but not be limited to, inflation as measured by PPI as reported by the U.S. Bureau of Labor Statistics provided Supplier shall have notified Supernus of such price adjustment at least ** in advance and any such total annual price increase does not exceed **. Notwithstanding the foregoing or any change in the PPI, whenever the cost for Materials increases by ** or more, such increases shall be passed through to Supernus as an increase in the Unit Price, Price adjustments due to process related improvements (other than reduction of the number of weight checks during encapsulation) shall be shared based on the relative contribution of each party to the process improvement. ** The reduction in price post implementation of process related improvements shall be reflected in the Unit Price promptly following implementation of the new weight check schedule.

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- 113 <u>Validation Services</u>. Supernus shall pay to Supplier the fees for Validation Services set forth on Schedule E. Supplier shall submit an invoice to Supernus for such fees upon the completion of the relevant phase of the Validation Services.
- 11.4 <u>Development Batches.</u> Each batch produced under this Agreement, including those (i) necessary to support the validation portion of Supernus' submissions for Regulatory Approvals and (ii) Manufactured following a permitted change in Specification or equipment, will be considered to be a "development batch" unless and until Manufacturing has been validated. Supernus shall be responsible for the cost of each such batch, even if such Batch fails to meet the Specifications, unless Supplier was grossly negligent in the Manufacture of the out-of-Specification batch. Supplier and Supernus shall cooperate in good faith to resolve any problems causing the out-of-Specification batch.
- 11.5 Taxes. All taxes, duties and other amounts assessed (excluding tax based on net income and franchise taxes) on API, ** Supernus-Supplied Materials, services or Product prior to or upon provision or sale to Supplier or Supernus, as the case may be, are the responsibility of Supernus, and Supernus shall reimburse Supplier for all such taxes, duties or other expenses paid by Supplier or such sums will be added to invoices directed to Supernus, where applicable.
- 11.6 <u>Supernus and Third Party Expenses.</u> Except as may be expressly covered by Product Maintenance Service fees, Supernus shall be responsible for 100% of its own and all third-party expenses associated with the development, Regulatory Approvals and commercialization of Product, including regulatory filings and post-approval marketing studies.
- 12 <u>Regulatory Approvals</u>. Supernus 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 Facilities for sale in the United States and other countries by Supernus or its sublicensees.
- Trademarks. Supernus, in its sole discretion, shall determine the trademarks and trade names owned or licensed by Supernus 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. Supernus shall advise Supplier as to the trademarks and trade names Supernus 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 Supernus 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 Supernus, Supplier shall give Supernus all reasonable assistance in securing or maintaining registration of any trademarks, copyright, or trade names used in connection with the Products with the PTO. Supernus 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 Supernus has determined it no longer wants to use.

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14 Restrictions; Ability to Subcontract.

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 Supernus; 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. Supplier shall have the right to cause any of its Affiliates to perform any of its obligations hereunder with prior written approval from Supernus which shall not be unreasonably withheld as long as permitted by Applicable Law and regulations that govern the Product NDA or applicable Regulatory Approval document.

- Safety Data. Supernus will provide Supplier with data on the chemical and physical properties, toxicity, and handling, storing, and shipping information for any API and Materials supplied to Supplier by Supernus and the Product (MSDS or equivalent) and any other information available to Supernus that is necessary for the safe conduct of the manufacturing of the Product by Supplier. Supernus shall supply Supplier with pertinent information relating to API and Materials supplied to Supplier by Supernus or the Product regarding health or safety hazards to Supplier's workers. Supernus shall update all of such information provided to Supplier as such information becomes available to Supernus.
 - 16 Representations and Warranties of Supplier. Supplier represents and warrants to Supernus that:
- 16.1 Supplier will comply with Applicable Laws in the performance of work under this Agreement.
- 16.2 Supplier will not ship to Supernus 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;
- 16.3 the execution, delivery and performance of this Agreement does not result in a breach of any of the terms or provisions of any other contractual obligation of Supplier;
- Any Supplier supplied Intellectual Property used by Supplier to perform the Manufacturing (i) is Supplier's or its Affiliate's property, (ii) may be lawfully used by Supplier, and (iii) to its knowledge, does not infringe and will not infringe upon any trademark, tradename, copyright, patent, trade secret, or other intellectual property or other right held by any person or entity; and
- 16.5 All Manufacturing under this Agreement will be conducted in accordance with the Specifications, cGMPs, and Applicable Laws and in all respects with the application Regulatory Scheme; and
- 16.6 Supplier has and will maintain throughout the term of this Agreement the expertise, with respect to personnel and facilities to comply with its obligations hereunder.

- 16.7 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 4.5 above.
- 16.8 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 have, 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 under the FDC Act.
- 16.9 THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS SECTION 16 ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES MADE BY SUPPLIER TO SUPERNUS, AND SUPPLIER MAKES NO OTHER REPRESENTATIONS, WARRANTIES OR GUARANTEES OF ANY KIND WHATSOEVER, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.
 - 17 Representations and Warranties of Supernus. Supernus represents and warrants to Supplier that:
- 17.1 all API and other Supernus-supplied Materials shall have been produced in accordance with Applicable Laws, shall comply with all applicable specifications, including the Specifications, shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws, and shall have been provided in accordance with the terms and conditions of this Agreement;
 - the content of all artwork provided to Supplier shall comply with all Applicable Laws;
- 17.3 all Product delivered to Supernus by Supplier shall be held, used and disposed of by or on behalf of Supernus in accordance with all Applicable Laws, and Supernus will otherwise comply with all laws, rules, regulations and guidelines applicable to Supernus's performance under this Agreement;
- 17.4 Supernus will not release any batch of Product if the required certificates of conformance indicate that Product does not comply with the Specifications or if Supernus does not hold all necessary Regulatory Approvals to market and sell the Product;
- 17.5 Supernus, to the best of its knowledge as of the Effective Date, has all necessary authority to use and to permit Supplier to use pursuant to this Agreement all intellectual property related to Product, API or Supernus-supplied Materials (including artwork), and the Manufacturing of the foregoing, including any copyrights, trademarks, trade secrets, patents, inventions and developments; and
- 17.6 the services to be performed by Supplier under this Agreement will not violate or infringe upon any trademark, tradename, copyright, patent, trade secret, or other intellectual property or other right held by any person or entity, provided that Supernus makes no representation with respect to Supplier IP.

17.7 THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS SECTION 17 ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES MADE BY SUPERNUS TO SUPPLIER, AND SUPERNUS MAKES NO OTHER REPRESENTATIONS, WARRANTIES OR GUARANTEES OF ANY KIND WHATSOEVER, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

18 <u>Confidential Information</u>.

