FORM 10-Q/A

Quarterly report pursuant to sections 13 or 15(d) [amend]

Filing Date: **2013-01-15** | Period of Report: **2012-09-30**
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FILER

NPS PHARMACEUTICALS INC
CIK:**890465**| IRS No.: **870439579** | State of Incorp.:**DE** | Fiscal Year End: **1231**
Type: **10-Q/A** | Act: **34** | File No.: **000-23272** | Film No.: **13530692**
SIC: **2836** Biological products, (no disgnostic substances)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q/A

Amendment No. 1

☒ **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended September 30, 2012

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the Transition Period from to

Commission File Number 0-23272

NPS PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**87-0439579**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
550 Hills Drive, Bedminster, New Jersey	**07921**
(Address of Principal Executive Offices)	(Zip Code)

(908) 450-5300

(Registrant' s Telephone Number, Including Area Code)

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

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

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

Large accelerated filer ☒	Accelerated filer ☐
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

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

The number of shares outstanding of each of the issuer' s classes of common stock, as of the latest practicable date is as follows:

Class	Outstanding at November 6, 2012
Common Stock $.001 par value	86,647,326

EXPLANATORY NOTE

The sole purpose of this Form 10-Q/A is to file a revised Exhibit 10.02 to the Registrant' s Form 10-Q that was originally filed with the Securities and Exchange Commission on November 9, 2012. Certain portions of Exhibit 10.2 that were previously redacted in the original filing have been unredacted. In addition, at the request of the Securities and Exchange Commission, Appendices 10 and 11 have been attached to Exhibit 10.2.

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NPS PHARMACEUTICALS, INC.

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EXHIBIT 10.2
EXHIBIT 31.1
EXHIBIT 31.2

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PART II
OTHER INFORMATION

Item 6. Exhibits.

Exhibit Number	Description of Document
10.1*	Change in Control Severance Pay Plan, as amended on August 20, 2012
10.2**(1)	Commercial Manufacturing Agreement dated as of December 21, 2009, by and between the Registrant and Vetter Pharma International GmbH
10.3+*	Employment Agreement with Glenn Melrose
31.1**	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
31.2**	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer
32***	Section 1350 Certification of Periodic Financial Report by the Chief Executive Officer and Chief Financial Officer
101.INS(2)	XBRL Instance Document
101.SCH(2)	XBRL Taxonomy Extension Schema Document
101.CAL(2)	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF(2)	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB(2)	XBRL Taxonomy Extension Label Linkbase Document
101.PRE(2)	XBRL Taxonomy Extension Presentation Linkbase Document

*	Previously filed.
**	Filed herewith.
***	Previously furnished.
+	Management contract, compensatory plan or arrangement.
(1)	Confidential information was omitted from this exhibit pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.
(2)	This exhibit was previously furnished and is not deemed filed with the Securities and Exchange Commission, and is not incorporated by reference into any filing of NPS Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date it was furnished and irrespective of any general incorporation language contained in such filing.

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SIGNATURES

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

NPS PHARMACEUTICALS, INC.

Date: January 15, 2013

By: /s/ Francois Nader

Francois Nader,
President and Chief Executive Officer (Principal Executive Officer)

Date: January 15, 2013

By: /s/ Luke M. Beshar

Luke M. Beshar,
Chief Financial Officer (Principal Financial and Accounting Officer)

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EXHIBIT INDEX

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Exhibit 10.2

NOTE: CERTAIN CONFIDENTIAL INFORMATION HAS BEEN OMITTED FROM THIS DOCUMENT AND REPLACED BY "[*]". A COMPLETE COPY OF THIS DOCUMENT INCLUDING THE CONFIDENTIAL INFORMATION HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

COMMERCIAL MANUFACTURING AGREEMENT

between

NPS Pharmaceuticals, Inc.

and

Vetter Pharma International GmbH

Dated as of December 21, 2009

CONFIDENTIAL

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APPENDICES

This Commercial Manufacturing Agreement ("Agreement"), made and entered into as of this 21st day of December, 2009, by and between NPS Pharmaceuticals, Inc., a company duly organized and existing under the laws of the State of Delaware and having its principal place of business at 550 Hills Drive, Bedminster, NJ 07921 ("NPS"), and Vetter Pharma International GmbH, a company duly organized and existing under the laws of Germany, having its principal place of business at Schützenstrasse 87, 88212 Ravensburg, Germany ("VPI") (singly also referred to as "Party" and collectively as "Parties").

WITNESSETH:

WHEREAS, NPS owns certain rights in the raw materials and the Product to be manufactured, in accordance with the Specifications, for sale in the Territory; and

WHEREAS, VPI owns and possesses or has the right to use know-how for the manufacture of medical products and is desirous of undertaking such manufacture for NPS on the terms and conditions herein; and

NOW, THEREFORE, in consideration of the premises and of the mutual covenants and agreements hereinafter set forth, and subject to the terms and conditions of this Commercial Manufacturing Agreement, the Parties hereto agree as follows:

ARTICLE 1: DEFINITIONS

For all purposes of this Commercial Manufacturing Agreement, and all amendments hereto, as well as the Quality Agreement, as it may be amended, the terms defined in this Article 1 shall have the meanings herein specified, unless the context otherwise requires:

(1) "Affiliate" shall mean, in respect of NPS, any company or legal entity controlled by NPS, and, in the case of VPI, any company or legal entity that is beneficially owned or held, directly or indirectly, by VPI (or the stockholders of VPF or the executor(s) of the estate of Helmut Vetter, or any beneficiaries or heirs of Helmut Vetter or any such stockholder of VPF). As so used, "control" shall mean that the ownership, directly or indirectly, of not less than a majority of the issued and outstanding shares of any class of capital stock, or of the ownership interests, entitled to vote for the election of directors (or equivalent governing body or persons), is beneficially owned or held, directly or indirectly, by NPS or VPI (or the stockholders of VPF or the executor(s) of the estate of Helmut Vetter, or any beneficiaries or heirs of Helmut Vetter or any such stockholder of VPF), as the case may be. It is understood by the Parties that VPF (as defined below) is an Affiliate of VPI.

(2) "Agreement" shall mean this Commercial Manufacturing Agreement.

(3) "API" shall mean recombinant parathyroid hormone (1-84) supplied [*].

(4) "Approval Date" shall have the meaning set forth in Article 8(1).

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(5) "Batch" shall mean a batch [*] of Product at [*].

(6) "Batch Record" shall mean the complete written record of the history of the Batch and its production thereof as required under GMP and in accordance with the provisions of the Quality Agreement and the Specifications.

(7) "Business Day" shall have the meaning set forth in Article 26(1).

(8) "COA" shall mean a certificate of analysis document for the Product or any NPS Supplied Materials, Vetter Supplied Materials or Raw Materials, Components and Packaging Materials as set forth in the Quality Agreement. The COA for the Product will include the name of the Product, the lot number and the date of production. The COA for the Product will also list (i) the Product release Quality Control tests performed by VPF and/or by contract testing laboratories, and (ii) actual test results.

(9) "COC" shall mean a Certificate of Conformity document. The COC for the Product will include a statement that the Product has been Produced, tested and released in accordance with GMP and the Specifications.

(10) "Change Control Procedure" shall mean the documented system utilized by VPF for the control of quality related changes to the Product or the Production, all as set forth in more detail in the Quality Agreement.

(11) "Commencement Date" shall mean the date set forth in the first paragraph of this Agreement.

(12) "Confidential Information" shall the meaning set forth in the Confidentiality Agreement.

(13) "Confidentiality Agreement" shall mean the Confidentiality Agreement attached hereto as Appendix 10.

(14) "Costs" shall have the meaning set forth in Article 18(2).

(15) "Development Agreement" shall mean the Development Agreement between the NPS and VPF dated as of [*], as amended by them pursuant to the Amendment Agreement dated as of [*].

(16) "EMEA" shall mean the European Medicines Evaluation Agency.

(17) "Facility" shall mean the facility(ies) of VPF located in [*] used to Produce the Product.

(18) "FDA" shall mean the United States Food and Drug Administration.

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(19) "Final Release" shall mean release by NPS of the Product for use in humans.

(20) "[*]" shall have the meaning set forth in Article 8(2)(b).

(21) "Force Majeure" shall have the meaning set forth in Article 17(1).

(22) "GMP" shall mean the current Good Manufacturing Practices promulgated and officially published by the Regulatory Authorities that are applicable to the Production of the Product.

(23) "Indemnity Agreement" shall mean that certain Indemnity Agreement entered into by and between NPS and VPF and fully executed [*].

(24) "Information" shall mean, in respect of any Party (including for the purposes of this paragraph any Affiliate of a Party) hereto, manufacturing, technical information and other information and other data, specifications, trade secrets, patents or patented designs or processes and know-how, including, without limitation, such as may be embodied or evidenced in formulae, manufacturing data, production specifications or other documents, as well as other tangible or intangible professional, scientific or technological information, and any information or matter that a reasonable business person would or should know is confidential or proprietary and all such information and data which is, directly and wholly, derived, or results, there from.

(25) "Intellectual Property" shall mean patents, trade secrets, trade marks, service marks, registered designs, lab notebooks, applications for any of the foregoing, trade and business names, unregistered trade marks and service marks, copyrights, rights in designs, inventions, know-how, rights under licenses, consents, orders, statutes or otherwise in relation to any such rights, and rights of the same or similar effect or nature, in any part of the world as well as SOPs and Specifications of whatever nature or form.

(26) "[*]" shall have the meaning set forth in Article 5(2).

(27) "[*]" shall have the meaning set forth in Article 5(2).

(28) "[*]" shall have the meaning set forth in Article 5(2).

(29) "Major Default" shall have the meaning set forth in Article 16(2).

(30) "Manufacturer' s Release" shall mean release by VPI of the Product to NPS for Final Release for use in humans as set forth in the Quality Agreement provided.

(31) "Manufacturing Manual and Testing Specifications" or "Specifications" shall mean the specifications and other technical information and instructions, as agreed to by

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NPS and VPF, concerning the manufacture, handling, testing, storage and processing of the Product, in-process intermediates and Raw Materials, Components and Packaging Materials, all as set forth in Appendix 5 to the Quality Agreement.

(32) "NPS" shall have the meaning set forth in the first paragraph of this Agreement.

(33) "NPS Supplied Materials" shall mean the Raw Materials, Components and Packaging Materials provided by, or sourced by, NPS as set forth in Appendix 2 to the Quality Agreement.

(34) "Party" and "Parties" shall have the meanings set forth in the first paragraph of this Agreement.

(35) "Product" shall mean API together with those certain Raw Materials, Components and Packaging Materials manufactured and labeled, [*] all in accordance with the Specifications as set forth in Appendix 5 of the Quality Agreement.

(36) "Product Specifications" shall mean the specifications which the Product must meet for Final Release as set forth in Appendix 4 to the Quality Agreement.

(37) "Production" or "Produce" shall mean the manufacturing of the Product from the Raw Materials, Components and Packaging Materials supplied as herein provided or contemplated, all in accordance with the Specifications set forth in Appendix 5 of the Quality Agreement.

(38) "Product Specific IP" shall have the meaning set forth in Article 14(2).

(39) "Purchase Order" shall mean a purchase order signed by NPS which shall be [*] and shall be used for the purpose of confirming quantities, and [*].

(40) "Quality Agreement" shall mean the agreement attached hereto as Appendix 11.

(41) "[*]" shall have the meaning set forth in Article 5(1).

(42) "[*]" shall have the meaning set forth in Article 5(1).

(43) "[*]" shall have the meaning set forth in Article 5(1).

(44) "Raw Materials, Components and Packaging Materials" shall mean the pharmaceutical ingredients, supplies and materials to be provided as herein contemplated all as set forth in Appendices 2 and 3 to the Quality Agreement.

(45) "Regulatory Authority" (singly) or "Regulatory Authorities" (combined) shall mean the FDA, the EMEA and German national health authorities.

(46) "Rolling Forecast" shall have the meaning set forth in Article 8(2)(a).

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(47) "Root Cause" shall mean a deviation regarding the limits as set forth in the agreed Specifications that becomes apparent, is discovered or otherwise detected ("detection") during Manufacturing or final analytical testing of the Product, notwithstanding that VPF has, during the manufacturing and testing processes, followed the agreed Specifications, it being understood and agreed that such detection is not necessarily possible during such manufacturing and testing processes.

(48) "Specifications" shall mean the Manufacturing Manual and Testing Procedures.

(49) "Term" shall have the meaning set forth in Article 16.

(50) "Territory" shall mean [*] shall be subject in all respects to the provisions of Article 3(3) below.

(51) "VPF" shall mean Vetter Pharma-Fertigung GmbH & Co. KG.

(52) "Vetter Supplied Materials" shall mean the Raw Materials, Components and Packaging Materials provided by or sourced by, as set forth in Appendix 3 of the Quality Agreement.

ARTICLE 2: USE AND DISCLOSURE OF SPECIFICATIONS
AND OTHER INFORMATION

(1) NPS shall provide to VPI at NPS' own cost the Product Specifications as set forth in Appendix 4 of the Quality Agreement. NPS shall, from time to time, disclose to VPI changes in the Product Specifications and shall specifically inform VPI if any such changes have, or could have, an adverse or negative chemical, physical or other effect on the Production or the Product provided NPS is, or should be reasonably, aware of any such consequences. NPS shall bear all responsibility for the consequences of the failure to adequately disclose or describe such effect or such information and shall bear all costs and expenses of VPI, it being understood and agreed that such costs and expenses shall include that of its Affiliates, which may be associated with such changes in the Product Specifications. The Manufacturing Manual and Testing Specifications, including such part of NPS´ Product Specifications relevant for the Production of the Product (the "Specifications"), which shall be set forth in Appendix 5 of the Quality Agreement, shall be agreed upon as provided in the Quality Agreement.

(2) All changes concerning the Specifications, the Product Specifications, the Production or the Product, or testing thereof shall be subject to the Change Control Procedure to be agreed upon as provided in and as set forth in the Quality Agreement. In addition, any changes that could reasonably affect the quality and efficacy of the Product including changes to the Facility, equipment

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used in the Production, Raw Materials, Components and Packaging Materials, or testing thereof, shall be subject to the Change Control Procedure.