- 18.1 <u>Definition.</u> As used herein, the term "<u>Confidential Information</u>" means, subject to the limitations and exceptions set forth in this Section 18, all information received by a Party pursuant to this Agreement from the other Party during the Term. In particular, Confidential Information shall be deemed to include, but is not limited to, any patent application or drawing, any trade secret, information, invention, idea, process, formula, or test procedures or data relating to any research project, work in process, future development engineering, manufacturing, regulatory, marketing, servicing, financing, regulatory status, or personnel matter relating to the disclosing Party, its present or future products, sales, suppliers, clients, customers, employees, investors, or business, whether in oral, written, graphic, or electronic form.
- General. The provisions of this Section 18.2 are subject to the exceptions contained in Section 18.3. During the Term, and for a period of five years after the expiration or termination of this Agreement, each Party will maintain all Confidential Information of the other Party received by it under this Agreement in trust and confidence and will not disclose any such Confidential Information to any third party or use any such Confidential Information for any purposes other than those necessary or permitted for performance under this Agreement. In particular, neither Party shall use any know-how of the other Party received under the Agreement for the manufacture or sale of any product other than Product. Each Party may use such Confidential Information only to the extent required to accomplish the purposes of this Agreement. Confidential Information shall not be used for any purpose or in any manner that would constitute a violation of Applicable Law. Confidential Information shall not be reproduced in any form except as required to accomplish the intent of the Agreement, No Confidential Information shall be disclosed to any employee, agent, consultant, affiliate, or sublicensee who does not have a need for such information. To the extent that disclosure is authorized by this Agreement, the disclosing Party will obtain prior agreement from its employees, agents, consultants, affiliates, sublicensees, or clinical investigators to whom disclosure is to be made to hold in confidence and not make use of such information for any purpose other than those permitted by this Agreement. Each Party will use at least the same standard of care with respect to the Confidential Information of the other Party as it uses to protect its own Confidential Information of a similar nature to ensure that such employees, agents, consultants, and clinical investigators do not disclose or make any unauthorized use of such Confidential Information, but no less than reasonable care. Each Party will promptly notify the other upon discovery of any unauthorized use or disclosure of the Confidential Information.
 - 18.3 Exceptions. Confidential Information shall not include any information that:

18.3.1 is or becomes publicly available without a breach by the receiving Party of this Agreement;

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- 18.3.2 was known to the receiving Party, without obligation to keep it confidential, prior to when it was received from the disclosing Party;
- 18.3.3 is hereafter furnished to the receiving Party by a Third Party, as a matter of right and without restriction on disclosure;
- 18.3.4 is independently developed by the receiving Party without any breach of this Agreement; or
- is the subject of a written permission by owner of Confidential

Information.

- 18.4 <u>Financial Terms Confidential</u>. The Parties agree that the material financial terms of the Agreements will be considered Confidential Information of both Parties. Notwithstanding the foregoing, either Party may disclose such terms to bona fide potential corporate partners and to financial underwriters and other parties with a need to know such information. All such disclosures shall be made only to parties under an obligation of confidentiality.
- 18.5 <u>Authorized Disclosure</u>. Notwithstanding any other provision of the Agreements, each Party may disclose Confidential Information if such disclosure:
- 18.5.1 is in response to a valid order of a court or other governmental body of the United States or a foreign country, or any political subdivision thereof; provided, however, that the responding Party shall first have given notice to the other Party and shall have made a reasonable effort to obtain a protective order requiring that the Confidential Information so disclosed be used only for the purposes for which the order was issued;
- 18.5.2 is otherwise required by Applicable Law, including securities law, the rules and regulations of the U.S. Securities and Exchange Commission, the NASDAQ Stock Market, and their respective foreign equivalents; or
- 18.5.3 is otherwise necessary to comply with applicable governmental regulations, but only to the extent that any such disclosure is necessary.
- 18.6 Return of Confidential Information. Upon termination of this Agreement for any reason, each Party will use commercially reasonable efforts to return all Confidential Information received by it from the other Party in connection with this Agreement or destroy such information if so directed, except that the returning Party may keep one copy of all Confidential Information in the custody of its legal department for legal archival purposes. Access to the copy so retained shall be restricted to the Party's legal counsel and the Confidential Information so retained shall not be used except in the resolution of any claims or disputes arising out of this Agreement. For purposes of this Section 18.6, a Party's obligation to use commercially reasonable efforts to return Confidential Information of the other will not require the Party to search back-up computer files that are not readily accessible or are kept off-site or to use forensic methods to retrieve data from hard disks or other storage devices.
- 18.7 <u>Publication</u>. Neither Party shall submit for written or oral publication any manuscript, abstract, or other medium that includes Confidential Information without first obtaining the prior written consent of such other Party, which consent shall not be unreasonably withheld or delayed. The requesting Party shall make any such request a reasonably sufficient

time in advance of the proposed submission date and shall ensure that any resulting publication notes the contribution of each Party whether by acknowledgment, co-authorship, or otherwise.

- 18.8 Equitable Remedies. The Parties acknowledge and agree that money damages may not be a sufficient remedy for any breach or threatened breach of this Section 18 and that the Parties shall be entitled, without the requirement of posting a bond or other security, to seek specific performance and injunctive or other equitable relief as a remedy for any such breach or threatened breach. Such remedies shall not be deemed to be the exclusive remedies for a breach or threatened breach of this Section 18.8 but shall be in addition to all other remedies available to the Parties at law or in equity.
- 18.9 <u>Procedure for Public Announcements</u>. Neither Party will issue any press release or make any public announcement concerning this Agreement without obtaining the prior consent of the other Party. This Section 18.9 does not limit either Party's right to make disclosures to the extent required by Applicable Law or by any governmental agency or the rules of any stock exchange on which the securities of the disclosing Party are listed. In addition, Supernus may disclose the existence and nature of this Agreement (but not its terms other than the length of its duration) to investment bankers, strategic or financial investors and qualified institutional buyers who Supernus reasonably believes may have a bona-fide interest in participating in Supernus' initial public offering of its common stock or issuance of equity securities once public under the Securities Act of 1933, as amended.
- 18.10 Confidential Treatment. Supernus covenants that prior to filing this Agreement as an exhibit to any of its filings with the Securities and Exchange Commission (the "SEC") it will use commercially reasonable efforts to obtain confidential treatment of certain mutually agreed upon terms of this Agreement pursuant to Rule 24b-2 promulgated by the SEC under the Securities Exchange Act of 1934, as amended. Supernus will give Supplier as is practically reasonable the opportunity to review and comment upon the requested confidential treatment of this Agreement prior to filing it with the SEC, and will consider Supplier's comments in good faith.

19 <u>Intellectual Property</u>.

- 19.1 For purposed hereof, "Supernus IP" means all intellectual property and embodiments thereof owned by or licensed to Supernus as of the date hereof or developed by Supernus other than in connection with the Product; "Supplier IP" means all intellectual property and embodiments thereof owned by or licensed to Supplier as of the date hereof or developed by Supplier other than in connection with the Product. "Invention" means any intellectual property developed by either party in connection with the Product. All Supernus IP shall be owned solely by Supernus and no right therein is granted to Supplier under this Agreement except for use in performing the services related to the Product. All Supplier IP shall be owned solely by Supplier and no right herein is granted to Supernus under this Agreement except as specified hereunder.
- 19.2 All Inventions, ideas, discoveries, developments, methods, 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) generated or derived by Supplier or Supernus whether alone or together in the course or performing the services which are related to or dependent upon Supernus' proprietary Product or are based on or derived from Supernus' Confidential Information shall be the exclusive property of Supernus ("Supernus New IP"). Supernus hereby

grants to Supplier a non-exclusive, non-assignable, paid-up, royalty-free, non-transferable, license to use the Supernus New IP to the extent necessary to perform the Services hereunder.

- 19.3 All Inventions, ideas, discoveries, developments, methods, 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) generated or derived by Supplier in the course or performing the services which are not related to or dependent upon Supernus' proprietary Product or are not based on or derived from Supernus' Confidential Information, or which have application to developing, manufacturing, filling, processing, packaging, analyzing or testing drug products shall be the exclusive property of Supplier ("Supplier New IP"). Supplier hereby grants to Supernus a non-exclusive, non-assignable, paid-up, royalty-free, non-transferable, license to use the Supplier New IP solely to the extent necessary to use the Product developed during performance of the Services hereunder.
- 19.4 Each party shall promptly and fully disclose, in writing, to the other any and all such New IP. Each party hereby assigns and agrees to assign to the other all applicable right, title and interest in and to any such New IP. Each party agrees to cooperate fully in obtaining patent, copyright or other proprietary protection for such New IP, all in the name of the applicable party and at such party's cost and expense, and shall execute and deliver all requested applications, assignments and other documents, and take such other measures as reasonably requested in order to perfect and enforce rights in such New IP.

20 Indemnification.

- 20.1 Supernus agrees to indemnify, and hold harmless Supplier and Supplier's Affiliates, and its and their stockholders, 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 arising out of or in connection with any suit, demand or action by a third party arising out of or resulting from:
- 20.1.1 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 in whole or in part the result of Supplier's negligence or willful misconduct in performing the services hereunder or breach of any covenant or agreement hereunder;
- 20.1.2 negligence or willful misconduct in advertising, labeling, improper handling, or storage of Product by any person other than Supplier, its Affiliates or subcontractors;
- 20.1.3 any manufacture, packaging, sale, promotion, distribution or use of or exposure to Product, API or other Supernus-supplied Materials, including product liability and strict liability, except to the extent that the foregoing arises out of or results from Supplier's negligence, willful misconduct or breach of this Agreement;
 - 20.1.4 any negligence or willful misconduct by Supernus;

- 20.1.5 any misrepresentation by Supernus or breach by Supernus of any covenant or agreement hereunder, or
- $20.1.6 \qquad \text{any actual or alleged infringement, misappropriation or violation of any third party patent, trade secret, copyright, trademark or other proprietary rights by intellectual property or other information provided by Supernus, including relating to any API, Materials or Supernus Intellectual Property.}$
- Supplier shall indemnify and hold harmless Supernus and Supernus's Affiliates, and its and their stockholders, 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 arising out of or in connection with any suit, demand or action by a third party arising out of or resulting from:
- any negligence or willful misconduct of Supplier and/or Supplier's 20.2.1 agents in performing the services hereunder; or
- 20.2.2 any misrepresentation by Supplier or breach by Supplier of any covenant or agreement hereunder.
- 20.2.3 any actual or alleged infringement, misappropriation or violation of any third party patent, trade secret, copyright, trademark or other proprietary rights by intellectual property or other information provided by Supplier relating to the services provided by Supplier other than any API, Materials and Supernus Intellectual Property.
- In no event shall either Party be liable to the other for punitive, indirect damages and consequential damages, including without limitation, lost profits or revenues.
- 20.4 In the event that either Party seeks indemnification (an "Indemnified Party") under the terms of this Section 20, 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 Indemnifed 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,
- In the event that the negligence or willful misconduct of both Supplier and Supernus contribute to any such loss, claim, injury, damage, cost or expense, Supplier and Supernus 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.
- 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 per-occurrence limit of not less than ** 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, including transit/warehouse insurance, in an amount equal to the full

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

replacement value of its property while in, or in transit to or from, the Supplier (Catalent) facility as required under this Agreement. Each party may self-insure all or any portion of the required insurance as long as, together with its Affiliates, its US GAAP net worth is greater than \$200 million or its annual EBITDA (earnings before interest, taxes, depreciation and amortization) is greater than \$100 million. Each required insurance policy, other than self insurance, shall be obtained from an insurance carrier with an A.M. Best rating of at least A- 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 but such waivers shall not be effective if loss is due to the negligence of the waiver-granted 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 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.

- 21 Exclusivity. During the term of this Agreement and any subsequent supply or manufacturing agreement between the parties relating to the Product, and so long as Supernus is not in material breach of this Agreement, Supplier agrees that solely with respect to its ** sites (the "Supplier Sites"), it will not undertake any new ** for any third party (a "Competitive Product"). For the avoidance of doubt and notwithstanding any other provision in this Agreement to the contrary, the restrictions contained here in do not apply to, without limitation: ** owned or controlled by Catalent or its Affiliates. For further avoidance of doubt, the above restriction on ** is intended to restrict Supplier from assisting a third party in creating a manufacturing process for a **, but is not intended to restrict Supplier from manufacturing a Competitive Product for a third party where such third party has provided the manufacturing process and specifications to Supplier and so long as Supplier does not utilize Supernus Confidential Information and takes specific actions to prevent the sharing of Supernus Confidential Information and its use by Supplier personnel involved in the manufacture of such Competing Products.
- 22 <u>Limitations of Liability</u>. EXCEPT FOR CLAIMS AND DAMAGES OF A THIRD PARTY ARISING UNDER SECTION 20 (Indemnification) RELATING TO BODILY OR MEDICAL INJURIES, SUPPLIER'S TOTAL LIABILITY UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED ** THE TOTAL FEES PAID UNDER THIS AGREEMENT DURING THE 12 MONTHS IMMEDIATELY PRECEDING THE MANUFACTURE OF THE BATCH OR PROVISION OF THE SERVICES GIVING RISE TO THE CLAIM.

SUPPLIER'S LIABILITY UNDER THIS AGREEMENT FOR ANY AND ALL CLAIMS FOR LOST, DAMAGED OR DESTROYED API OR SUPERNUS SUPPLIED MATERIALS, WHETHER OR NOT INCORPORATED INTO PRODUCT, SHALL NOT EXCEED THE MAXIMUM CREDIT VALUE IN ANY CALENDAR YEAR.

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

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

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23 <u>Notices</u>.

- Any notice or other communication 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).
- Duly authorized Purchase Orders and forecasts required pursuant to Section 3 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:

Jack Khattar President and CEO Supernus Pharmaceuticals 1550 East Gude Drive Rockville, MD 20850 (o) (301) 838-2500

With a copy to:

Jones W. Bryan, Ph.D. Vice President, Business Development and Licensing Supernus Pharmaceuticals 1550 East Gude Drive Rockville, MD 20850 (o) 301-838-2681 For Supplier:

Catalent Pharma Solutions, LLC 1100 Enterprise Drive Winchester, KY 40391 Attn: General Manager Facsimile: **

With a copy to:

Catalent Pharma Solutions, LLC 14 Schoolhouse Road Somerset, NJ 08873 Attn: Legal Department Facsimile: **

24 General Terms and Conditions.

24.1 <u>Disputes:</u>

If a dispute arises between the parties in connection with this Agreement, the respective presidents or Senior Executives of Supplier and Supernus shall first attempt to resolve the dispute. If such parties cannot resolve the dispute, such dispute shall be resolved in the jurisdiction of the State of Delaware by binding arbitration in accordance with the then existing commercial arbitration rules of the CPR Institute for Dispute Resolution, 366 Madison Avenue, New York, NY 10017.

24.2 Applicable Law/Jurisdiction.

(a) 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.

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

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- (b) 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 maybe 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 24.2 shall be deemed effective service of process on such party.
- (c) 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.
- (d) 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.
- (e) 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.
- (f) 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.
- (g) 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.
- 24.3 <u>No Waiver</u>. 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.
- 24.4 <u>Assignment.</u> 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 (i) third party that assumes ownership or control of the Facilities or (ii) successor to substantially all of the business or assets of the Supplier or the Supplier's business unit

responsible for performance of this Agreement. 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 or (c) successor to substantially all of the business or assets of the Supernus or Supernus' business unit responsible for performance of this Agreement.

- 24.5 <u>Severability.</u> 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.
- 24.6 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, Supernus 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 Supernus' 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 ninety (90) 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.
- 24.7 <u>Third-Party Beneficiaries.</u> This Agreement is not intended to, and the Parties agree that it does not, bestow any benefit or right upon any third party.
- 24.8 <u>Use of Names</u>. 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.
- 24.9 <u>Independent Contractor.</u> Nothing contained in this Agreement shall be deemed to constitute a partnership between Supernus 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.
- 24.10 <u>Headings</u>. 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.
- 24.11 <u>Entire Agreement.</u> 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,

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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.