(3) VPI shall have the Product Produced in accordance with the Specifications set forth in Appendix 5 of the Quality Agreement, it being agreed and understood that VPI shall not Produce as herein provided or contemplated but shall cause to have such Production done as by an Affiliate, namely VPF, in accordance with an agreement between VPI and VPF. It is further agreed that VPI shall cause VPF to enter into the Quality Agreement, attached hereto as Appendix 11, with NPS

(4) In accordance with the Change Control Procedure, NPS shall be kept informed of, and NPS shall have the right to pre-approve significant contemplated changes, including improvements, in the Vetter Supplied Materials to be incorporated in the Product. If NPS does not agree to incorporate any such changes in the Product, VPI may cause the cessation of Production of the Product immediately if these changes are necessary to comply with any laws or regulations as well as practices of Regulatory Authorities. If VPI agrees to cause the continuation of the Production of the Product without the incorporation of such changes, and NPS has withheld its consent unreasonably, NPS shall bear all responsibility (including any product liability) for the consequences of any such non-incorporation.

(5) In accordance with the Change Control Procedure, NPS may request that changes be incorporated in the manufacture of the Product, and VPI shall cause the implementation of such changes, subject to VPI and NPS agreeing to any necessary amendments to this Agreement, including, without limitation, price adjustment, capacity and ability of VPI' s Affiliate to incorporate such changes and approvals of any other customers of VPI as may be required.

ARTICLE 3: PRODUCTION

(1) VPI agrees to have Produced the Product from the Raw Materials, Components and Packaging Materials in accordance with GMP and the Specifications. VPI shall sell and have delivered the Product, for the prices herein set forth, and/or determined in accordance with the terms hereof, to NPS.

(2) NPS shall keep VPI informed of the legislation and the rules and the regulations of the Regulatory Authorities which are particular to the Product and its Production, along with all relevant requirements of any other regulatory authority to which the Parties may mutually agree in writing as provided in Article 3(3) below, and shall specifically inform VPI of the effect of any changes thereof to the extent NPS has knowledge of such. VPI and its Affiliates shall have no liability with respect to the Product, if VPI has cause the manufacture of the Product in accordance with GMP, the Specifications, the Product Specifications and as otherwise specifically provided

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for herein. Changes to the Product Specifications are subject to the Change Control Procedure.

(3) Notwithstanding anything to the contrary herein contained, VPI shall not have to comply with, and is not required to cause to comply, any requirements of any regulatory authority, other than Regulatory Authorities, in respect of any country within the Territory, [*], unless and until NPS and VPI have agreed in writing as to how to address the consequences for VPI and/or its Affiliates concerning compliance with such requirements, including (i) any costs thereof for VPI, which may include costs of its Affiliates, it being understood that such costs will have to be compensated to VPI by NPS, and (ii) technical requirements in respect thereof, which VPI shall reasonably cause compliance provided it is reasonably technically feasible at the applicable Facility, and the issue of costs thereof has been agreed to with NPS aforesaid, it being understood that VPI may decline to have incorporated or installed any such requirements if the incorporation or installation thereof shall unreasonably interfere with the other operations of VPI or its Affiliates.

ARTICLE 4: MATERIALS

(1) NPS shall timely supply and deliver, as VPI shall direct, [*], the necessary quantities of NPS Supplied Materials which are required to properly undertake necessary preparations for Production and to timely fulfill NPS' Purchase Orders.

The NPS Supplied Materials shall be used only for Production. NPS shall be notified by VPI of any surplus thereof and any such surplus shall be disposed of, returned to NPS or otherwise handled, all as reasonably directed by NPS and at NPS' cost and expense.

(2) NPS shall provide proper manufacturers' Certificate of Analysis and other appropriate data and certificates for NPS Supplied Materials, as well as such other documentation as may be required by law, applicable Regulatory Authorities or as VPI may reasonably request, or as may be requested under the Quality Agreement. Further NPS shall specifically inform VPI if NPS Supplied Materials require any special handling or processing.

In respect to certain NPS Supplied Materials, VPI shall have performed an identity (ID) test to confirm the NPS Supplied Materials. VPI has no other obligation to undertake, or have undertaken, any other testing or to otherwise certify the same. Other than the ID testing, it is agreed that VPI and its Affiliates may rely completely on the correctness of the quality certificates issued in respect thereof.

(3) VPI shall have supplied all Vetter Supplied Materials required to timely fulfill NPS' Purchase Orders.

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(4) VPI shall have examined, qualify and/or test all Vetter Supplied Materials in accordance with the Specifications. Such examination shall involve the aforesaid together with the applicable Certificate of Analysis.

(5) Except for the obligations of Vetter to examine, qualify and/or test Vetter Supplied Materials, as set forth in Article 4(4), Vetter shall have no obligation or liability with respect to any Vetter Supplied Materials.

(6) With respect to the quality and the condition of the Raw Materials, Components and Packaging Materials, including their conforming to the Specifications, or with respect to any other aspect thereof, Vetter shall have no obligation or liability, except as herein otherwise provided. Other than as provided above in Article 4(2), it is agreed that Vetter shall have no obligation to make an inspection thereof upon receipt from NPS of NPS Supplied Material and may rely completely on the correctness of the Certificate of Analysis issued in respect thereof.

ARTICLE 5: LOSS OF PRODUCT

(1) With respect to the Production of Product at [*], the Parties shall evaluate and mutually determine after completion of both the [*], having regard to the previous calendar year' s performance, to process enhancements, to the relevant requirements of any Regulatory Authority, to GMP requirements and to all other relevant circumstances, it being understood and agreed that the previous calendar year' s performance shall not be determinative for such review and agreement. The Parties shall, at the end of each calendar year, mutually determine and agree on the cumulative actual losses of NPS Raw Materials over the relevant calendar year [*]. To the extent that the [*]. VPI shall reimburse NPS for the cost of any deficiency wherein the [*], all as set forth in Appendix 2, but in no event shall the combined total of the reimbursed amount(s) [*]; provided, that such reimbursement shall only be made, if at all, after any [*].

(2) The Parties both acknowledge that, with respect to the Production of Product at [*], assessment of quantitative Production factors cannot begin until observations after commencement of such Production; hence, the Parties shall evaluate and mutually determine after completion of [*] which during the normal course of Production at the [*] would be required and acceptable to achieve a specified result, [*]; provided, however, that the Parties agree that, notwithstanding anything to the contrary herein, the targets in this Article 5(2) are not firm commitments and VPI shall, in consultation with NPS, [*]. Until the [*] has been established as set forth herein, all loss of NPS Raw Materials shall be borne by NPS. Such [*] shall not be applicable [*]. The first [*] shall subject to the foregoing, apply for the remainder of the Batches Produced in that year following its determination. Thereafter, the [*] shall be reviewed annually and agreed on by the Parties for each calendar year during the continuance of this agreement through good faith negotiations, having regard to the previous calendar year' s performance, to process enhancements, to the relevant requirements of any Regulatory Authority, to GMP requirements and to all other

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relevant circumstances, it being understood and agreed that the previous calendar year' s performance shall not be determinative for such review and agreement. [*], to be used as set forth herein below. Vetter shall reimburse NPS for the cost of [*]; provided, that such reimbursement shall only be made, if at all, [*].

(3) VPI shall have the NPS Supplied Materials and Vetter Supplied Materials stored in accordance with GMP and the Specifications and otherwise in accordance with standard operating procedures of VPF.

(4) NPS shall, at its own cost and expense, unless it shall self-insure, provide for and cover the costs of adequate theft, casualty and extended loss insurance in an amount and on terms satisfactory to NPS for NPS Supplied Materials (whether included as part of the Product or otherwise) during the course of Production as well as all transportation, shipment and storage. Notwithstanding anything to the contrary contained in this Agreement, neither VPI nor any Affiliate of VPF shall have any obligation or liability to NPS (or any Party acting in the name of or on behalf of NPS) in respect of the foregoing items in the occurrence of any theft, casualty or such extended loss, to the extent that any loss or damage arising therefrom shall be, or could have been, covered by insurance or self-insurance as provided above; and, furthermore, in the event that insurance coverage shall not be, or could not have been, available to NPS because of VPI' s or any Affiliate of VPI' s conduct causing such loss or damage, the only liability shall be for [*] as set forth in Appendix 9 [*].

ARTICLE 6: INSPECTION AND TESTING OF THE PRODUCT

(1) VPI shall cause a Manufacturer' s Release to be provided to NPS prior to shipment and in accordance with GMP. The Manufacturer' s Release shall include inspecting/testing of the Product, as set out in the Specifications.

(2) NPS agrees to inspect and test the Product in accordance with the release specifications set forth in the Product Specifications.

(3) NPS shall inspect and test all Product upon receipt and without delay, but in no [*] after receipt unless otherwise agreed to by the Parties. If such Product does not pass such inspection and testing, then NPS shall promptly notify Vetter of its rejection, and, either shall return the rejected batch to VPI, at VPI' s cost and expense, or shall otherwise dispose of the Product as agreed upon by the Parties.

(4) Product which is not rejected as provided in Article 6(3) shall be deemed accepted and approved to the extent that it contains any non-latent defect. Any Product which contains any latent defect shall be deemed accepted and approved unless NPS shall notify VPI of its rejection thereof [*]. NPS agrees to notify VPI promptly after the discovery of any Product defect.

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(5) VPI shall have no obligation to correct, or dispose of, any defective Product or supply a replacement Product at its own cost, unless the defect is based solely on VPI' s, or its Affiliate' s, [*] to provide the Product in [*]; provided, however, that there shall be no negligence if VPI can show or have shown by way of the full batch documentation including a COA as provided herein that the Product has been manufactured in accordance with GMP, the Specifications and the Product Specifications.

(6) VPI shall cause the correction of any defective Product as provided in the Quality Agreement that has been rejected in accordance with Article 6(3) or otherwise, and if this is not possible, VPI shall, upon request, have supplied a replacement Product. It is agreed that for the purposes hereof, NPS shall supply the necessary NPS Supplied Materials and that VPI shall reimburse NPS for the value of the NPS Supplied Materials as set forth in Appendix 9.

ARTICLE 7: PACKAGING AND DOCUMENTATION

(1) VPI shall cause that the Product be packaged as bulk cartridges, as set forth on Appendix 11.

(2) With each delivery of Product, VPI shall cause to be submitted to NPS documents customarily required from a contract manufacturer for the applicable customs clearance in the Territory as set forth in the Quality Agreement.

(3) VPI shall cause to be prepared a Batch Record for each Batch and VPI shall cause to be retained samples as provided in the Quality Agreement. VPI agrees to have maintained such Batch Record documentation [*] as may be permitted by GMP. VPI shall notify NPS [*] to destroying any Batch Record documentation and shall send to NPS, or cause it to be dispose of at NPS' direction and cost.

(4) For [*], NPS will receive [*]. Thereafter, for each Batch, VPI shall cause to be provided to NPS [*]. If NPS requires any additional documents or information, the cost thereof will be separately charged. If for any reason re-validation is required, VPI shall again cause to be provided [*].

ARTICLE 8: ROLLING FORECASTS; PURCHASE ORDERS; DELIVERY

(1) Preliminary Forecasts Prior to Approval. NPS will provide to VPI a preliminary (prior to marketing approval as set forth below) forecast on [*]. This preliminary forecast will [*]. This preliminary forecast will be subject to [*], of such preliminary forecast [*]; provided, however VPI may take [*]. NPS will inform VPI [*]. It is agreed that VPI may [*].

(2) Rolling Forecasts After Approval. On or around the first day and at [*] after the Approval Date during the Term, NPS shall inform VPI in writing of NPS estimated quantity requirements for the Product, by specifying prospective delivery dates

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during each of the [*] as depicted in Appendix 12 hereof). Each Rolling Forecast shall be subject to [*] of each such Rolling Forecast; provided that [*].

(a) The estimates set forth in a Rolling Forecast for [*], and NPS, along with each Rolling Forecast provided to VPI as set forth in Article 8(2) above, shall at the same time provide VPI with a Purchase Order in respect of [*] period covered by this Article 8(2)(b), which shall specify the quantity of the Product desired and the date(s) by which delivery in accordance with Article 8(4) below is to be made; provided that no such delivery date(s) shall be in advance of [*].

(b) The estimates set forth in a Rolling Forecast for [*]; provided, however, that, , in subsequent Rolling Forecasts until such time as the forecast in respect of a particular calendar month becomes subject to Article 8(2)(b) above, NPS [*], as the case may be, of the quantity previously forecast and accepted by VPI for such particular month [*].

(c) The estimates set forth in a Rolling Forecast for [*] are not intended to be binding upon the Parties in any manner, whereas the good faith intent of the Parties in respect of such portion of the Rolling Forecast is to facilitate VPI' s need to advance plan for NPS estimated requirements hereunder.

(d) It is agreed and understood that, based upon the respective Rolling Forecast (upon which estimates, once approved by VPI as set forth in Article 8(2)(a) above, VPI may reasonably rely), VPI shall have placed, in accordance with applicable customary business practices, [*].

(e) NPS and VPI agree to discuss in good faith requested revisions to modify quantities or timing of deliveries which fall outside the parameters of the binding portion of a Rolling Forecast.

(3) Purchase Orders.

(a) If a Purchase Order on its face appears to be duly signed by NPS, VPI may fully rely thereupon without independent investigation, and such Purchase Order shall be valid and effective for all purposes hereof. Each Purchase Order shall set forth the quantity of the Product ordered, the date by which such Product is to be delivered, and the destination for delivery of such order.

(b) VPI shall inform NPS [*]. VPI shall accept such Purchase Orders to the extent consistent with corresponding fixed and binding periods within the Rolling Forecast (once the same has been approved by VPI as set forth in Article 8(2)(b) above) and shall fulfill such Purchase Orders and conduct the Manufacturer' s Release in order to ensure timely delivery of Product.

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(4) Delivery. VPI shall deliver, and NPS shall obtain title to, Product, ex Facilities (EXW Incoterms 2000).

ARTICLE 9: PRICE

(1) In respect of the Product, NPS shall pay, subject to the provisions hereof, to Vetter the price determined in accordance with Appendix 7, ex Facilities, plus any applicable Product taxes, governmental fees and assessments. [*].