24.12 <u>Counterparts</u>. 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]

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

CATALENT PHARMA SOLUTIONS, LLC

By:

Name: Ian Muir
Title: President, MRT

SUPERNUS PHARMACEUTICALS, INC.

By:

/s/ Jack Khattar Name: Jack Khattar Title: CEO

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SCHEDULE A <u>API</u>

Active Materials	Manufacturer/Supplier
the generic compound	**
Topiramate	

API CREDIT VALUE

The API Credit Value will be the lesser of (i) ** per kilogram and (ii) Supernus' average ** of the API for the preceding Year.

MAXIMUM CREDIT VALUE

Supplier's liability for Supernus Supplied Materials calculated in accordance with Section 5 of the Agreement for the Product in a calendar year will not exceed, in the aggregate **.

Long Lead Time Materials

**

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

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SCHEDULE B QUARTERLY ACTIVE MATERIALS INVENTORY REPORT

TO:	Supernus		
FROM:	Catalent Pharma Solutions		
RE:	Active Materials quarterly inventory report und the Manufacturing Services Agreement dated • "Agreement")		_
Reporting quarter:		kg -	
Active Materials at beginning of quarter:	on hand	kg -	(A)
Active Materials at end of quarter:	on hand	kg -	(B)
Quantity Received during quarter:		kg -	(C)
Quantity Dispensed ¹ during quarter: (A + C - B)		kg -	
Quantity Converted during quarter: (total Active Ma and not rejected	terials in Products produced, recalled or returned)	kg -	
Capitalized term	s used in this report have the meanings given to	the terms in the Agreement.	
Catalent Pharma	Solutions, LLC DATE:		
Per: Name: Title:			-
1. Excludes	the items set forth in Section 5.3. Page 34 of 41		

SCHEDULE C REPORT OF ANNUAL API INVENTORY RECONCILIATION AND CALCULATION OF ACTUAL ANNUAL YIELD

TO: FROM:	Supernus			
RE:	Catalent Pharma Solutions, I API annual inventory recon Yield under Section(s) 5.3 a dated • (the "Agreement")	ciliation report and calcul-		
Reporting Ye	ar ending:	December 31,		
Active Materi at beginning o			_ kg	(A)
Active Materi at end of Year			_ kg	(B)
Quantity Reco	eived during Year:		_ kg	(C)
Quantity Disp (A+C-B)	pensed ¹ during Year:		_ kg	(D)
(total Active I	verted during Year: Materials in Products produced ted, recalled or returned)		_ kg	(E)
API Credit Va	alue:	\$	/ kg	(F)
Target Yield:			%	(G)
Actual Annua ((E/D) * 100)			%	(H)
Shortfall:		\$ (if a negative number, in	nsert zero)	(I)
Based on the fo	oregoing reimbursement calculat	ion Supplier will reimburse	e Supernus	the amount of \$

^{1.} Excludes the items set forth in Section 5.3.

^{**} This portion has been redacted pursuant to a confidential treatment request.

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

DATE:	
Catalent P	harma Solutions, LLC
Per: Name: Title:	
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SCHEDULE D - PRICING

UNIT PRICING*			
Product	Dosage Form / Unit Strength	Initial Unit Price (does not include API, release testing or ··) per 1000 capsules	
Trokendi	**	**	

- •One unit is one capsule; One Batch is ** capsules or ** capsules, or ** capsules or ** capsules. Prices do not include cost of API, tooling or other Product-specific items, artwork, shipping, insurance or duty. Prices also do not include any testing, retesting or testing supplies other than as expressly set forth in the Specifications. Prices are based on certain assumptions as to manufacturing processes, storage conditions, etc., including those set forth in that certain quotation letter COE-SUP-12022009A.04 dated 10 February 2012. Accordingly, prices are subject to adjustment in the event any such assumptions are subject to revision in connection with the validation of the Product.

 *Pricing assumes that each Purchase Order will be for multiple batches in the aggregate (for all dose strengths)
- Pricing assumes that each Purchase Order will be for multiple batches in the aggregate (for all dose strengths) and, each dose strength will be for the applicable number of batches (or multiple thereof) as set forth below.
 Supernus may request different campaign sizes which may be subject to additional costs or cost reductions

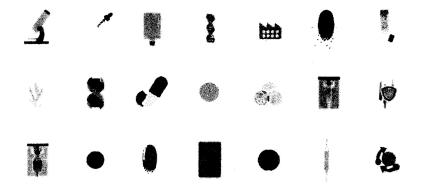
Dose Strength	Minimum Batch Number
**	**
**	**
**	**
**	**

^{*} This portion has been redacted pursuant to a confidential treatment request.

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SCHEDULE E - THE VALIDATION SERVICES

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Solution for Process Validation Topiramate Extended Release Capsules VERSION: QTE-SUP-11-3036.01

Prepared for

Supernus Pharmaceuticals, Inc. 1550 East Gude Drive Rockville, MD 20850 E-mail: **

Provided by Catatent Pharma Solutions T **

E-mail: **

Prepared by. E-mail: **







Catalent

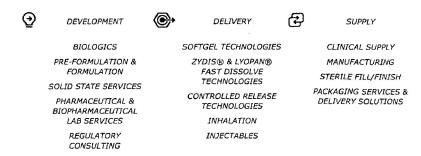
Thank you for choosing a solution from Catalent.

Catalyst + Talent. Our name combines these ideas. From drug and biologic development to delivery technologies and supply solutions, we are the catalyst for your success. With over 75 years of experience, we have the deepest expertise, the broadest offerings and the most innovative technologies in brand and generic pharmaceuticals, veterinary medicine, consumer health, and biologics.

We help you get more molecules to market faster, solve bioavailability and development challenges, enhance product performance and patient adherence, create the optimal dose form, and drive superior supply chain, manufacturing, and packaging results.

Whether you are looking for a single, tailored solution or multiple answers throughout your product's lifecycle, we can improve the total value of your treatments-from discovery to market and beyond.

 $Catalent.\ More\ products.\ Better\ treatments,\ Reliably\ supplied.\ ^{TM}$



Section 1Executive Summary

Catalent Pharma Solutions, LLC located in ** ("Catalent") proposes to carry out the following activities for Supernus Pharmaceuticals, Inc. ("Client"), pursuant to the Catalent and Supernus negotiated terms and conditions as referenced in the attachment.

Catalent proposes to provide manufacturing services to support the process validation of Topiramate extended release capsules. The scope of the manufacturing is noted in the Processing Tables. ** requirement from the version QTE-SUP-11-3036.00 of the validation processing.

This program has been developed in good faith based on assumptions regarding development outcomes and Client objectives with no complete assurance of processing meeting product specific performance specifications. Therefore, risks inherent to development are borne by the work plan in order to expedite submission of this estimate and strategy. If the product does not meet the performance specifications during formulation and process development or the dosage form fails a stability challenge, Client approved scope change would be required for further development by Catalent to align product performance with specifications.

This quote has been presented based on assumptions regarding the ability for appropriate safe handling of the API and subsequent blends and solutions of the API and notification of current customers of the introduction of this class of API to the manufacturing facility. Any past, current, or future information regarding product and API safety is considered vital to share among all project stakeholders and is the responsibility of project participants.

Section 2 Project Activities, Support, and Supplies

Project Initiation/Continuance

Catalent will carry out the following project initiation activities:

- Identify project team members.
 Establish project timeline.
- Provide project management and communication plans for the following:
 - Excipient ordering as noted in Section 2.4.
 - Equipment ordering as noted in Section 2.4. b.
 - Identify and receive necessary reference standards, API lots, and excipients for the manufacturing.
 - d.
- Propose and document specifications, batch records, and protocols as applicable in support of the project.