(2) (i) From time to time during the Term or any subsequent term hereof, VPI may adjust its prices to reflect an increase to VPI, direct or indirect, in the costs of [*] to the extent that VPI can make an objectively reasonable demonstration of such increase to NPS, which adjustment shall be effective in respect of all [*] which are subject to such price increase, whether direct or indirect, to VPI.

(ii) In addition, VPI may increase its other costs no more than once per year (on or about December 31) to reflect direct or indirect, [*].

(3) If VPI shall adjust its prices to reflect an increase in the direct or indirect, cost of Production due to such overhead expenses as described in Article 9(2)(ii) by [*], then VPI shall provide NPS with clear and objectively reasonable written evidence of 10(2)(ii). If VPI shall adjust its prices to reflect such increase by [*], in this instance only, may, subject to the terms and conditions applicable to [*], or seek an accommodation with VPI in which, provided that VPI has expressly consented in writing to the terms of such accommodation, if any, NPS shall [*].

ARTICLE 10: PAYMENT

All payments shall be [*] issued in accordance with the terms hereunder and shall be made in Euro (EUR). In the event NPS pays (receipt of readily available funds by VPI) [*] of receipt of the invoice, then [*]. In the event NPS pays (receipt of readily available funds by VPI) [*] of receipt of the invoice (except when payment is subject to a good-faith dispute), VPI shall be entitled to interest payments in the amount of [*] the invoiced amount per month from and after such date and NPS shall add such interest accumulated in accordance with this Article 10 as of the time of payment, to the invoiced amount with NPS' payment.

ARTICLE 11: REPRESENTATIONS AND AGREEMENTS

(1) NPS Representations and Agreements:

(a) NPS represents and warrants that it has the right to provide NPS' Specifications and Product Specifications for the purposes herein contemplated.

(2) VPI Representations and Agreements:

(a) VPI represents that after completion of the process validation the Production of Product (including the process, plant, equipment and personnel) and the storage/release/delivery of Product will all be done or caused to be done in accordance within the Specifications and GMP.

(b) VPI represents that it shall cause VPF to maintain all necessary permits and authorizations as required under applicable laws Germany as well EMEA and US FDA and under GMP.

(c) VPI represents that the Facility which will be used to commercially manufacture Product has undergone an FDA inspection and VPI represents that neither it nor any Affiliate has received any FDA Warning Letters or similar EMEA notifications. VPI represents that it shall notify NPS within two (2) business days if VPI or any Affiliate receives any FDA 483s, FDA Warning Letters, or other comparable FDA notifications (or similar European EMEA notifications) concerning the Product or if VPI or any Affiliate receives communication or notification of any planned or unplanned inspection directed to the Product by the FDA or other regulatory authority during the term of this Agreement.

(d) VPI represents that it will not have carried on any activities in a Facility which VPI or its Affiliate knows, as of the date hereof, as evidenced by a writing from NPS to VPI, could prevent Product from being manufactured, packaged, released or stored in accordance with this Agreement or the Quality Agreement.

(e) VPI represents that it, or its Affiliate, owns, controls or has the right to use the intellectual property used in the Product and has the right to grant NPS and its sublicensees, the necessary license to such intellectual property to distribute, use and sell the Product, provided, however such representation is limited to the laws of the European Union as composed prior to May 1, 2004 and the United States.

(f) VPI represents and warrants that it has reviewed, or caused to be reviewed the Specifications and the Product Specifications and that the Facilities are sufficient to Produce Product in accordance with such Product Specifications and Specifications.

(g) VPI represents that it will obtain, or cause to be obtained, NPS' written approval, not to be unreasonably withheld, in advance of any changes concerning or having impact on the Product, all as set forth in the Quality Agreement.

ARTICLE 12: GOVERNMENT APPROVAL

(1) NPS shall be responsible for obtaining and maintaining, at its cost, all appropriate governmental approvals, consents and clearances for the matters herein contemplated, including the sale and distribution of the Product in the Territory, and NPS shall not sell the Product without first securing such approvals, consents and clearances. For sake of clarification, these costs shall include, but not be limited to, such costs associated with governmental audits of VPI or its Affiliate pertaining to the Product. VPI shall cooperate, or shall cause the cooperation, and make and have made every reasonable effort, at NPS' expense, in providing such information and other assistance as NPS may reasonably request to expedite all such governmental approvals.

(2) NPS understands and acknowledges that the Regulatory Authorities will have to approve the Production of the Product at the Facilities and that VPI does not represent or warrant to NPS such approval. VPI shall notify NPS, or cause that NPS be notified, of any Regulatory Authorities inspections as provided in the Quality Agreement.

ARTICLE 13: TRADEMARK

(1) The trademark(s) set forth in Appendix 8A shall be and remain the property of VPI or an Affiliate and NPS shall only have the right to use such trademarks in connection with the sale and distribution of the Product.

(2) The trademark(s) set forth in Appendix 8B shall be and remain the property of NPS and VPI and its Affiliate shall only have the right to use such trademarks of NPS in connection with the packaging of the Product.

ARTICLE 14: INTELLECTUAL PROPERTY; INFRINGEMENT

(1) Notwithstanding anything herein to the contrary, each Party shall own and continue to own all of its pre-existing Intellectual Property existing prior to the Effective Date, and, except as granted herein to the other Party, neither VPI, any of its Affiliates nor any third party shall acquire any right, title or interest in any such pre-existing Intellectual Property of NPS and similarly, neither NPS nor any third party shall acquire any right, title or interest in any such pre-existing Intellectual Property of VPI or its Affiliate.

(2) Except as provided in Article 14(4), NPS shall own and have the sole right to use the Intellectual Property developed under this Agreement (or the Quality Agreement) related to the Product; provided, however, that such Intellectual Property relates solely to the API together with those certain Raw Materials, Components and Packaging Materials and, provided further that such Intellectual Property when used in the Production of the Product cannot be used separately

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from or without such API, wherein such Intellectual Property includes Product-specific SOPs, Product-specific Specifications, Product test results, and Product Batch Records (all such Intellectual Property referred to as "Product Specific IP"), for all purposes, other than any Product Specific IP generated, in whole or in part, by VPI or its Affiliate which may not be used or disclosed in connection with the production or manufacture of the Product by any party other than VPI and its Affiliate, it being agreed and understood that this Agreement is being entered into by VPI with the understanding and objective of having the Product produced and manufactured through VPI. VPI and its Affiliates, notwithstanding the foregoing, shall have the right to use the Product Specific IP for the satisfaction of VPI' s obligations under this Agreement and VPF' s obligations under the Quality Agreement or any other agreement with NPS as well as VPI' s or VPF' s agreements with Nycomed relating to the rights to a product acquired from NPS by Nycomed.

(3) Except as provided in Articles 14(4) and 14(6), VPI and its Affiliates shall own and have the sole right to use for all purposes all SOPs, Specifications and such other Intellectual Property that does not constitute Product Specific IP.

(4) Any Intellectual Property, whether conceived or made solely by one or more employees of one Party and/or an Affiliate of a Party, or jointly by one or more employees of both Parties (and/or any Affiliate of a Party), which Intellectual Property relates solely to the API shall be owned solely by NPS.

(5) Any Intellectual Property, whether conceived or made solely by one or more employees of one Party and/or an Affiliate of a Party, or jointly by one or more employees of both Parties (and/or an Affiliate of a Party), which Intellectual Property relates solely to Production, including any process(es), [*], shall be owned solely by VPI and/or its Affiliate.

(6) Any Intellectual Property, which is not the property of NPS or the property of VPI or its Affiliate as above indicated and is accordingly conceived or made solely by one or more employees of one Party (and/or any Affiliate of a Party), or jointly by one or more employees of both Parties (and/or any Affiliate of a Party), and pertains to the API and/or the Product and to the Production of Product only (and is therefore not applicable to the manufacture and supply of any other product) shall be the joint property of both Parties (or the respective Affiliate as the case may be). Neither Party (nor any Affiliate of a Party) shall

use such jointly owned Intellectual Property without the prior written consent of the other Party (or such Affiliate, as the case may be).

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(7) Each Party shall promptly notify the other Party of any Intellectual Property which is conceived or made solely by one or more employees of such notifying Party (and/or any Affiliate of such Party) or jointly by one or more employees of both Parties (and/or any Affiliate of such Party) (which constitutes joint property under Article 14(5) or in respect of which such notifying Party has an obligation to other Party as hereinafter set forth in this Article.

(8) NPS hereby grants and transfers to VPI (or upon the request of VPI an Affiliate of VPI) any and all of the rights that NPS may have to any Intellectual Property referred to or described in Article 14(5). NPS agrees to execute all such agreements necessary to effect the foregoing.

(9) VPI hereby grants and transfers, or shall cause to be granted and transferred, to NPS any and all of the rights that VPI or any Affiliate of VPI may have to any Intellectual Property referred to or described in Article 14(4). VPI agrees to, and shall cause its Affiliates to, execute all such agreements necessary to effect the foregoing.

(10) NPS shall be solely responsible, at its discretion, for the filing, prosecution, and maintenance of all Intellectual Property that is owned by NPS as above provided.

(11) VPI shall be responsible, at its discretion, for the filing, prosecution, and maintenance of all Intellectual Property that is owned by VPI or any of its Affiliate as above.

(12) NPS and VPI shall be jointly responsible for the filing, prosecution and maintenance of all Intellectual Property which is jointly owned by NPS and VPI, (and/or an Affiliate of VPI or NPS as the case may be), as above provided and any costs associated therewith shall be shared equally.

(13) The Parties shall co-operate with each other (or any Affiliate of the other Party as the case may be) in registering all Intellectual Property rights herein contemplated as reasonably required.

(14) NPS hereby grants a license to VPI and its Affiliate, VPF, to all of the Intellectual Property NPS owns or otherwise has rights to, including under licenses, required by VPI or said Affiliate for the Production for NPS as contemplated under this Agreement and the Quality Agreement. The license is irrevocable for the term of this Agreement, royalty-free, non-exclusive, non-transferable, and non-sub-licensable and solely for the purpose of Production for NPS as contemplated under this Agreement.

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(15) VPI agrees, upon the request of NPS, that it shall in good faith negotiate with NPS for a grant to NPS of a non-exclusive license in respect of such nations as may be mutually agreed, which shall include appropriate indemnifications of VPI and its Affiliates for the use of the license, to any Intellectual Property developed hereunder or the Quality Agreement and owned by VPI or any of its Affiliate, whether solely or jointly, as above provided, for which Intellectual Property a patent has been applied for by VPI and/or its Affiliate.

(16) NPS shall defend, indemnify and hold harmless VPI and its Affiliates from and against any and all claims, actions and/or proceedings (including damages and reasonable attorneys fees) based upon any assertion that NPS Supplied Material, or Information of NPS or materials provided by NPS in connection herewith or the use by VPI and/or its Affiliate of such NPS Supplied Material, or Information of NPS (except to the extent that it is developed by or proprietary to VPI and/or its

Affiliates) or materials provided by NPS infringes or otherwise violates any third party' s patent, trademark or other intellectual proprietary rights.

(17) VPI shall defend, indemnify and hold harmless NPS from and against any and all claims, actions and/or proceedings (including damages and reasonable attorneys fees) based upon any assertion that Information of VPI or any of its Affiliates or the Production of Product (other than for claims, actions and/or proceedings subject to indemnification pursuant to Article 15) or the use by NPS of such Information of VPI and/or its Affiliates (except to the extent that it is developed by or proprietary to NPS) infringes or otherwise violates any third party' s patent, trademark or other intellectual proprietary rights in the countries of the European Union as composed prior to [*] and the United States.

(18) The Parties shall keep each other informed about any such claims, actions and/or proceedings, and shall provide reasonable cooperation to each other in the defense of any such claim, action and/or proceeding at the expense of the indemnifying Party. The indemnifying Party shall not settle any such claim, action and/or proceeding [*].

ARTICLE 15: INDEMNIFICATION AND RECALL OF PRODUCT

(1) VPI and NPS shall each indemnify and hold the other, including each other' s Affiliates harmless from and against any and all claims of any third party, which shall not include an Affiliate of VPI or NPS, as the case may be, resulting from or arising out of any negligence by VPI (and/or Affiliate of VPI) or NPS, as the case may be, or any breach by VPI (including in respect of VPI for the purposes hereof a breach by VPF of the Quality Agreement) or NPS, as the case may be, of its representations, warranties, agreements or other obligations contained in this Agreement. In amplification of the foregoing, and not in limitation thereof, NPS shall indemnify and hold VPI and its Affiliates harmless from all Costs in excess of the amount subject to insurance coverage as in Article 15(4) provided or which arise out of VPI' s or its Affiliate' s compliance with the Product Specifications or any other instruction or direction by NPS, the use of the NPS Supplied Material or the distribution, sale or use of the Product. [*], which means, among other matters, VPI

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and its Affiliates may rely on the correctness and completeness of the Product Specifications and any other instruction of NPS, are followed. NPS shall indemnify VPI and its Affiliates as set forth herein, except to the extent such costs or loss has arisen from VPI' s or its Affiliate' s [*]. Compliance with the obligations under the foregoing sentence shall be deemed conclusively proven by the batch documentation provided in accordance with this Agreement or the Quality Agreement.

(2) The Parties shall promptly notify each other of any claims and suits brought or threatened and shall permit the other Party to join in the defense thereof.

(3) It is understood that neither VPI nor any Affiliate of VPI warrants to NPS or any other party materials manufactured or supplied by any third party, provided, however, VPI agrees to transfer, or cause to be transferred, to NPS any warranties of such parties in respect of such materials.

(4) During the term of this Agreement, all renewal terms, and for [*], VPI shall maintain, general liability insurance, including product liability insurance, as long as commercially reasonable and practicable, for a sum of not less than [*] per property damage, with a reputable insurance company, which insurance amount shall be reduced by the cost of any attorneys. VPI shall furnish to NPS, upon request, a certificate of insurance evidencing compliance with the requirements of this Article 15(4). VPI shall provide to NPS written notice of any cancellation or material change in such insurance not less than thirty (30) days prior to the date of such cancellation or change.

(5) After the Approval Date, NPS shall maintain [*], with a reputable insurance company, to support its obligations to VPI and its Affiliates and related as set forth in Article 15.1, and such insurance shall be maintained for [*] or expiration of this

Agreement, whichever is the later period. In the event that said insurance is subject to cancellation or materially adverse changes, including but not limited to, reduction of coverage, this Agreement, including the Production obligations of VPI herein contemplated, may be terminated at VPI' s option. It is furthermore agreed and understood by NPS that the coverage of abovementioned insurance sum shall extend to NPS' indemnity obligations under this Agreement, and NPS shall, if so requested by VPI, produce the policy of insurance and a receipt for the then-current premium to VPI for VPI' s inspection. [*].

(6) In the event that any Product is recalled by order of any government authority, neither VPI nor any Affiliate of VPI shall have any liability with respect to such recall unless such recall is [*] VPI' s or its Affiliate' s, [*], in which event VPI, as it may determine, shall [*] the amount paid by NPS to VPI in respect of the recalled Product as set forth in Article 6(4) and [*].

ARTICLE 16: TERM AND TERMINATION

(1) This Agreement shall be effective for a term of five (5) years, commencing on the Commencement Date. Thereafter, this Agreement shall automatically renew for terms of three (3) years unless NPS or VPI shall provide notice of termination at least two (2) years in advance of the expiration of either the initial five (5) year term or any subsequent three (3) year term.

(2) Each Party has the right to terminate (with immediate effect or, if applicable, after the expiration of [*] hereinafter referred to) this Agreement upon prior written notice in the event the other Party (including in respect of VPI, VPF) is in major default in the fulfillment of any obligation hereunder (or in the case of VPI, VPF is in major default under the Quality Agreement). The term "major default" shall include, but not be limited to:

(a) the insolvency, bankruptcy or liquidation of a Party (or in the case of VPI, of VPF) or the appointment of a receiver of any significant part of the property of a Party (or in the case of VPI, of VPF) or the occurrence of any similar event; and

(b) in respect of NPS, the failure to pay any amount when due or in the case of any other default which can be cured, the failure to remedy or make good the default during [*] after the giving of any notice specifying such default. If such [*] notice has been given, no additional notice shall have to be given to effect the termination of this Agreement.

(c) the demand by any Regulatory Authority that VPI or its Affiliates, VPF, should implement any changes which are related to Product and for which NPS reasonably declines to pay, provided such amount is in excess [*].

(d) in respect of NPS, the failure of VPI or its Affiliates, not attributable to NPS, to produce or have produced Product in accordance with the Specifications, and/or the Product Specifications or the Purchase Orders for such Product for a period extending beyond [*].

(e) in respect of VPI, failure of its Affiliate, VPF, to pass Regulatory Authority inspection by EMEA and such failure is not cured [*].

(3) Upon any termination of this Agreement, for any reason whatsoever, VPI shall sell to NPS, and NPS shall purchase, at the prices herein provided, all Product for which Purchase Orders have been placed, or are required to be placed, on or prior to the date of termination, and, at the cost thereof, all components and other materials as have been ordered as contemplated or permitted in this Agreement,.

VPI shall also deliver or have delivered, unless otherwise directed by NPS, to NPS, at its cost and expense, any quantities of NPS Supplied Material in VPI' s or its Affiliate' s possession. VPI shall also return, or cause to be returned, to NPS all documentation constituting Information of NPS (including copies thereof) which has

been provided by NPS to VPI or its Affiliates in connection herewith. Notwithstanding the foregoing, VPI may retain, or cause to be retained, such limited amount of Product, NPS Supplied Material as well as such documentation, as may be necessary for proper record keeping or the satisfaction of, GMP and/or legal requirements.

(4) NPS shall return to VPI all documentation constituting Information of VPI or any of its Affiliates (including copies thereof) which has been provided by VPI, or cause to be provided, to NPS hereunder; provided, however, NPS may retain such limited number thereof as may be necessary for proper record keeping or the satisfaction of, GMP and/or legal requirements.

(5) If NPS terminates the Capacity Reservation Agreement pursuant to Section VI of the Capacity Reservation Agreement, this Commercial Manufacturing Agreement shall automatically terminate on thirty (30) days notice.

(6) The provisions of Articles 13, 14, 15, 18 and 20, and related provisions, as well as any other provisions and obligations by their terms would reasonably not terminate or expire, shall survive any termination or expiration of this Agreement.

ARTICLE 17: FORCE MAJEURE

(1) Neither Party, nor any Affiliate of a Party, shall be responsible to the other for failure or delay in performing any of its obligations under this Agreement or for other non-performance hereof if such failure, delay or non-performance is caused by or arises from strike, stoppage of labor, lockout or any other labor trouble, shortage of energy or raw material or any other inability to obtain any materials or shipping space, breakdown or delays of carriers or shippers, default or delay by any supplier or sub-contractor, fire, flood, lightning, fog, storm, or other unusual weather conditions, explosion, accident, earthquake, epidemics, act of God, any public enemy, sabotage, invasion, war (declared or undeclared), riot, embargo, governmental or administrative act or restraint, prohibition on import or export of the Product or materials incorporated therein or parts thereof, or any other cause that is unavoidable or beyond the reasonable control of the affected Party (or in the case of VPI, VPF), including such events which stem from the internalization of such operations and services which typically and customarily are provided by a third party (any such matter or cause, "Force Majeure"). A Party (or in the case of VPI, VPF) shall be under no obligation to settle a strike, labor stoppage, lockout, or any other labor trouble by entering into any agreement to settle such matter and until such matter is settled to the satisfaction of the affected Party (or in the case of VPI, VPF), such matter shall continue to be a matter beyond the reasonable control of the affected Party (or in the case of VPI, VPF).

(2) The Party claiming Force Majeure hereunder shall promptly notify the other specifying the cause and probable duration of the delay or non-performance. VPI

shall be under no obligation to fulfill any Purchase Orders which have been, or should have been, scheduled to be performed during a time period of Force Majeure; however, each affected Party shall undertake, or cause to be undertaken, every reasonable effort to fulfill its contractual obligations to the extent reasonably possible under the circumstances.

(3) If VPI claims Force Majeure hereunder and is not able to have produced Product for a period extending beyond ninety (90) days, then NPS shall have the right to terminate this Agreement pursuant to paragraph 17(2)(d).

ARTICLE 18: CONFIDENTIALITY

(1) The provisions of the Confidentiality Agreement shall govern this Agreement in every respect; except that this confidentiality obligation shall survive the termination of this Agreement and shall remain in full force and effect for a period of [*] of either the initial or any renewal term of this Agreement whichever may be later.

(2) VPI and NPS hereby each agree to indemnify and hold the other harmless from all [*], for any violation of the provisions of this Article 18.

ARTICLE 19: UNITED NATIONS CONVENTION

Notwithstanding anything herein to the contrary contained in this Agreement, the United Nations Convention on Contracts for the International Sale of Goods shall have no application to, and shall be of no force and effect with respect to, this Agreement or the matters herein set forth or contemplated.

ARTICLE 20: LIMITATION

(1) Notwithstanding anything to the contrary in this Agreement contained, neither Party (including any Affiliate of a Party) shall be responsible or liable to the other or any Affiliate of the other (even upon the occurrence of a tort with respect to the Product or otherwise) for loss of profits (except any profits, as contained in the prices herein provided, to which VPI may be entitled for performance of its contractual obligations hereunder), loss of goodwill, loss of business, or special or consequential or indirect damages.

(2) **EXCEPT AS IN THIS AGREEMENT SET FORTH, THE PARTIES, INCLUDING IN RESPECT OF VPI ITS AFFILIATE VPF, DO NOT MAKE ANY OTHER REPRESENTATION, WARRANTY, COVENANT OR AGREEMENT (WHETHER EXPRESS OR IMPLIED) WITH RESPECT TO THE PRODUCT. ANY REPRESENTATION, WARRANTY, COVENANT OR AGREEMENT SET FORTH IN THIS AGREEMENT (INCLUDING FOR THE PURPOSES HEREOF THE QUALITY AGREEMENT) IS EXCLUSIVE AND IN LIEU OF ANY OTHER WARRANTIES, WRITTEN OR ORAL, DIRECT, IMPLIED OR STATUTORY,**

INCLUDING, BUT NOT LIMITED TO, EXPRESS OR IMPLIED WARRANTIES FOR MERCHANTABILITY, QUALITY OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 21: TIMELY PERFORMANCE

Failure by a Party, at any time, to require performance by the other Party or to claim a breach of this Agreement, unless reduced to writing, will not be construed as a waiver of any right under this Agreement, nor affect any subsequent breach nor affect the effectiveness of this Agreement or any part hereof, nor prejudice such Party with respect to any subsequent action.

ARTICLE 22: ENTIRE AGREEMENT

(1) This Agreement, together with all Appendices attached hereto, constitutes the entire agreement between the Parties with respect to the subject matter hereof and supersedes in all respects all prior proposals, negotiations, conversations, discussions and agreements between the Parties concerning the subject matter hereof, including the Development Agreement and the Indemnity Agreement.

(2) Any term of this Agreement which might be, or become, void, invalid or unenforceable shall be replaced by mutually agreed terms in compliance with the commercial and lawful purposes of this Agreement. The voidance, invalidity or unenforceability

of the entire Agreement remains independent of any void provision, except in the event the Parties would not have entered into this Agreement without these significant provisions.

(3) In case of any gap in this Agreement a reasonable provision shall be effective in order to complete this Agreement approaching to what the Parties would have agreed upon if they would have considered that point.

ARTICLE 23: CONFLICT

In the event that there should be any conflict between any provision of this Agreement and any other agreement between the Parties, the provisions of this Agreement shall govern in all respects.

ARTICLE 24: AMENDMENTS

Any amendment to or alteration of the provisions herein contained, including this Article 24, shall take effect only by a written document signed by the duly appointed representatives of both Parties.

ARTICLE 25: ASSIGNMENT

Neither this Agreement nor any rights hereunder shall be assignable or transferable by

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either of the Parties hereto without the prior written consent of the other Party; provided, however, that [*].

ARTICLE 26: NOTICES

(1) All notices, requests, demands and other communications hereunder shall be addressed as follows (or to such other address, telex number with confirmed answer back or fax number as each Party hereto may specify herein or in a notice pursuant to this Article 26) and be deemed to have been duly given upon receipt (provided receipt is on Monday, Tuesday, Wednesday, Thursday or Friday which is not a national holiday at the place of receipt and during normal business hours of the recipient (the "Business Day"), otherwise on the next succeeding Business Day), when delivered personally, mailed by registered or certified mail, return receipt requested or telexed with confirmed answer back or faxed:

To NPS:
NPS Pharmaceuticals, Inc.
550 Hills Drive
Bedminster, New Jersey
07921 U.S.A.
Attn: Legal Department

To Vetter:
Vetter Pharma International GmbH Eyewiesenstrasse 5
88212 Ravensburg
Germany, Fed. Rep. of
Attn.: Director of Key Account Management

(2) Each Party hereto may change its address set forth above by giving notice to the other Party as herein provided.

ARTICLE 27: HEADINGS

The headlines of the Articles hereof are for convenience of reference only and shall not affect the interpretation of the respective Articles of this Agreement.

ARTICLE 28: ENGLISH

All notices and other communications hereunder shall be in English.

ARTICLE 29: GOVERNING LAW

This Agreement shall be construed in accordance with and governed by the [*] without giving effect to any conflict-of-laws provisions and the competent [*] shall have exclusive jurisdiction.

ARTICLE 30: CHANGE CONTROL

This Agreement shall not be assigned or transferred by either Party without the other Party' s prior written consent. Either Party shall give advance written notice to the other Party or any pending change of control of the former Party (meaning the transfer − which transfer shall include, but not be limited to, change in stock ownership, asset sale, merger and reverse triangular merger − of all, or substantially all, the business of such Party) to a third party and the Parties shall discuss and mutually agree on the further proceedings.

* * * * *

IN WITNESS WHEREOF, the duly authorized representatives of the Parties hereto as of the day and year first above written have executed this Agreement.

NPS PHARMACEUTICALS, INC.:

(signed) /s/ FRANCOIS NADER
Name: Francois Nader
Title: *President and Chief Executive Officer*

VETTER PHARMA INTERNATIONAL GmbH & Co. KG

(signed) /s/ PETER SOELKNER
Name: Peter Soelkner
Title: *Managing Director*

(signed) /s/ EUGEN FRASCH
Name: Eugen Frasch
Title *Key Account Manager*

APPENDIX 1: PRODUCT

INTENTIONALLY LEFT BLANK

APPENDIX 2:

YIELD

[*]

APPENDIX 3:TERRITORY

[*]

APPENDIX 4: INTENTIONALLY OMITTED

APPENDIX 5: INTENTIONALLY OMITTED

APPENDIX 6: INTENTIONALLY OMITTED

APPENDIX 7: PRICES

[*]

APPENDIX 8A: TRADEMARKS OF VPI and AFFILIATES

NONE LISTED

APPENDIX 8B: TRADEMARKS OF NPS

NPS

NPS

PREOS

APPENDIX 9: AGREED VALUE OF NPS' RAW MATERIALS

[*]

APPENDIX 10: CONFIDENTIALITY AGREEMENT

MUTUAL CONFIDENTIAL DISCLOSURE AGREEMENT
(As amended May 14, 2008)

THIS AGREEMENT, made as of the eleventh day of October, 2004,

BETWEEN:

NPS ALLELIX CORP.,

Of 6850 Goreway Drive, Mississauga, Ontario L4V 1V7, Canada,

(hereinafter referred to as "NPS ALLELIX")

-AND-

VETTER PHARMA-FERTIGUNG GmbH & Co, KG

of Schutzenstrasse 87, 88212 Ravensburg, Germany,

(hereinafter referred to as "VETTER")

For the purpose of assessing their interest to enter into an arrangement through which VETTER would perform for NPS ALLELIX certain sterile filling and lyophilization of glucagonlike peptide-2 in respect of NPS ALLELIX' s proprietary compounds (the "Purpose") as well as to discuss other interests with respect to and through which Vetter would perform other professional services, the parties wish to disclose to each other certain information regarded as confidential. To ensure that the information which may be disclosed to each other is treated in strictest confidence to the same extent each party keeps its own confidential information confidential, the parties agree as follows:

1. All information disclosed in oral, written, photographic or recorded form or in the form of samples of chemical or biological material, or in any other form related to the Purpose by one party to the other party shall be deemed to be "Confidential Information". Either party' s Confidential Information may be disclosed to the other by the disclosing party' s employees or employees of its Affiliates. As used herein "Affiliates" means any corporation, which directly or indirectly controls, is controlled by or is under common control with either party by means of ownership of more than 50% of the voting shares, or comparable interest.