 Review the Material Safety Data Sheets ("MSDS") and other safety Information available from the Client to categorize the safety/handling precautions for this product.

Activity	Estimated (\$)
Project Continuation Fee	**

2.2 Manufacturing
Catalent will carry out the following manufacturing activities in support of the project:

- Prepare batch records and protocols necessary.
 Clean the process equipment.
- Trepare other records and protects necessary.
 Clean the process equipment.
 Manufacture the product as outlined in the appropriate batch record.

Processing Tables

Campaign I - Process Validation GMP

** This portion has been redacted pursuant to a confidential treatment request. September 28, 2011QTE-SUP-3036.01Page 3 of 15

	ription	# of Lots	~ lot size kg or # of capsules
**		3	**
**		3	**
**	**	6	**
**	**	6	**
**	**	6	**
**		3	**
**		3	**
**		3	**
**		3	**

Process Map



Table - Manufacturing Cost Summary

Activity	Estimated (\$)
Manufacturing Campaign I	**
Validation Protocol	**
Manufacturing Costs Sub-Total	**

2.3 Analytical Support
Supernus provides in-process, release, and validation testing services. Catalent will carry out the following analytical activities for the testing of raw materials as needed in support of the project following execution of processing for Registration/stability batches noted in QTE-SUP11-3067.01.

Table – Analytical Activity

Activity	Estimated (\$)
Cleaning Verification Campaign I – ** – Encapsulation	**
Analytical Support Costs Sub-Total	**

Based upon the method complexity, Catalent reserves the right to amend the estimated costs. All raw material and release testing assumes one composite sample per batch. Raw material testing assumes one lot of each excipient. If there are additional lots of excipients, a QAR will be written to cover the cost of the testing. ID test and release API. Note that ID/release is only acceptable for cGMP usage if the API is delivered and has been fully tested by the Client or other third party and shipped with the manufacturer certificate of analysis.

2.4 Raw Materials, Equipment, and Supplies
Catalent will carry out the following raw materials procurement and equipment procurement noted in QAR02 QTE-SUP-11-3029.00.
Update to raw material requirements to be issued following execution of processing for Registration/stability batches noted in QTE-SUP11-3067.01.

Catalent has provided an estimated timeline (Table below) for the proposed activities outlined above. All timelines are estimates based on Catalent's experience and do not reflect other circumstances beyond Catalent's control.

^{**} This portion has been redacted pursuant to a confidential treatment request. September 28, 2011QTE-SUP-3036.01Page 4 of 15

Section 3 Preliminary Timeline

Activity	Duration
Manufacturing	3 to 6 weeks
Analytical Evaluation	Supernus

Section 4 Cost Proposal

Table – Estimated Project Cost

Activity	Estimated Cost (\$)
Project Initiation	**
Manufacturing Campaign I	**
Analytical Support	**
Raw Materials/Equipment/Supplies Procurement	**
Project Estimated Total	**

The summary of costs detailed above does not include any extra reformulation activities, any post submission activities and/or any activities required for commercial batch manufacture, unless otherwise specified. Additionally, it does not include any post approval tasks such as annual stability testing or storage. If requested by the Client, these costs will be quoted separately.

Project Initiation/Continuance Costs

The Client shall pay a non-refundable payment for the Project Initiation/Continuing Fee for a total of ** with signed delivery of the proposal to Catalent.

Revisions to Pricing

Catalent reserves the right to revise the quoted costs for any project as a result of initial scope change, revisions in protocols, modifications of test methods, final review of test methods, undocumented requirements, retesting or any unforeseen difficulty in executing the project. In addition, the quoted costs are subject to annual review to account for changes in inflation. The additional work will be performed based on written agreement from the Client and will be documented on a Catalent Quotation Amendment Record ("QAR").

Patent Challenges and Litigation

With respect to any and all disputes regarding the filing of an ANDA Paragraph IV patent challenge which involves this Project and/or Product(s) hereunder, Catalent reserves the right to charge additional fees of up to ** to address Catalent's time and materials costs of responding to subpoena (es), compiling and delivering documents, providing access to Catalent personnel for depositions, in-house counsel review, and any other items related to the Paragraph IV challenge.

Section 5 Project Management & Project Considerations

In order to establish a collaborative relationship between the Client and Catalent, both parties will appoint a Project Manager to serve as a point of contact to oversee the progress on this project. Upon initiation of the project, Catalent and the Client will establish a communication plan that may include conference calls, visits and timelines. Client communication Is encouraged.

Transfer and Confirmation Milestone Evaluation

Catalent with Client will evaluate the project for commercial viability and quality/regulatory systems impact at milestone time points throughout the project. The milestone evaluation allows Catalent and Client to have decision making methodology for review of project to allow continuance for validation and commercial launch of product or products involved in each project.

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Catalent Project Management Responsibilities

- Excipient ordering for batches as described.
 Equipment ordering for batches as described.
 Identify and receive necessary reference standards, API lots, and excipients for the manufacturing.
- Propose and document specifications, batch records, and protocols as applicable in support of the project.
- 5. Catalent will provide sampling of raw materials, project in process materials, and project finished materials for the Client during the QC sampling of the raw materials during the direct processing and release of the product batches for this project. If additional samples not directly associated with the QC sampling of the raw materials for this project or the processing and release associated with this project are required, Catalent will charge a sampling fee of ** per sample to cover the handling and additional Inventory accounting costs associated with the sampling. Shipping associated with these samples will be rebilled to the Client.

Client Project Management Responsibilities

- The Client will sign the quote and provide a P.O. to cover the project.
 The Client will provide a technical contact that will be available for technical discussions and to make decisions that are needed for this project.
- 3. The Client will provide previous and current batch records, development reports, materials, and product specifications as required for initiation and continuation of this project.
 - The Client will provide the cleaning verification analytical methodology for transfer to Catalent.
 - The Client will provide the API for this project.
- 6. If the product does not meet the performance specifications during formulation and process development, or the dosage form fails a stability challenge, then a Client-approved scope change will be required for further development by Catalent.
- 7. All required investigational work (such as OOS investigations, trouble shooting, etc.) can be conducted without prior approval from the Client for up to 16 scientist hours per occurrence. If additional work requires going beyond 16 hours, the customer will be contacted prior to continuation. All investigational retesting performed that is not directly due to a Catalent error will be invoiced to the
 - The Client will provide all documented product and raw material specifications necessary to perform this project.
 - The Client will provide the validated product analytical testing methods.
- 10. Unused raw materials, finished products and waste, including organic solvents, will be returned or destroyed at the conclusion of each series of trials at the Client's expense. (These materials will be destroyed viaincineration @ ** for solid and ** for liquid waste).

 11. Client must review inventory and advise Catalent on a monthly basis of the material status and planned date of usage. After 60 days
- of no project activity, Catalent reserves the right to return, dispose, or maintain any of material inventories of the Client's. Client may incur pallet storage fees of ** per pallet per month plus additional handling charges based on inventory evaluation between Client and Catalent.

Project Initiation and Scheduling

- The following must be submitted prior to any project work to guarantee scheduled time in the manufacturing facility.

 1. The Client must provide a signed purchase order and the signed quote by fax, email, or mail a minimum of four (4) weeks prior to any work to allow adequate time for project initiation and cleaning verification methodology transfer.
- 2. If raw material purchases are included in this purchase order, then the P.O. and signed quote must be received prior to the order of any raw materials (see requirements for raw materials below).
- The Client must provide batch record details four (4) weeks prior to any batch manufacture. Batch record completion and approval (by Catalent and the Client) must be completed five (5) business days prior to the scheduled batch manufacture.
 The Client must provide raw materials a minimum of three (3) weeks prior to batch manufacture for feasibility or demonstration.
- work and four (4) weeks prior to batch manufacture for cGMP work. If full compendial testing is required, delivery must be a minimum of four (4) weeks prior to batch manufacture.
 - 5. The Client must provide an MSOS for all materials to be used in processing this product.