2. Neither party shall disclose the Confidential Information or any part thereof received from the other party to any third party and only to employees or employees of its Affiliates on a need-to-know basis. Each party is responsible for its employees' and the employees of its Affiliates' compliance with the terms of this Agreement.

3. Neither party shall use the Confidential Information or any part thereof received from the other party for any purpose except to determine their mutual interest in connection with the Purpose.

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4. Confidential Information supplied shall not be reproduced in any form except as required to accomplish the intent of this Agreement.

5. Unless otherwise specified in writing, all documents and materials containing or embodying Confidential Information shall remain the property of the disclosing party. Upon request of the disclosing party, the receiving party agrees to return all documents and materials containing or embodying any Confidential Information of the disclosing party, as well as all copies thereof, except that the receiving party may retain one copy solely to ensure compliance with any regulatory requirements.

6. The foregoing provisions of confidentiality and non-use shall not apply to Confidential Information which:

(a) is now, or which hereafter, through no act or failure to act on the part of the receiving party, becomes generally known or available to the public without breach of this Agreement;

(b) is known to the receiving party at the time of disclosure of such Confidential Information provided that the receiving party can satisfactorily demonstrate such prior knowledge by reference to its written or electronic records;

(c) is hereafter furnished to the receiving party in good faith by a third party without breach by that third party either directly or indirectly of an obligation of secrecy to the disclosing party;

(d) is independently developed by the receiving party, provided that the person or persons developing same have not had access, either directly or indirectly, to the Confidential Information received; and/or

(e) is required by law to be disclosed.

7. Notwithstanding any termination of this Agreement the provisions of confidentiality shall apply for a period often (10) years from the date hereof.

8. This Agreement shall in no way be construed as the granting of a license by either party to the other directly or indirectly under any patent or patent application or other form of proprietary property owned by the disclosing party. Furthermore, nothing in this Agreement shall be interpreted so as to oblige either party to enter into a further agreement.

9. The invalidity of any provision or part of this Agreement will not affect the validity or enforceability of any other provision or part thereof.

10. This Agreement shall be construed and governed in accordance with the laws of Germany.

IN WITNESS thereof the parties have executed this Agreement the day and year first above written.

FOR AND ON BEHALF OF NPS ALLELIX CORP.

By: /s/ Kevin Ontiveros
Title: Acting General Counsel and Secretary

FOR AND ON BEHALF OF VETTER PHARMA-FERTIGUNG GMBH & CO. KG

By: /s/ Peter Soelkner November 12, 2004
Title: Director Key Account Management

By: /s/ Robert Cashman November 18, 2004
Title: Key Account Manager

APPENDIX 11 QUALITY AGREEMENT

QUALITY AGREEMENT

by and between

NPS Allelix Corp.
("NPS")

and

Vetter Pharma-Fertigung GmbH & Co. KG
("Vetter")

Dated as of April 27th, 2004

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THIS QUALITY AGREEMENT, made and entered into as of the Commencement Date of the Commercial Manufacturing Agreement and attached thereto as Appendix 12 (the "QA"), by and between NPS and Vetter.

WITNESSETH:

WHEREAS, this QA outlines the responsibilities of NPS and Vetter with respect to the quality of the product listed in **APPENDIX 1** hereof (the "Product");

WHEREAS, this QA is an integral part of the Commercial Manufacturing Agreement and of the Confidentiality Agreement all by and between NPS and Vetter;

NOW, THEREFORE, in consideration of the premises and of the mutual covenants and agreements hereinafter set forth, and subject to the terms and conditions of this QA as well as the Commercial Manufacturing Agreement and the Confidentiality Agreement, NPS and Vetter agree as follows:

ARTICLE 1: DEFINITIONS

For all purposes of this QA, and all amendments hereto, the terms defined in this Article shall have the meanings herein specified, unless the context otherwise requires. Terms defined in this QA shall have the same meaning where used in the Commercial Manufacturing Agreement and the Confidentiality Agreement and vice-versa.

(1) "Commercial Manufacturing Agreement" shall mean supply agreement entered into by and between NPS and Vetter.

(2) "Deviation" shall mean any out-of-Specification result and/or any manufacturing, packaging, labeling or testing deviation as more fully defined in **ARTICLE 15**.

(3) "GMP" or "cGMP" means the current good manufacturing practices officially published by EMEA and FDA that are applicable to the Manufacture of the Products, which practices to the extent that they are Product specific shall have been provided by NPS to Vetter.

(4) "NPS" shall mean NPS Allelix Corp., a corporation organized and existing under the laws of the Province of Ontario, Canada, with its principal place of business at 6850 Goreway Drive, Mississauga, Ontario L4V 1V7 Canada.

(5) "SOP" shall mean the standard operating procedures of Vetter.

(6) "Vetter" shall mean Vetter Pharma-Fertigung GmbH & Co. KG, a corporation organized and existing under the laws of Germany, with its principal place of business at Schützenstraße 87, 88212 Ravensburg, Germany.

ARTICLE 2: PRINCIPLE RESPONSIBILITY

(1) NPS is responsible for the Product as set forth in **APPENDIX 1**. NPS and its authorized partners are responsible for the final release of Product to the markets of the Territory.

(2) (a) The responsibilities of NPS and Vetter with respect to the quality of the Product are as listed and set forth in **APPENDIX 6** hereof.

(b) Vetter shall be responsible for operating under cGMP and adhere to its Quality System to prevent contamination of Vetter Supplied Materials and Product and NPS Supplied Materials upon receipt by Vetter.

(c) Vetter shall adhere strictly to the Specifications as set forth in **APPENDIX 5** for Vetter Supplied Materials and Product.

(3) Vetter agrees not to appoint a third party for the processing, packaging, analyses, and storage (except warehousing and internal logistic operations as well as re-qualification of certain Materials provided to Vetter by suppliers thereof, by an external laboratory or other party) of the Product without prior written approval of NPS, which shall not unreasonably be withheld. Any such approval given for such third party shall not release Vetter from its obligations under cGMP. In the event that Vetter appoints a third party, Vetter will assure that such third parties will meet all requirements as set forth in **APPENDIX 5**.

ARTICLE 3: MATERIALS AND COMPONENTS

(1) NPS shall provide to Vetter the NPS Supplied Materials, including the raw materials and components, all as set forth in **APPENDIX 2** hereof. NPS shall provide Vetter with proper manufacturers' quality certificates and other appropriate data and certificates for these NPS Supplied Materials, as well as such other documentation as may be required by law, applicable Regulatory Authorities or as Vetter may reasonably request. Furthermore, NPS shall specifically inform Vetter if NPS Supplied Materials require any specific handling and/or processing.

(2) In respect of these NPS Supplied Materials as set forth in **APPENDIX 2** hereof, Vetter has no and shall not have any obligation whatsoever to undertake any testing or otherwise certify the same. It is agreed that Vetter may fully and completely rely on the correctness of the quality certificates issued in respect thereof.

(3) Vetter shall supply the Vetter Supplied Materials, including components and packaging materials, all as set forth in **APPENDIX 3** hereof. Vetter agrees that the Vetter Supplied Materials as listed and set forth in **APPENDIX 3** hereof will, after delivery, be examined by Vetter in accordance with the mutually agreed Testing Specifications as more fully described and set forth in **APPENDIX 5** hereof. Upon completion of the examination, Vetter will have available a Certificate of analysis.

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(4) Except for these obligations of Vetter to examine the Vetter Supplied Materials as set forth in **APPENDIX 5** hereof, Vetter shall have no obligation or liability whatsoever in respect thereof.

ARTICLE 4: MANUFACTURING MANUAL AND TESTING SPECIFICATIONS

(1) NPS shall provide Vetter with NPS' Product Specifications including the submission documentation as set forth in **APPENDIX 4** hereof.

(2) NPS shall, from time to time, disclose to Vetter changes in NPS' Product Specifications and shall specifically inform Vetter if any such changes have or could have an adverse or negative chemical, physical or other effect on the Product and/or Production. NPS shall bear all responsibility for the consequences of the failure to adequately disclose or describe such effect

or such information and shall bear all costs and expenses of Vetter, which may be associated with such changes in Product Specifications.

(3) Vetter shall use Product Specifications, as set forth in **APPENDIX 4** hereof, to the extent such constitutes Confidential Information of NPS, only for the Production and shall not use it for any other purpose without the prior written approval of NPS.

(4) NPS shall keep Vetter informed of any legislation and any rules and regulations of the Regulatory Authorities within the Territory, which may affect the Product and/or its Production and shall specifically inform Vetter of the effect of any thereof. Subject to the change control procedures set forth in this Agreement and in Art. 2 (3) and (4) of the Commercial Manufacturing Agreement, Vetter shall comply with all such legislation and rules and regulations, including cGMP requirements.

(5) NPS and Vetter shall mutually agree upon the Specifications for the Production of the Product, written documentation of which shall be set forth in **APPENDIX 5** hereof and be signed by the duly authorized representatives of NPS and Vetter. NPS shall ensure that the mutually agreed Specifications set forth in **APPENDIX 5** correspond with the marketing authorization(s) for such Product.

(6) Any changes requested by NPS having an impact on the Specifications as set forth in **APPENDIX 5** hereof shall be subject to the change control procedures set forth in this Agreement and in Art. 2 (3) and (4) of the Commercial Manufacturing Agreement and shall be approved by Vetter in writing. Vetter shall not unreasonably withhold its approval; provided, however, Vetter may take into account such factors as facility capacity, production commitments, and similar business factors.

(7) Prior to implementation, Vetter shall reduce to writing and in electronic data form (fax or for example PDF file format) any and all changes of the Specifications as set forth in Appendix 5 and shall inform NPS of any of those changes by making an updated draft available to NPS for its written approval. NPS shall not unreasonably withhold its approval, taking into account GMP, any legislation, rules and regulations, its own Product Specifications as set forth in **APPENDIX 4** hereof, and the standard operating procedures ("SOP") of Vetter. NPS shall after receipt of such changes notify Vetter concerning any negative or adverse chemical, physical or other effect such process or

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matter has or could have on the Materials provided by Vetter or NPS. Changes to the Specifications shall be deemed approved and accepted when signed by NPS.

ARTICLE 5: PERSON-IN-PLANT (PIP)

(1) NPS may appoint at the most two employees to be persons-in-the-plant at Vetter Facilities near where production of the Products is taking place, which persons shall be subject to the rules and regulations of Vetter, as in effect from time-to-time, including, without limitation, rules on restricted areas and access, secrecy, and work schedules, it being agreed and understood that under no circumstances shall such persons have unrestricted access to Vetter Facilities, including areas where other customer products or information may be located. It is also agreed that if any information or written is provided by Vetter to such persons, it shall satisfy all applicable notice requirements set forth in the Commercial Manufacturing Agreement and/or this QA. it is further agreed that these persons shall be subject to the provisions of the Confidentiality Agreement in force between the Parties. In the event such persons in plant wish to visit Vetter Facilities it is agreed that such persons shall at all times stay together in a group to be accompanied by members of Vetter' s personnel. In the event that PIP personnel have to be in separate areas this will be mutually agreed between both parties in advance.

ARTICLE 6: INSPECTION AND TESTING OF THE PRODUCT

(1) Vetter shall, in accordance with its customary procedures, inspect and test the Product prior to its delivery to NPS, as mutually agreed to by and between the parties hereto in writing and as set forth in **APPENDIX 5** hereof.

(2) NPS shall inspect and test all of the Products upon receipt of samples. The methods of every inspection and testing by NPS should correspond with the inspection and testing methods detailed in **APPENDIX 4**. NPS expressly agrees not to undertake any additional sterility tests of the Products with the exception for Product stability evaluations and hereby waives any claim based on such sterility tests. In case of complaints where sterility of the Product is in question additional sterility testing shall be performed. This will only be done on a mutually agreed basis and in connection with investigation results available for both Parties

ARTICLE 7: BATCH NUMBERING, PRODUCT SHELF-LIFE, EXPIRY DATE

(1) The batch numbering shall be in accordance with the batch numbering system mutually agreed upon by NPS and Vetter as set forth in **APPENDIX 7** hereof.

(2) NPS shall provide Vetter with all of the information necessary to identify or determine the shelf-life and expiry date of the Product which shall be applicable to each batch thereof.

ARTICLE 8: PACKAGING

(1) If required by NPS, the Product shall be packaged by Vetter, together with any package inserts provided by NPS, in accordance with the Specifications as set forth in **APPENDIX 5** hereof.

(2) Vetter shall order from time to time the required printed Packaging Materials in respect of the binding and irrevocable Purchase Orders given by NPS, or such amounts meeting the requirement for a maximum period of three (3) months.

ARTICLE 9: SPECIAL REQUEST

(1) Any special request of NPS for re-packaging, re-labeling, or similar services, in respect of the Products manufactured by Vetter shall be accepted by Vetter in writing upon prior respective agreement by and between the parties clarifying the conditions of such a special request (the "Special Request"). All Special Requests (procedures and testing) shall be approved by NPS and Vetter Quality Assurance.

(2) In respect of the information provided by NPS, Vetter may fully and completely rely on such Products designated in connection with a Special Request are and/or, will be in accordance with all applicable Specifications. It is agreed and understood by and between the parties that Vetter has no and shall not have any obligation whatsoever to undertake any controls, identity testing, or income inspections, in order to satisfy any Special Request.

ARTICLE 10: STORAGE

(1) Vetter agrees to store the Products and the retained samples under storage conditions and in an area that complies with the SOP or the Specifications as set forth in **APPENDIX 5** hereof. Upon written request, copies of a computerized inventory list of the stored Product with respect to Vetter' s validated warehousing system shall be provided to NPS and not unreasonably be withheld by Vetter.

ARTICLE 11: RECORDS, DOCUMENTATION AND SAMPLING

(1) For each batch of Products manufactured by Vetter, Vetter shall provide NPS with copies of the manufacturing and packaging records and documentation as described and set forth in **APPENDIX 8**. After **[*]** Vetter and NPS will evaluate the need for full documentation. Appendix 8 shall then be revised by mutual written agreement accordingly. Vetter shall provide the necessary documents for the applicable customs clearance in the Territory as described in **APPENDIX 8**. If NPS requires any additional documents or information, the cost thereof will separately be invoiced.

In addition to the above, Vetter shall provide NPS with retained samples out of each batch of Products as set forth in the sampling plan mutually agreed to by and between the parties hereto in writing and which shall be subject to NPS' written approval, which shall not unreasonably be withheld and be given prior to the date of the release of the Products

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for delivery to NPS. Such approval by NPS shall practically and legally constitute Vetter' s authorization for release and delivery of such Products to NPS.

(2) Vetter shall have the right, but no obligation to keep reference samples out of each batch of Products for its own records, minimum amounts of such samples shall be sufficient for two (2) analyses of the Product.

(3) The manufacturing and packaging records and documentation as listed and set forth in **APPENDIX 8** hereof shall be kept on file in written or readable electronic data form by Vetter for nine (9) calendar years or such shorter period as may be permitted by applicable law.

Vetter shall inform NPS, prior to any destruction of such records and documentation. NPS may then request within thirty (30) days of such notification of Vetter that the records and documentation shall be sent to NPS. If Vetter receives no written response of NPS within such thirty (30) days, the records will be destroyed.

(4) Upon respective prior and written request, the records and documentation shall be available to NPS for review during normal business hours or for inspection by the Regulatory Authorities of any country to which the Product currently is exported within the Territory by the time such request is made.

ARTICLE 12: RELEASE AND SHIPMENT

(1) Vetter shall release the Products for delivery to NPS, whereas NPS or NPS through its authorized business partners shall in all respects be responsible for final release of the Products to the markets whether or not inside the Territory. A certificate of conformity (C of C) for a given lot will be sent to NPS before delivery of goods together with the documentation set forth in Appendix 8. Vetter will not deliver the Products to the place and address indicated by NPS until NPS has successfully performed final release of the Products. Upon prior written request, and assumption of all risks, responsibilities, and costs, associated thereto by NPS, quarantine shipment shall be performed by Vetter to NPS or any destination as requested by NPS.

(2) Any shipment of the Products shall be **[*]** under terms and conditions as set forth in the Commercial Manufacturing Agreement.

ARTICLE 13: INSPECTION AND REGULATORY CONTACTS

(1) NPS shall, upon prior written notice and during normal business hours, have the right to inspect such areas of Facilities utilized for Production. In no event shall the total amount of all such inspections be more than one (1) per year which shall in no event exceed the duration of five (5) Business Days; provided, however, and notwithstanding the foregoing, in the event of any critical concern in respect of the quality of the Product, the herein above mentioned limitation shall not apply. All NPS' audit teams, each member of which shall explicitly be bound in writing by the Confidentiality Agreement entered into by and

between the parties hereto, shall at all times be accompanied by members of Vetter' s personnel and not be divided into more than two (2) sub-teams.

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(2) Vetter shall notify NPS within five (5) Business Days of any quality related inspections, request for information, or other communication by Regulatory Authorities of the Production of the Products. Vetter shall not provide any Product related information to regulatory agencies without NPS' consent, unless such information is required by cGMP. Such information required by cGMP shall only be provided to regulatory agencies after discussion with NPS.

(3) In the case of **[*]** and observations by FDA or deficiencies cited by EMEA directly related to the quality of the Product, Vetter shall contact NPS within two (2) Business Days if the observations/deficiencies occurred during the production of the Product. Vetter shall contact NPS within three (3) Business days for the observations/deficiencies cited during general GMP inspections if Production of the Product was not in effect at the time of inspection.

(4) After such regulatory communication or inspection Vetter shall provide to NPS the results and reports received in respect thereof from the Regulatory Authorities.

(5) NPS agrees to notify Vetter of any planned inspection of the Product prior to the date of such an inspection. NPS agrees to notify Vetter of the result and subsequent communication with the FDA and/or any other Regulatory Authorities by NPS if Product quality is affected.

ARTICLE 14: CHANGE CONTROL

(1) Vetter shall utilize a documented system of procedures for the control of quality related changes to raw materials, components, packaging materials, Manufacturing Manual, and Specification, and suppliers.

(2) Any changes directly affecting the Production of the Product and its testing as set forth in Appendix 5 shall be reviewed and approved in writing by duly authorized representatives of NPS and Vetter prior to the respective implementation thereof.

(3) In accordance with said Change Control Procedure, Vetter shall keep NPS informed of, and NPS shall have pre-approval of, significant contemplated changes, including improvements, in the Vetter Supplied Materials to be incorporated in the Product. If NPS does not reasonably agree to incorporate any such changes in the Product, Vetter may cease Production of the Product immediately if these changes are necessary to comply with any laws or regulations as well as practices of Regulatory Authorities. If Vetter agrees to continue the Production of the Product without incorporation of such changes, and NPS has withheld its consent unreasonably, NPS shall bear all responsibility (including any product liability) for the consequences of any such non-incorporation.

(4) In accordance with the Change Control Procedure, NPS may request that changes be incorporated in the manufacture of the Product, and Vetter shall implement such changes, subject to Vetter and NPS agreeing to any necessary amendments to the Commercial Manufacturing Agreement, including, without limitation, price adjustment, capacity and ability to incorporate such changes and approvals of any other customers of Vetter as may be required.

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(5) Vetter agrees to keep NPS informed as set forth in this Article 23 as long this QA is in effect and force, provided however that Vetter actually manufactures the Product. In the event the Product is not manufactured within a time period of more than three (3) years, Vetter shall have no obligation under this QA to inform NPS accordingly. However Vetter will inform NPS in writing of their intention not to continue alerting NPS to changes. If manufacture of the Product resumes after a period of greater than

three (3) years then the changes that occurred in the intervening period will be reviewed by both parties before production starts.

ARTICLE 15: DEVIATIONS

(1) All quality related Deviations, including such Deviations not affecting the Specifications as set forth in **APPENDIX 5** hereof **[*]**, shall be investigated and documented by Vetter. NPS shall be informed (Preliminary information) within five (5) Business Days from the day of discovery. This documentation of such Deviations shall be kept on file by Vetter in such a way that they can be traced to the batch affected.

(2) Of all such quality related Deviations which may affect Product quality as set forth in **APPENDIX 5** hereof **[*]**, Vetter shall notify (Preliminary information) NPS within five (5) Business Days from the day of its respective discovery. In the event of Deviations already having affected the quality of the Product and/or the Specifications as set forth in **APPENDIX 5** hereof **[*]**, Vetter shall notify NPS thereof within three (3) Business Days from the time of its respective classification. Together with the aforementioned notification Vetter shall propose an approach to address the deviation.

(3) NPS shall respond to Vetter within three (3) Business Days with respect to the information of a **[*]**. Regarding **[*]** Vetter will expect NPS to respond within five (5) Business Days. It is agreed that Vetter shall begin the investigations of a **[*]**, but shall not implement corrective and preventative actions (CAPA) according to its SOPs without NPS consent.

(4) All Deviations will be documented and will be sent to NPS as part of the batch documentation as set forth in **APPENDIX 8**. For all Deviation Reports, NPS shall have the final responsibility to determine the significance of the impact of such Deviation on the Product as well as, accordingly, determine the further disposition of the affected lots of Product. Solely upon NPS' respective written notification, Vetter shall dispose of, or otherwise handle such lots as requested.

ARTICLE 16: COMPLAINTS

(1) NPS shall provide Vetter with a summary of any quality related and or affecting complaints on a periodically basis, within a time period, which shall not exceed one year.

(2) Upon prior written request by NPS, Vetter shall investigate quality related and/or affecting complaints and provide a written report on the results thereof, any and all costs of which shall be borne by NPS.

ARTICLE 17: RECALL

(1) NPS and Vetter shall immediately notify each other of any finding that may cause the Product to be recalled. Vetter shall not recall the Product in any circumstance. NPS is responsible for final evaluation of such findings and for initiation of a recall.

(2) In the event of any recall of Product Vetter shall allocate the status "Rejected" to such affected lots of Product then-currently be found at the Facilities. NPS shall undertake any and all efforts to completely withdraw any recalled, or potentially recalled Products from all markets inside the Territory.

ARTICLE 18: VALIDATION AND QUALIFICATION

(1) NPS and Vetter shall mutually agree in writing upon a validation and qualification documentation to ensure that any Product specific and quality related validation, such as process validation, packaging validation, analytical method validation, cleaning validation, and equipment qualification, is in accordance with GMP and the responsibilities set forth in **APPENDIX 6** hereof.

(2) Vetter shall provide to NPS the Product quality related validation and qualification documents for review and approval.

(3) Vetter agrees that its suppliers of Materials, including packaging materials, substances, and excipients, shall be re-qualified as required by GMP. Therefore, Vetter shall, all in accordance with the Pharmacopeia, appoint an external laboratory or other qualified party with the testing of such Materials, substances, and excipients.

ARTICLE 19: ANNUAL PRODUCT REVIEW

(1) Vetter shall provide to NPS Quality Assurance an annual compilation of information for a review period as mutually agreed by both parties relevant to the manufacturing and testing of the Product including, but not limited to, changes related to the Product, its manufacturing and testing, trending of environmental data, **[*]** for compilation of an annual Product review by NPS. NPS and Vetter shall agree upon all data to be reported.

ARTICLE 20: STABILITY STUDIES

(1) NPS shall be responsible for any stability testing, data interpretation, reports, documentation, and stability information, performed for Regulatory Authorities. Any stability related procedures required during Production of the Products shall be part of the Specifications as set forth in **APPENDIX 5** hereof.

ARTICLE 21: ENTIRE AGREEMENT

(1) This Quality Agreement together both with the Commercial Manufacturing Agreement and the Confidentiality Agreement all entered into by and between the parties hereto constitutes the entire agreements between the parties with respect to the subject matters

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hereof and supersedes in all respects all prior proposals, negotiations, conversations, discussions and agreements between Vetter and NPS.

(2) All of the provisions contained in the Commercial Manufacturing Agreement and in the Confidentiality Agreement shall also apply to this Quality Agreement and vice versa. In the event of any conflict between any provision of this Quality Agreement and any of those contained in the Commercial Manufacturing Agreement the provisions of the Commercial Manufacturing Agreement shall govern and control in all respects.

(3) Upon prior written request, this Quality Agreement shall, in accordance with applicable law, be disclosed to any Regulatory Authority within the applicable Territory. Each party hereof shall priorly inform the other party in writing of any such request by, and intended disclosure to, Regulatory Authorities.

ARTICLE 22: AMENDMENTS

(1) Any amendment to or alteration of any of the provisions contained in this QA, including this ARTICLE 22, and all of the Appendices attached hereto shall only take effect by a written document signed by the duly authorized and appointed representatives of both parties hereto. For the sake of clarification, NPS and Vetter shall therefore review and mutually approve in writing of any quality related changes and updates.

(2) In the requirement event of any additional quality document for regulatory purposes only, it is agreed and understood by and between the parties hereto that such additional quality document shall not be deemed an amendment to this QA, and that such

shall not affect or alter any of the provisions of this QA and/or the Commercial Manufacturing Agreement and/or the Confidentiality Agreement.

ARTICLE 23: TERM

(1) This QA shall be effective and remain in full force and effect synchronously with the Term of the Commercial Manufacturing Agreement.

ARTICLE 24: SURVIVAL

(1) The legal responsibilities of the parties, among others, as set forth in this QA with respect to the quality of the Product shall remain in full force and effect and shall survive any termination or expiry of the Commercial Manufacturing Agreement.

ARTICLE 25: GOVERNING LAW

(1) This QA shall be construed in accordance with and governed by the laws of **[*]** without giving effect to any conflict-of-laws provisions and the competent courts of **[*]** shall have exclusive jurisdiction.

ARTICLE 26: CONTACT PERSONS

(1) NPS and Vetter shall designate its respective contact persons for the other party in respect of manufacturing and quality issues all of whom shall be listed and set forth in **APPENDIX 9** hereof.

IN WITNESS WHEREOF, this Quality Agreement has been executed by the duly authorized representatives of the parties hereto as of the Commencement Date.

NPS ALLELIX CORP.:	**VETTER PHARMA-FERTIGUNG GMBH & CO. KG:**
(signed) /s/ Anthony E. Robinson	(signed) /s/ Dr. Carsten Coors
Name: Anthony E. Robinson	Name: Dr. Carsten Coors
Title: Director, Quality and Development	Title: Qualified Person

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APPENDIX 0

HISTORY of APPENDICES

Date of Change	Appendix #	Change
n.a.	n.a.	n.a.

n.a. : not applicable because this is the first version

APPENDIX 1

PRODUCT

Description	Vetter Code	Comment
[*]	[*]	[*]
[*]	[*]	[*]

APPENDIX 2

NPS SUPPLIED MATERIALS

Description	NPS article	Vetter code	Comments
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]

APPENDIX 3

VETTER SUPPLIED MATERIALS

Description	Vetter code	Comments
[*]	[*]	-
[*]	[*]	-
[*]	[*]	-
[*]	[*]	-
[*]	[*]	-
[*]	[*]	-
[*]	[*]	-
[*]	[*]	-
[*]	[*]	-

APPENDIX 4

PRODUCT SPECIFICATIONS OF NPS

Test	Test Method	Release limits	Shelf life limits
Chamber 1 (lyophilized powder)			
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]

[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
Chamber 2 (diluent for reconstitution)			
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
Reconstituted PTH product			
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
Reconstituted PTH product (continued)			
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]

The following additional tests are performed for North American release.