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Catalent's Safety Responsibilities

Catalent will assess all vendor and Client Material Safety Data Sheets ("MSDS") and all handling data for the samples and materials Catalent will assess all vendor and Client Material Safety Data Sneets (MSDS) and all handling data for the samples and materials associated with this project. If categorized as a Category four (4) or five (5) (out of a scale of five), the samples, materials and work will require special handling precautions and will be subject to a Hazardous Material Fee for all handling and testing directly associated with the samples and materials. As applicable, this Hazardous Materials Handling Surcharge has been included in the project costs.

Client's Safety Responsibilities

The Client will provide the MSDS and all sample and material handling data for the samples and materials associated with this project. If any sample or material has any special handling considerations, the Client will notify Catalent prior to the initiation of the project.

Equipment Failure

Catalent is not in any manner responsible for material, scheduling or financial losses due to equipment failure (beyond the direct cost of materials contained within the respective product container). In the event of equipment failure, every effort will be made to repair the equipment and reschedule the Client in the timeliest manner.

Non-Validated Work

If product will be manufactured, the Client shall pay for all product batches, including batches that do not conform to applicable specifications, unless all methods and processes associated with the manufacture, testing and storage of that product have been fully validated in accordance with generally accepted standards of the pharmaceutical industry.

Either party may terminate the project or any portion thereof at any time by providing sixty (60) days written notice. Upon receipt of any such notice of termination, Catalent shall promptly wind down the affected portion of the project work or study and avoid (or minimize, where not cancellable) any further related expenses.

Cancellation of batch manufacture by Client within 30 days will incur a charge as provided in the following table:

Time ii	n Calendar Days	30 or greater	29 -20	19 -10	9 – 4	3 – 0
Associ		**	**	**	**	**

General Shipping

All supplies that are shipped to Catalent in ** must be clearly marked with the Client company name and addressed "Attention: Process

All materials shipped to Catalent in ** freight collect or COD will incur an additional handling surcharge of ** or ** of the respective bill (whichever is greater).

All materials shipped to Catalent in ** that require US customs clearance must be assigned a customs broker arranged for by the Client.

All materials shipped to Catalent in ** on wood pallets must be heat treated in accordance with IPPC-ISPM 15 International Export regulations. Specifically, Heat Treated (HT) pallets must be marked with the IPPC logo in accordance with the International Standard.

No chemicals or chemical treatments, including Haloanisoles or brominated phenols including 2, 4, 6-tribromianisole (TBA) or 2, 4, 6trichloroanisole (TCA), shall be applied to any wood pallets used to ship materials to Catalent in *

Any wood pallets that fail to comply with the requirements set forth above shall be rejected and returned to the supplier of the material at

Analytical Rush Services

Rush services are available at Customer's request. If rush services are agreed between Customer and Catalent, additional costs will be invoiced based on the schedule below.

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Confidential

0	% Turn Around Time (TAT) Reduction	% Rush Charge	
	**	**	
	**	**	
	**	**	
	**	**	

Section 6Invoicing and Payment Terms

Invoicing Terms
Catalent will issue invoices monthly for work completed in that month.

Payments toward all invoices are due within 30 days from date of the invoice and are non-refundable. Any applicable wire transfer fees must be included in the payment issued to Catalent. All Shipments are EXW (Incoterms 2000) Winchester, Kentucky. Remit all payments to:

Wire to:	Overnight mail to:	Regular mail to:
J.P. Morgan Chase	J.P. Morgan Chase	Catalent Pharma
**	Attn: Catalent Pharma	Solutions-Winchester
	**	25106 Network Place
	131 S. Dearborn Street, 6 th	Chicago, IL 60673-1251
	Floor	
	Chicago II 60603	

Terms and Conditions

es agree that this quotation and all work performed hereunder is subject to the Terms and Conditions set forth in Attachment.

Section 7Revision History

Revision Number	Comments
3036.00	Initial Proposal
3036.01	Increase manufacturing scope and put into new quote template.

^{**} This portion has been redacted pursuant to a confidential treatment request. September 28, 2011QTE-SUP-3036.01Page 8 of 15

Section 8Project Approval and Authorization

Client agrees to the terms and conditions set forth in this Quotation Invoicing for the Project should be sent to:

Name:	Gregory S. Patrick		
Department:	Accounting Department		
Telephone No.:	**		
Address:	1550 East Gude Drive		
	Rockville, MD 20850		
Purchase Order Num	nber		
	·		
Supernus Pharmacei	uticals, Inc.	Catalent Pharma Solutions LLC	
		-	
/s/ Padmanabh P. B	hatt, Ph.D.	/s/ Stephen Havel	
Signature		Signature	
Padmanabh P. Bhatt	t, Ph.D.	Stephen Havel	
Printed Name		Printed Name	
Vice President		General Manager	
Title		Title	
. 20 2012		20.5 . 1 2011	
January 20, 2012		28 September 2011	
Date		Date	
Mail amail ar fay tl	his completed Project Approval a	nd Authorization page to:	
vian, eman, or iax u	ins completed 1 roject Approvar a	iu Authorization page to:	
		**	
	Catalent Pharma Solutions 1100 Enterprise Drive		
		Winchester, KY 40391	
		**	

If this signed document is not returned within 5 days, any tentative manufacturing dates noted in this proposal or otherwise communicated may be assigned to another Client.

^{**} This portion has been redacted pursuant to a confidential treatment request. September 28, 2011QTE-SUP-3036.01Page 9 of 15

For purposes of these Terms and Conditions: 'Quotation' means any and all quotations appended to these Terms and Conditions, which are then governed by these Terms and Conditions:

A. Expiration. This Quotation is valid for 30 days from the date hereof, and becomes binding for an initial term of five (5) years ('Initial Terri) if signed and delivered by both parties during such 30 day period. The Initial Term will be automatically renewed for additional one year term(s), unless either party notifies the other not less than ninety (90) days prior to the end of the Initial Term, or any subsequent term that such party does not wish to renew this Quotation.

Client may terminate this Quotation for any reason upon ninety (90) days prior written notice to Catalent

Either party may terminate this Quotation, upon written notice to the other party, if the other party materially breaches this Quotation and such party fails to cure said breach within sixty (80) days after receipt of written notice from the non-breaching party outlining the breach and its intention to terminate.

Should Client choose to terminate this Quotation prior to completion, for any reason, other then Catalent's material breach of this quotation. Client agrees to pay Catalent:

- (i) all reasonable costs earned hereunder for Services performed up to the Effective Data of termination in accordance with the terms of this Quotation;
- (ii) all non-cancelable expenses and pass-through costs incurred in connection with any Services being terminated to the date of termination; and (iii) any third party pass-through costs associated with terminating such services.

B. Audits. Client may conduct one quality assurance facility audit per year at no cost. Additional audits will be invoiced separately at the current rate for such services unless they are required because of non-compliance by Catalent.

C. Records. Reports and Inspections. (1) During the term of this Quotation, and for a period of four (4) years after its expiry or termination. Catalent shall, keep at its normal place of business detailed, accurate and up to date records showing any regulatory filings made in relation to the Services (the "Records"). Under no circumstances shall Catalent destroy any Records without giving the Client a fifteen (15) day prior written notice.

(2)On no less than seven (7) business days notice from Client, Catalent shall make the Records available for Inspection during business hours by Client or its nominee for the purpose of general review or audit. Client, or its nominee, shall be entitled to take copies or extracts from the Records during any such review or audit.

(3)Client shall be solely responsible for its costs in making such review and audit.

(4)Client may enter Catalent's premises upon reasonable notice to Catalent during Catalent's normal business hours for the purpose of reviewing the facilities, procedures and any relevant records solely relating to the Services (including but not limited to, all batch sheets

^{**}This portion has been redacted pursuant to a confidential treatment request.

and records for all manufacturing steps). In addition, Client shall have the right to be present during the performance of Services, upon reasonable advance notice to Catalent which shall be no less than seven (7) business days, and with prior written notice and agreement by Catalent. No such review shall diminish Catalent's obligations hereunder. In the event that any of Catalent's facilities used for the Services hereunder are inspected by representatives or any U.S. federal, state or local regulatory agency in connection with the Project, Catalent shall notify Client promptly by telephone and follow up in writing, upon teaming of such inspection, and shall supply Client with copies of any reports or responses specific to the Client's Product(s) or the Services including, but not limited to the relevant portions of any Form 483s or Establishment Inspection Reports (EIRs) prepared by the agency or Catalent relating to such inspection, inspection, Client may send representatives to such Facilities upon invitation by Catalent and may be present at the facility during such inspection. Notwithstanding the foregoing, Client shall not participate in any such inspection unless specifically requested by Catalent or such agency.

D. Price Changes. Catalent may revise the prices provided in this Quotation (i) if Client's requirements or any Client-provided information is inaccurate or incomplete; (ii) if Client revises Catalent's responsibilities or the Project specifications, instructions, procedures, assumptions, processes, test protocols, test methods or analytical requirements; or (iii) for such other reasons set forth in this Quotation.

E. <u>Payments</u>. Catalent will invoice Client as set forth in this Quotation. After 5 business days from receipt of a written notice by Supernus from Catalent of an overdue invoice, Catalent may charge a late payment fee of ** per month for payments not received by the date specified in this Quotation (or if no data is specified, within 30 days of invoice date) on undisputed invoices. Failure to bill for interest due shall not be a waiver of Catalent's right to charge interest.

F.<u>Taxes.</u> All sales, use, gross receipts, compensating, value-added or other taxes, duties, licenses or fees (excluding Catalent's net income and franchise taxes) assessed by any tax jurisdiction arising from the Project are the responsibility of Client, whether paid by Catalent or Client.

G. Hazardous Materials. Client warrants to Catalent that no specific safe handling instructions are applicable to any Client-supplied materials, except as disclosed to Catalent in writing by the Client in sufficient time for review and training by Catalent prior to delivery. Where appropriate or required by law, Client will provide a Material Safety Data Sheet for all Client-supplied materials and finished product.

H. Shipment. Unless otherwise specified in this Quotation, all products and other materials shipped by Catalent are delivered EXW (Incoterms 2000) Catalent's facilities and the title shall pass to Client upon such delivery. All products and materials shall be transported in accordance with Client's instructions, if Catalent provides storage

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OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

Catalent represents and warrants to Client that neither it nor any of its employees or consultants engaged in the Project 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. Catatent will immediately notify the Client in writing if any such proceedings have commenced or if a respective representative is debarred by the FDA. Catalent will perform the Project in accordance with; (i) the written specifications and Project instructions expressly set forth or referenced In this Quotation, and (ii) all applicable United States laws, statutes, rules, and regulations, including applicable ICH and current Good Manufacturing Practices, current Good Laboratory Practices and any other FDA guidelines. Without limitation, Catalent will be responsible for obtaining all necessary permissions and licenses applicable to the performance of manufacturing services on the Project, in accordance with the applicable United States laws, statutes, rules, and regulations.

M. Client Obligations. Unless otherwise agreed to by the parties in writing, Client is solely responsible to (i) provide as applicable and available complete and accurate scientific data regarding the Project; (ii) if applicable, review and approve all in-process and finished product test results to ensure conformity of such results with the product specifications, regardless of which party is responsible for finished product release; (iii) prepare all submissions to regulatory authorities; and (iv) perform such other obligations of Client set forth in this Quotation.

N. Indemnification. Client will indemnify Catalent, its affiliates and their respective directors, officers, employees and agents against any third-party claim arising directly or Indirectly from (i) the manufacture, or use of the activities performed under this Quotation or exposure to, the Product, API and Client-supplied materials that are the subject of the Project; (ii) the negligence or willful misconduct of Client; (iii) the breach of this Quotation by Client, or (iv) the use of any intellectual property provided by Client to Catalent. Catalent will indemnify Client against any third-party claim arising directly or indirectly from the negligence or wilful misconduct of Catalent, the breach of this Quotation by Catalent or the use of any intellectual property provided by Catalent

O. Set-Off. Without limiting Catalent's rights under law or in equity, Catalent and its affiliates, parent Or related entities, collectively or individually. may exercise a right of set-off against all amounts due to Catalent from Client For purposes of this Article, Catalent, its affiliates, parent or related entities, shall be deemed to be a single creditor.

P. Force Majeure. Neither party will be liable for any failure to perform or for delay In performance resulting from any cause beyond its reasonable control, including without limitation acts of God, fires, floods or weather, strikes or lockouts, factory shutdowns, embargoes, wars, hostilities or riots, or shortages in transportation. If the cause continues unabated for 90 days, then both parties shall meet to discuss and negotiate In good faith what modifications to this Quotation should result from such cause.

Q.<u>Use and Disposal</u>. Client represents and warrants to Catalent that Client will hold, use and/or dispose of products

and other materials provided by Catalent in accordance with all applicable laws, rules and regulations. Client grants Catalent full authority to use any Client-supplied materials for purposes of the Project.

R.Independent Contractor. The relationship of the parties is that of independent contractors and not of joint venturers, co-partners, employer/employee or principal/agent.

S. <u>Publicity</u>. Neither party will make any press release or other public disclosure regarding this Quotation or the transactions contemplated hereby without the other party's express prior written consent, except as required by applicable law, by any governmental agency or by the rules of any stock exchange on which the shares of the disclosing party are listed, in which case the party required to make the press release or public disclosure shall use commercially reasonable efforts to obtain the approval of the other party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or public disclosure.

T. Amendment & Precedence. These Terms and Conditions constitute a part of the Quotation to which they are attached (collectively, "this Quotation"); provided, that these Terms and Conditions supersede any conflicting terms and conditions set forth in the Quotation to which they are attached or any Client purchase order This Quotation constitutes the entire understanding between the parties, and supersedes any contracts, agreements or understandings (oral or written) of the parties, with respect to the Project. No term of this Quotation may be amended except upon written agreement of both parties.

U.<u>Dispute Resolution.</u> If a dispute arises between the parties in connection with this Quotation, the respective presidents or Senior Executives of Catalent and Client shall first attempt to resolve the dispute. If such parties cannot resolve the dispute, such dispute shall be resolved in the jurisdiction of the State of Delaware by binding arbitration in accordance with the then existing commercial arbitration rules of The CPR Institute for Dispute Resolution, 366 Madison Avenue, New York, NY, 1001.7

V. Survival. Subject to execution, the rights and obligations of Client and Catalent in Articles I, J, K(1), K(2), N, 5, U, W and V of these Terms and Conditions shall survive termination or expiration of this Quotation.

W. Law and Jurisdiction. Each party hereto 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 Quotation, or for recognition or enforcement of any judgment, and each of the parties hereto 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 of the parties hereto agrees that a final

^{**}This portion has been redacted pursuant to a confidential treatment request.

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 an such party as provided in this Section shall be deemed effective service of process on such party.