Test	Test Method	Limits
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]

APPENDIX 5

AGREED MANUFACTURING MANUALS AND TESTING SPECIFICATIONS

Reference Codes: MM-AO5065, TS-AO5065
MM-AO5071, TS-AO5071

APPENDIX 6

DELINEATION OF RESPONSIBILITIES

[*]

APPENDIX 7

BATCH NUMBERING SYSTEM AND EXPIRY DATE

[*]

The expiry date will be determined on the basis of stability studies and following communication with the regulatory authorities.

APPENDIX 8

RECORDS REQUIRED BY NPS

Method of documentation:	**Index copies of following production protocols:**
Copy	Certificate of Conformity • Certificate of Analysis • Certificate WFI • Certificate Silicone Oil • Certificate of raw materials • Test Protocol Primary Packaging Material with certificate from supplier • Deviation Report • Investigation Report **Compounding of Buffer Solution** • Complete production protocols **Filtration of Buffer Solution** • Complete production protocols **Compounding of PTH Solution** • Complete production protocols **Filtration of PTH Solution** • Complete production protocols **Compounding of Solvent Cresol Solution** • Complete production protocols **Filtration of Solvent Cresol Solution** • Complete production protocols **Preparation of Components** • Complete production protocols **Filling Chamber I (PTH-Solution)**

- Complete production protocols

Filling Chamber II (Solvent)

- Complete production protocols

Visual Inspection / Packaging

- Complete production protocols

Note: Other documents may be added as necessary, when mutually agreed by both parties.

APPENDIX 9

List of contact persons to QUALITY AGREEMENT AGREEMENT between NPS and VETTER

	NPS	Telephone / Fax +1 905 362	E-Mail ...@NPS.com	Vetter	Telephone / Fax +49- (0) 751-3700-...	E-Mail ...@vetter-pharma.com
Batch Release	[*]	[*]	[*]	[*]	[*]	[*]
Batch Documentation	[*]	[*]	[*]	[*]	[*]	[*]
Quality Operations (Day to Day Business, incl. Deviations)	[*]	[*]	[*]	[*]	[*]	[*]
Manufacturing	[*]	[*]	[*]	[*]	[*]	[*]
Batch Allocation	[*]	[*]	[*]	[*]	[*]	[*]
Planning	[*]	[*]	[*]	[*]	[*]	[*]
Change Control	[*]	[*]	[*]	[*]	[*]	[*]
Product Complaints	[*]	[*]	[*]	[*]	[*]	[*]
Product Recalls	[*]	[*]	[*]	[*]	[*]	[*]
Customer Service Key Account	[*]	[*]	[*]	[*]	[*]	[*]

Vetter main contact persons:

Batch Documentation: **[*]**

Customer Service: **[*]**

CONSENT, ASSIGNMENT AND ASSUMPTION AGREEMENT

THIS CONSENT, ASSIGNMENT AND ASSUMPTION AGREEMENT (this "Consent"), dated as of January 1, 2008 (the "Effective Date"), is by and among NPS Pharmaceuticals, Inc. ("NPS"), a company duly organized and existing under the laws of the State of New Jersey, USA, with its principal place of business at 550 Hills Drive, Bedminster, New Jersey 07921 USA; NPS Allelix Corp. ("Allelix"), a wholly owned subsidiary of NPS, duly organized and existing under the laws of the Province of Ontario, Canada, with its

principal place of business at 199 Bay Street, Toronto, Ontario, Canada M5L 1A9; and Vetter Pharma-Fertigung GmbH & Co. KG ("Vetter"), a company duly organized and existing under the laws of Germany, with its principal place of business at Schützenstrasse 87, 88212 Ravensburg, Germany (NPS, Allelix and Vetter collectively, the "Parties"; and each singly, a "Party").

WHEREAS, Allelix and Vetter have entered into certain agreements related to the development and manufacture of ALX1-11 as formulated and filled in dual chamber cartridges conforming to certain specifications (the "Product") for use in humans, including that certain Development Agreement dated as of **[*]** (the "Development Agreement"), that certain Quality Agreement dated as of April 27, 2004 (the "Quality Agreement") and that certain Indemnity Agreement dated as of **[*]** (the "Indemnity Agreement"); and

WHEREAS, NPS has determined it to be advisable to assume from Allelix all responsibility for the development and manufacture of the Product held by Allelix, and accordingly Allelix wishes to assign to NPS all of the interests held by it in the Product, including the Quality Agreement and the other agreements listed on Schedule 1 attached hereto (the "Transfer Agreements"); and

WHEREAS, subject to the terms and conditions set forth herein below, Vetter hereby wishes to consent to such assignment and assumption,

NOW, THEREFORE, in consideration of the disclosures to be made to each other, of the premises and of the mutual covenants and agreements hereinafter set forth and subject to the terms and conditions of this Consent, the Parties, intending to be legally bound, hereby agree as follows with effect from the Effective Date:

1. Allelix does hereby transfer and assign to NPS, and NPS does hereby accept the assignment of, all of Allelix' s rights, and NPS hereby assumes all of Allelix' s obligations under the Transfer Agreements with effect from and after the Effective Date and agrees to observe and perform such obligations and to be bound by the respective terms and conditions of the Transfer Agreements as if NPS had at all times been a party to the Transfer Agreements and named therein in place of Allelix (the "Assignment"); provided, however, and in conformance with paragraph 2 hereof, that Allelix shall remain responsible and liable under the Transfer Agreements to the extent of all its accrued obligations regarding, among other things, the confidentiality and non-use other than for the Purpose of Vetter' s Confidential Information (as both such terms are defined under the respective Transfer Agreements).

2. Vetter does hereby consent to the Assignment and does hereby acknowledge and agree to release and discharge Allelix from all obligations, except to the extent of any obligations that Allelix may expressly further accrue as respectively set forth in any of the Transfer Agreements (including without limitation as an affiliate of NPS which may receive Vetter' s Confidential Information thereunder), that Allelix is obligated to maintain the confidentiality of Vetter' s Confidential Information, which accrue on or after the Effective Date under the Transfer Agreements and shall accept the liability of NPS under the Transfer Agreements in respect of such obligations in place of the liability of Allelix. All of Allelix' s rights and obligations which have accrued under the Transfer Agreements prior to the Effective Date shall remain with Allelix and Allelix shall continue to be liable to Vetter in respect of such obligations.

3. NPS acknowledges and agrees that pursuant to each of the agreements listed in Appendix 2 attached hereto (the "Non-Transferred Agreements"), it is and shall for the full term of Allelix' s respective obligations under each of the Non-Transferred Agreements be, jointly and severally responsible and liable to Vetter for all such Allelix obligations.

4. NPS shall fully and promptly compensate Vetter for all of Vetter' s reasonably incurred costs and efforts in connection with the preparation and implementation of the Consent, including without limitation technology transfer, substitutions and integration of personnel on all levels, regulatory filings and additional audits and all other such costs and efforts which directly or indirectly result from the transfer from Allelix to NPS of duties and obligations with respect to the Development Work and

other performance (as such term is defined in the Quality Agreement) pursuant to or under the Assignment, it being understood and agreed that the purpose of the foregoing is for Vetter to achieve the same service and development level with NPS as exists or would have existed with Allelix had there been no Assignment.

5. Each Party represents and warrants that in entering into this Consent and fulfilling its obligations hereunder and under Transfer Agreements, it will not violate any of the terms of any other agreement to which it is a party.

6. If any provision of this Consent shall be found by a court to be void, invalid or unenforceable, the same shall either be reformed to comply with applicable law or stricken if not so conformable, so as not to affect the validity or enforceability of this Consent or the basis of the agreement of the Parties.

7. This Consent may be executed by facsimile and may be executed in one or more counterparts, each of which so executed shall constitute an original, and all of which together shall constitute one and the same consent.

8. This Consent shall be governed by, construed and interpreted in accordance with the laws of **[*]**, with the competent courts of **[*]** having exclusive jurisdiction.

(remainder of page intentionally left blank)

IN WITNESS WHEREOF, each of the Parties have caused this Consent to be executed by their respective authorized representatives on the dates and at the places set forth below.

NPS Allelix Corp.:

Signed: /s/ Andrew Rackear

Name: Andrew Rackear

Title: General Counsel & Secretary

Dated: 12/9/08
(Month/Day/Year)

Place: Bedminster, N.J.

NPS Pharmaceuticals, Inc.:

Signed: /s/ Doug Dobak

Name: Doug Dobak

Title: Acting Head, Reg. Affairs, Drug Safety and Quality Assurance

Dated: 12/9/08
(Month/Day/Year)

Place: Bedminster, N.J.

Vetter Pharma-Fertigung GmbH & Co. KG

Signed: /s/ Oskar Gold

Name: Oskar Gold

Title: Vice President, Key Account Management

Signed: /s/ Christine Furst

Name: Christine Furst

Title: Key Account Manager

Dated:	12/10/2008 (Month/Day/Year)	Dated:	12/10/2008 (Month/Day/Year)
Place:	Ravensburg, Germany	Place:	Ravensburg, Germany

APPENDIX 1

1. Three-Way Confidential Disclosure Agreement among NPS Allelix Corp., Vetter Pharma-Fertigung GmbH & Co. KG and ASTS Inc., dated as of March 13, 2003 [Paragraph 9 provides that the agreement may be assigned to an Affiliate (including NPS Pharmaceuticals, Inc.) without a prior written consent requirement]

2. Three-Way Confidential Disclosure Agreement among NPS Allelix Corp., Vetter Pharma-Fertigung GmbH & Co. KG and HTD Biosystems Inc., dated as of April 8, 2003 [contains identical provisions in Paragraph 9 as noted in (1)]

3. Three-Way Confidential Disclosure Agreement among NPS Allelix Corp., Vetter Pharma-Fertigung GmbH & Co. KG and Pharmeng Technology Inc., dated as of November 12, 2003 [contains identical provisions in Paragraph 9 as noted in (1)]

4. Three-Way Confidential Disclosure Agreement among NPS Allelix Corp., Vetter Pharma-Fertigung GmbH & Co. KG and Chestnut Solutions Inc., dated as of November 12, 2003 [contains identical provisions in Paragraph 9 as noted in (1)]

5. Three-Way Confidential Disclosure Agreement among NPS Allelix Corp., Vetter Pharma-Fertigung GmbH & Co. KG and Disetronic Injection Systems AG, dated as of November 12, 2003 [contains identical provisions in Paragraph 9 as noted in (1)]

6. Three-Way Confidentiality Agreement among NPS Allelix Corp.,Vetter Pharma-Fertigung GmbH & Co. KG and Northstar Regulatory Services, Inc., dated as of December, 2003 [contains identical provisions in Paragraph 9 as noted in (1) above]

7. Three-Way Confidentiality Agreement among NPS Allelix Corp.,Vetter Pharma-Fertigung GmbH & Co. KG and P/L Biomedical, dated as of December, 2003 [contains identical provisions in Paragraph 9 as noted in (1) above]

8. Three-Way Confidentiality Agreement among NPS Allelix Corp.,Vetter Pharma-Fertigung GmbH & Co. KG and Bioreliance Limited, dated as of December 1, 2003 [contains identical provisions in Paragraph 9 as noted in (1) above]

9. Quality Agreement between NPS Allelix Corp. and Vetter Pharma-Fertigung GmbH & Co. KG, dated as of April 27, 2004

10. Mutual Confidential Disclosure Agreement between NPS Allelix Corp. and Vetter Pharma-Fertigung GmbH & Co. KG, dated as of October 11, 2004

APPENDIX 2

1. Three-Way Confidentiality Agreement among NPS Allelix Corp., Vetter Pharma-Fertigung GmbH & Co. KG and David Begg Associates Ltd., dated as of July 26, 2005 [Pursuant to paragraph 10, an assignment would require written consent of all three parties. Paragraph 1(c), however, provides that "[e]ach Party, together with its respective Affiliates, shall be jointly and severally responsible for compliance by such respective Affiliates with the confidentiality and restrictive use obligations as so assumed hereunder and jointly and severally liable for any breach thereof]

2. Three-Way Confidentiality Agreement among NPS Allelix Corp., Vetter Pharma-Fertigung GmbH & Co. KG and Nycomed Danmark ApS, dated as of July 26, 2005 [contains same provision in Paragraph 1(c) as noted in (1); NPS Pharmaceuticals, Inc. is a party, along with Vetter Pharma-Fertigung GmbH & Co. KG and Nycomed Danmark ApS, to an identical Three-Way Confidentiality Agreement dated as of May 14, 2007]

3. Three-Way Confidentiality Agreement among NPS Allelix Corp., Vetter Pharma-Fertigung GmbH & Co. KG and Lachman Consultant Services Inc., dated as of January 2, 2007 [contains same provision in Paragraph 1(c) as noted in (1)]

4. Three-Way Confidentiality Agreement among NPS Allelix Corp., Vetter Pharma-Fertigung GmbH & Co. KG and SGS Canada, dated as of April 23, 2007 [contains same provision in Paragraph 1(c) as noted in (1)]

Execution Draft

AMENDMENT AND ADOPTION AGREEMENT

This AMENDMENT AND ADOPTION AGREEMENT (this "Agreement") is made and entered into as of January 1, 2008 (the "Effective Date"), by and between NPS Pharmaceuticals, Inc., a company duly organized and existing under the laws of the State of New Jersey, with its principal place of business at 550 Hills Drive, Bedminster, New Jersey 07921, USA ("NPS") and Vetter Pharma-Fertigung GmbH & Co. KG, a company duly organized and existing under the laws of Germany, with its principal place of business at Schützenstrasse 87, 88212 Ravensburg, Germany ("Vetter") (NPS and Vetter together hereinafter the "Parties" and each singly a "Party").