(i) Each of the parties hereto 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 Quotation in any court referred to herein,

(ii)Each of the parties hereto 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 rules or orders that it will not exercise jurisdiction over any such action or proceeding.

(iii)To the extent that a party hereto 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 Quotation.

(iv)Each of the parties hereto 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 of the parties hereto 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 Quotation.

 $(v) \underline{\text{Waiver of Jury Trial.}} \text{ EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATED TO THIS QUOTATION OR THE TRANSACTIONS CONTEMPLATED HEREBY. } \\$

X. Assignment. This Quotation may not be assigned by either party without the other's prior written consent, which consent shall not be unreasonably withheld; provided, however, that each party may assign this Quotation without consent to any successor In interest by merger, consolidation, recapitalization, or sale of substantially all of its assets or a majority of the control of its common stock.

Y. <u>Development Batches</u>. Each batch produced under this Quotation, including those necessary to support the validation portion of Client's submissions for regulatory approvals, will be considered to be a "development batch" unless and until processing has been validated. Client shall be responsible for the cost of each such batch, even if such batch fails to meet the specifications, unless Catalent was grossly negligent in the manufacture of the out-of-specification batch. Catalent

^{**}This portion has been redacted pursuant to a confidential treatment request.

and Client shall cooperate in good faith to resolve any problems causing the out-of-specification batch.

Z. Notice. Whenever any notice is to be given pursuant to this Quotation, it must be in writing using first-class certified mail, return receipt requested, nationally recognized overnight carrier, or facsimile, postage prepaid to the addresses set forth below:

Catalent Pharms Solutions 1100 Enterprise Drive Winchester, KY40391 Attention: General Manager Telefax No. **

For Commercial Packaging Services:

Catalent Pharma Solutions 3001 Red Lion Road Philadelphia PA 19114 Attention: General Manager Telefax No: **

For Analytical services:

Catalent Pharma Solutions 180 Cardinal Health Way Morrisville, NC 27560 Attention: General Manager Telefax No: **

For Clinical Packaging Services:

Catalent Pharma Solutions 3001 Red Lion Rd. Philadelphia, PA t9114 Attention: General Manager Telefax No. **

If Applicable;

Catalent Pharma Solutions Steinbeisstr. 2 D-73614 Schomdorf, Germany Attention: General Manager Telefax No: **

Catalent Pharma Solutions Lancaster Way Wingates Industrial Park, Westhoughton Bolton, Lancashire UK BL5 3XX Attention: General Manager Telefax No: **

With a copy to:

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

Catalent Pharma Solutions 14 Schoolhouse Rd. Somerset, NJ 08873 Attn: General Counsel Telefax: **

If to Client:

Supernus Pharmaceutcals, Inc. 1550 E Gude Drive Rockville, MD 20850 Attention: Jack Khattar or Pad Bhalt Telefax No: **

Such notice shall be effective five (5) days after deposit if sent by mail, the next business day if sent by overnight carrier, and upon receipt of electronic confirmation of delivery it sent by facsimile.

Z(1).Insurance.

Catalent Insurance. Catelent shall, at its own cost and expense, obtain and maintain In full force and effect the following insurance during the Term: (A) Commercial General Liability Insurance with a per-occurrence limit of not less than **; (B) Products and Completed Operations Liability Insurance with a per-occurrence limit of not less than **; (C) Workers Compensation and Employers Liability Insurance, with statutory limits for Workers Compensation and Employers Liability Insurance, with statutory limits for workers Compensation and Employers Liability Insurance with per-claim and aggregate limits of not less than **. The parties hereby acknowledge and agree that Catalent may self-insure all or any portion of the required Insurance. In the event that any of the required policies of insurance are written on a claims made basis, then such policies shall be maintained during the entire Term and for a period of not less than 3 years following the expiration or termination of this Agreement. Each insurance policy which is required under this Agreement, other than self-insurance, shall be obtained from an insurance canter with an A.M. Best rating of at least A- VII.

Client Insurance. Client shall, at its own cost and expense, obtain and maintain in full force and effect the following insurance during the Term: (A) Commercial General Liability Insurance with a per occurrence limit of not less than **; (B) Products and Completed Operations Liability Insurance (including coverage for Products used In clinical trials) with a per occurrence limit of not less than **; (C) Workers Compensation and Employers Liability Insurance with statutory limits for Workers Compensation and Employers Liability Insurance with statutory limits for Workers Compensation and Employers Liability Insurance, including transit coverage, in an amount equal to full replacement value covering Client's property while it is at the Facility or in transit to, from or between Catalent's facilities. The parties hereby acknowledge and agree that Client may self-insure all or any portion of the above-required insurance, Client shall maintain levels of insurance or self Insurance sufficient to meet its obligations under this Agreement. In the event that any of the required policies of insurance are written on a claims made basis, then such policies shall be maintained during the entire Term and for a period of not less than 3 years following the expiration or termination of this

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Agreement. Each insurance policy which Is required under this Agreement other than self-insurance, shall be obtained from an Insurance carrier with an AM. Best rating of at least A- VII.

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Supernus Announces Final FDA Approval and Upcoming Launch of Trokendi XRTM

Rockville, MD, August 19, 2013 --Supernus Pharmaceuticals, Inc. (NASDAQ: SUPN), a specialty pharmaceutical company, received final approval from the Food & Drug Administration (the "FDA") for Trokendi XR, a novel once-daily extended release formulation of topiramate for the treatment of epilepsy. The company expects to launch the product and for it to be available in pharmacies over the next few weeks.

The approval letter states that the FDA has completed its review of the application and that Trokendi XR is approved effective August 16, 2013 for use as recommended in the agreed-upon labeling. The FDA granted a waiver for certain pediatric study requirements and a deferral for submission of post-marketing pediatric pharmacokinetic assessments that are due in 2019 followed by clinical assessments in 2025.

"We are very excited about the approval of Trokendi XR and its upcoming launch. This is excellent news for Supernus, its shareholders, and patients with epilepsy. We remain committed to the epilepsy community and very much look forward to now having two products, Trokendi XR and Oxtellar XR, available to patients," said Jack Khattar, Chief Executive Officer, President and Director of Supernus.

About Trokendi XRTM

Trokendi XR is a novel once- daily extended release formulation of topiramate. Trokendi XR is an antiepileptic drug (AED) indicated for initial monotherapy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures; adjunctive therapy in patients 6 years of age and older with partial onset or primary generalized tonic-clonic seizures, and adjunctive therapy in patients 6 years of age and older with seizures associated with Lennox-Gastaut syndrome. The product will be available in 25mg, 50mg, 100mg and 200mg extended-release capsules.

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 XRTM (extended-release oxcarbazepine), and one approved product for epilepsy, Trokendi XRTM (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 contains forward-looking statements regarding the potential for Trokendi XR to treat epilepsy, and the timing of the product's availability to physicians. Actual results may differ materially from those in these forward-looking statements as a result of various factors, including, but not limited to, risks regarding the company's ability to commercialize the product successfully, whether physicians will prescribe and patients will use the product, once available, and competition in the market. For a further description of these and other risks facing the Company, please see the risk factors described in the Company's Annual Report Form 10-K that was filed with the United States Securities and Exchange Commission on March 15, 2013 and under the caption "Risk Factors" and the updates to these risk factors in the Company's quarterly report form 10-Q that was filed with the Commission on August 15, 2013. Forward-looking statements speak only as of the date of this press release, and the company undertakes no obligation to update or revise these statements, except as may be required by law.

CONTACTS: Jack Khattar, President & CEO Gregory S. Patrick, Vice President and CFO Supernus Pharmaceuticals, Inc. Tel: (301) 838-2591