WITNESSETH:

WHEREAS, NPS' s wholly owned subsidiary, NPS Allelix Corp. ("Allelix") and Vetter have entered into certain agreements related to the development and manufacture of ALX1-11 as formulated and filled in dual chamber cartridges conforming to certain specifications (the "Product") for use in humans, including that certain Development Agreement dated as of January 1, 2000 (the "DEVELOPMENT AGREEMENT"), that certain Quality Agreement dated as of April 27, 2004 (the "QUALITY AGREEMENT") and that certain Indemnity Agreement dated as of June 19, 2000 (the "INDEMNITY AGREEMENT"); and

WHEREAS, pursuant to the Assignment, Assumption and Consent Agreement dated as of January 1, 2008 (the "Assignment"), among other things as further set forth therein, Allelix transferred and assigned to NPS all of Allelix' s rights and the performance of Allelix' s obligations under the QUALITY AGREEMENT with effect from and after the Effective Date and Vetter consented to the same; and

WHEREAS, NPS and Vetter are currently engaged in the negotiation of a supply agreement (the "COMMERCIAL MANUFACTURING AGREEMENT"), to which the QUALITY AGREEMENT shall be attached and expressly incorporated, in which the parties thereto shall comprehensively set forth the terms and conditions regarding the production of the Product for human use by Vetter for NPS ("Manufacture" or "Manufacturing" of the Product; as such terms are further set forth in the QUALITY AGREEMENT) for sale within the territory defined in the COMMERCIAL MANUFACTURING AGREEMENT; and

WHEREAS, NPS and Vetter now wish to amend the QUALITY AGREEMENT in order to include the Manufacture of the Product by Vetter on behalf of NPS for clinical trials to be held by or on behalf of NPS, in other pharmaceutical strengths, all as set forth in the revised Appendices to the QUALITY AGREEMEENT; and

WHEREAS, NPS and Vetter intend that the Manufacture of such clinical trial batches shall be governed by the terms and conditions set forth in the DEVELOPMENT AGREEMENT (despite expiration of the DEVELOPMENT AGREEMENT) and the INDEMNITY AGREEMENT until such time as NPS Pharmaceuticals, Inc. and Vetter have completed the negotiation of, and each of them has duly executed, the COMMERCIAL MANUFACTURING AGREEMENT, which shall include terms

substantially similar to those in the DEVELOPMENT AGREEMENT together with the INDEMNITY AGREEMENT, along with certain mutually agreed modifications to be based in part on the commercial agreement entered into by Vetter for manufacture of Product for the European Union.

NOW, THEREFORE, pursuant to Article 22 of the QUALITY AGREEMENT, the Parties agree to amend the terms of the QUALITY AGREEMENT and hereby effect such other agreed upon actions and intentions as in the following set forth:

1. Article 2 of the QUALITY AGREEMENT ("Principal Responsibility") is hereby supplemented by the Parties to include the following new Article 2(4):

   (4) NPS shall inform Vetter, upon delivery of its purchase order, whether Products are considered for human use (e.g. in clinical trials). In addition hereto, NPS shall submit to Vetter a filled out "Human Use Authorisation Form" of Vetter prior to any Manufacturing of a Batch of Products for human use.

2. Article 20 of the QUALITY AGREEMENT ("Stability Studies") is hereby supplemented by the Parties to include the following new Article 20(2):

   (2) Vetter agrees, in accordance with its customary procedures and **[*]**, to send samples of the Product to an external laboratory designated and instructed by NPS (currently SGS Canada Inc., 310 Brunel Road, Mississauga, Ontario L4Z 2C2 Canada) for stability testing in accordance with Appendix 5a hereof. NPS agrees not to appoint another laboratory or change the location of the laboratory used for Product stability testing without reasonable prior written notice to Vetter.

3. As of the Effective Date, the following Appendices hereto attached shall in their entirety replace the existing Appendices of the QUALITY AGREEMENT:

   Appendix 0: History of Appendices
   (to replace existing Appendix 0)

   Appendix 1: Product
   (to replace existing Appendix 1)

   Appendix 2: NPS supplied Materials
   (to replace existing Appendix 2)

   Appendix 3: Vetter supplied Materials
   (to replace existing Appendix 3)

   Appendix 4: Product specifications of Nycomed
   (to replace existing Appendix 4)

Appendix 5: Manufacturing Manual and Testing Specifications for Product
(to replace existing Appendix 5)

Appendix 6: Delineation of Responsibilities
(to replace existing Appendix 6)

Appendix 7: Batch numbering system
(to replace existing Appendix 7)

Appendix 8: Records required by NPS
(to replace existing Appendix 8)

Appendix 9: Contact persons
(to replace existing Appendix 9)

4. Notwithstanding anything to the contrary contained in Section 10.1 of the DEVELOPMENT AGREEMENT, NPS and Vetter hereby agree that the respective provisions of the DEVELOPMENT AGREEMENT and of the INDEMNITY AGREEMENT shall be applicable to the Manufacture of the Product for clinical trials in accordance with the QUALITY AGREEMENT as well as to any and all use of the Product by NPS contemplated hereunder, and Vetter and NPS each hereby agree to adopt the provisions and assume all of the respective obligations set forth in the DEVELOPMENT AGREEMENT and the INDEMNITY AGREEMENT as are designated to Vetter and Allelix, as if such agreements were in effect upon the Effective Date and NPS was a party to the DEVELOPMENT AGREEMENT and the INDEMNITY AGREEMENT and named in both such agreements in place of Allelix, until and only until such time as NPS and Vetter enter into the COMMERCIAL MANUFACTURING AGREEMENT; provided, however, Section 7.1 of the DEVELOPMENT AGREEMENT shall have that certain Mutual Confidential Disclosure Agreement between Allelix and Vetter, dated as of October 11, 2004 (and assigned to NPS pursuant to the Assignment) substitute for the November, 1998 Confidentiality Agreement as set forth therein.

5. In the event of any conflict between the respective provisions of the QUALITY AGREEMENT, the DEVELOPMENT AGREEMENT and the INDEMNITY AGREEMENT, the provisions of the QUALITY AGREEMENT shall prevail over conflicting terms in the DEVELOPMENT AGREEMENT and the INDEMNITY AGREEMENT with respect to quality-technical issues only, and the provisions of the INDEMNITY AGREEMENT shall prevail over conflicting terms in the DEVELOPMENT AGREEMENT.

6. This Agreement shall be construed in accordance with and governed by the laws of **[*]** without giving effect to any conflict-of-laws provisions, and the competent courts of **[*]**, shall have exclusive jurisdiction. The Parties hereby agree that the rules and procedures for arbitration as are set forth in Section 12.10 of the DEVELOPMENT AGREEMENT shall not apply to the Manufacturing of the Product for human clinical trials.

7. Except to the extent otherwise expressly provided herein, all other terms and conditions of the QUALITY AGREEMENT shall remain in full force and effect.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives on the days and year below written.

Vetter Pharma-Fertigung GmbH & Co. KG

(signed)	/s/ Peter Soelkner	(signed)	/s/ Carsten Coors
Name:	Peter Soelkner	Name:	Dr. Carsten Coors
Title:	Managing Director	Title:	Qualified Person
(dated)	12/10/2008 (Month/Day/Year)	(dated)	12/10/2008 (Month/Day/Year)
Place:	Ravensburg, Germany	Place:	Ravensburg, Germany

NPS Pharmaceuticals, Inc.

(signed)	/s/Andrew Rackear
Name:	Andrew Rackear
Title:	Senior Vice President, General Counsel & Secretary
(dated)	12/9/2008 (Month/Day/Year)
Place:	Bedminster, N.J.

APPENDIX 0

HISTORY of APPENDIXES

App.1: update of Vetter codes
Inclusion of three additional Products + Placebo Product

App.2: update of Vetter codes

App 3: update of Vetter codes

App.4: update of NPS specifications

App.5: inclusion of three new Products + placebo Product

App.6: clarification for release and storage of excipient retain samples

App.7: update of batch numbering system

App.8: no update

App.9: update of personnel in contact list

APPENDIX 1

PRODUCT

Description(1)	Vetter Code	Comment
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]

[*]

APPENDIX 2

NPS SUPPLIED MATERIALS

Description	NPS article	Vetter code	Comments
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]

APPENDIX 3

VETTER SUPPLIED MATERIALS

Description	Vetter Code	Comments
[*]	[*]	-
[*]	[*]	-
[*]	[*]	-

[*]	[*]	-
[*]	[*]	-
[*]	[*]	-
[*]	[*]	-
[*]	[*]	-
[*]	[*]	-

APPENDIX 4

PRODUCT SPECIFICATIONS OF NPS

100µg Dose [1.4 mg/mL dual-chamber cartridge for s.c. injection], Reference Vetter Description: V-DK-O PTH 1,34 mg/ml 1,2 ml alu

Test	Test Method	Limit/Specification
Chamber 1 (lyophilized powder)		
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
Chamber 2 (diluent for reconstitution)		
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
Reconstituted PTH product		
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]

75µg Dose [1.0 mg/mL dual-chamber cartridge for s.c. injection], Reference Vetter Description: V-DK-O PTH 1,0 mg/ml 1,2 ml BI-Bulk alu

Test	Test Method	Limit/Specification
Chamber 1 (lyophilized powder)		
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
Chamber 2 (diluent for reconstitution)		
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
Reconstituted PTH product		
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]

50µg Dose [0.70 mg/mL dual-chamber cartridge for s.c. injection], Reference Vetter Description: V-DK-O PTH 0,67 mg/ml 1,2 ml BI-Bulk alu

Test	Test Method	Limit/Specification
Chamber 1 (lyophilized powder)		
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]

[*]	[*]	[*]
Chamber 2 (diluent for reconstitution)		
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
Reconstituted PTH product		
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]

25µg Dose [0.35 mg/mL dual-chamber cartridge for s.c. injection], Reference Vetter Description: V-DK-O PTH 0,34 mg/ml 1,2 ml BI-Bulk alu

Test	Test Method	Limit/Specification
Chamber 1 (lyophilized powder)		
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
Chamber 2 (diluent for reconstitution)		
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
Reconstituted PTH product		
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]

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

APPENDIX 5

AGREED MANUFACTURING MANUALS AND TESTING SPECIFICATIONS

The following documents cover the 1,34mg / ml formulation including Placebo

- MM-AO5065, TS-AO5065 covering product AO7031 (SAP-no. 55000009)
- MM-AO5071, TS-AO5071 covering product AO7032 (SAP-no. 55000010)
- MM-AO5079, TS-AO5079 covering products AO7034 (SAP-no. 55000012) and AO7035 (SAP-no. 55000013)

For the following Products Vetter code: **[*]**

APPENDIX 6

DELINEATION OF RESPONSIBILITIES

[*]

APPENDIX 7

BATCH NUMBERING SYSTEM AND EXPIRY DATE

[*]

Customer System
6 characters

X	product code*
XX	last digits of the year

XXX continuous counting, every year starting with 001

*Product code
P → PTH BI Bulk
[*]
separate counting for P-, A-, F-, L- and D products!
[*]
*

[*]

Filling **chamber 1**

[*]

Customer system
[*]

XXXXXX compounding batch PTH / placebo PTH
C code filling chamber I

1 1. disturbance / interruption
2 2. disturbance / interruption
3 3. disturbance / interruption

[*] **chamber 2**
[*]
XXXXXX compounding batch PTH / Placebo PTH
D code filling chamber II
1 1. disturbance / interruption
2 2. disturbance / interruption
3 3. disturbance / interruption

Visual Inspection:
[*]

Exception:
For clinical studies the batchnumber will be switched into another batchnumber In accordance with the active substance concentration

[*]

Visual Inspection:
same batch-no. used as for filling chamber II

Packaging **No packaging at the moment**

APPENDIX 8

RECORDS REQUIRED BY NPS

Method of documentation:	Index copies of following production protocols:
	• Certificate of Conformity • Certificate of Analysis • Certificate WFI • Certificate Silicone Oil • Certificate of raw materials • Test Protocol Primary Packaging Material with certificate from supplier • Deviation Report • Investigation Report **Compounding of Buffer Solution** • Complete production protocols **Filtration of Buffer Solution** • Complete production protocols **Compounding of PTH Solution** • Complete production protocols **Filtration of PTH Solution** • Complete production protocols **Compounding of Solvent Cresol Solution** • Complete production protocols **Filtration of Solvent Cresol Solution** • Complete production protocols **Preparation of Components** • Complete production protocols **Filling Chamber I (PTH-Solution)** • Complete production protocols **Filling Chamber II (Solvent)** • Complete production protocols **Visual Inspection / Packaging** • Complete production protocols

Batch documentation may be reduced after mutual written agreement between both parties

APPENDIX 9

CONTACT PERSONS

	NPS	Phone / Fax	E-Mail ...@NPS.com	Vetter	Phone / Fax +49-(0) 751-3700 ...	E-Mail ...@vetter-pharma.com
Batch Release	[*]	[*]	[*]	[*]	[*]	[*]
Batch Documentation	[*]	[*]	[*]	[*]	[*]	[*]
Quality Operations (Day to Day Business, incl. Deviations)	[*]	[*]	[*]	[*]	[*]	[*]
Manufacturing	[*]	[*]	[*]	[*]	[*]	[*]
Batch Allocation	[*]	[*]	[*]	[*]	[*]	[*]
Planning	[*]	[*]	[*]	[*]	[*]	[*]
Change Control	[*]	[*]	[*]	[*]	[*]	[*]
Product Complaints	[*]	[*]	[*]	[*]	[*]	[*]
Product Recally	[*]	[*]	[*]	[*]	[*]	[*]
Customer Service Key Account	[*]	[*]	[*]	[*]	[*]	[*]

Vetter main contact persons:

Batch Documentation: [*]

Customer Service: **[*]**

APPENDIX 12: ROLLING FORECASTS AND PURCHASE ORDERS

[*]

Exhibit 31.1

RULE 13a-14(a)/15d-14(a) CERTIFICATION

I, Francois Nader, President and Chief Executive Officer, certify that:

1. I have reviewed this Amendment No. 1 to Quarterly Report on Form 10-Q/A of NPS Pharmaceuticals, Inc.; and

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: January 15, 2013

/s/ FRANCOIS NADER

Francois Nader
President and Chief Executive Officer

Exhibit 31.2

RULE 13a-14(a)/15d-14(a) CERTIFICATION

I, Luke M. Beshar, Senior Vice President and Chief Financial Officer, certify that:

1. I have reviewed this Amendment No. 1 to Quarterly Report on Form 10-Q/A of NPS Pharmaceuticals, Inc.; and

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: January 15, 2013

/s/ LUKE M. BESHAR

Luke M. Beshar
Executive Vice President and Chief Financial Officer