

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

**CONFIDENTIAL**

**TABLE OF CONTENTS**

ARTICLE 1:           DEFINITIONS .....

ARTICLE 2:           USE AND DISCLOSURE OF SPECIFICATIONS AND  
OTHER INFORMATION .....

ARTICLE 3:           PRODUCTION .....

ARTICLE 4:           MATERIALS .....

ARTICLE 5:           LOSS OF PRODUCT .....

ARTICLE 6:           INSPECTION AND TESTING OF THE PRODUCT .....

ARTICLE 7:           PACKAGING AND DOCUMENTATION.....

ARTICLE 8:           ROLLING FORECASTS; PURCHASE ORDERS; DELIVERY .....

ARTICLE 9:           PRICE .....

ARTICLE 10:           PAYMENT .....

ARTICLE 11:           REPRESENTATIONS AND AGREEMENTS .....

ARTICLE 12:           GOVERNMENT APPROVAL.....

ARTICLE 13:           TRADEMARK.....

ARTICLE 14:           INFRINGEMENT .....

ARTICLE 15:           INDEMNIFICATION AND RECALL OF PRODUCT .....

**CONFIDENTIAL**

ARTICLE 16:	TERM AND TERMINATION.....
ARTICLE 17:	FORCE MAJEURE.....
ARTICLE 18:	CONFIDENTIALITY.....
ARTICLE 19:	UNITED NATIONS CONVENTION.....
ARTICLE 20:	LIMITATION.....
ARTICLE 21:	TIMELY PERFORMANCE.....
ARTICLE 22:	ENTIRE AGREEMENT.....
ARTICLE 23:	CONFLICT.....
ARTICLE 24:	AMENDMENTS.....
ARTICLE 25:	ASSIGNMENT.....
ARTICLE 26:	NOTICES.....
ARTICLE 27:	HEADINGS.....
ARTICLE 28:	ENGLISH.....
ARTICLE 29:	GOVERNING LAW.....
ARTICLE 30:	CHANGE CONTROL.....

**CONFIDENTIAL**

## **APPENDICES**

**APPENDIX 1: PRODUCT**

**APPENDIX 2: YIELD**

**APPENDIX 3: TERRITORY**

**APPENDIX 4: INTENTIONALLY OMITTED**

**APPENDIX 5: INTENTIONALLY OMITTED**

**APPENDIX 6: INTENTIONALLY OMMITTED**

**APPENDIX 7: PRICES**

**APPENDIX 8A: TRADEMARKS OF VPI AND AFFILIATES**

**APPENDIX 8B: TRADEMARKS OF NPS**

**APPENDIX 9: AGREED VALUE OF NPS' RAW MATERIALS**

**APPENDIX 10: CONFIDENTIALITY AGREEMENT**

**APPENDIX 11: QUALITY AGREEMENT**

**APPENDIX 12: INTENTIONALLY OMITTED**

**APPENDIX 13: ROLLING FORECASTS AND PURCHASE ORDERS**

**CONFIDENTIAL**

This Commercial Manufacturing Agreement ("Agreement"), made and entered into as of this 21<sup>st</sup> 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.

**CONFIDENTIAL**

- (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).
- (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 [\*].

**CONFIDENTIAL**

- (16) "EMA" 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.
- (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).

**CONFIDENTIAL**

- (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 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.

**CONFIDENTIAL**

- (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).
- (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

**CONFIDENTIAL**

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 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

**CONFIDENTIAL**

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 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

**CONFIDENTIAL**

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.
- (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

**CONFIDENTIAL**

- (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 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

**CONFIDENTIAL**

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.
- (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

**CONFIDENTIAL**

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 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,

**CONFIDENTIAL**

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.

**CONFIDENTIAL**

- (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:

**CONFIDENTIAL**

- (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.

**CONFIDENTIAL**

- (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.

**CONFIDENTIAL**

- (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 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

**CONFIDENTIAL**

(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).

- (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

**CONFIDENTIAL**

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.

- (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

**CONFIDENTIAL**

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 VPI 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 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

**CONFIDENTIAL**

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 [\*], commencing on the Commencement Date. Thereafter, this Agreement shall automatically renew for terms of [\*].
- (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

**CONFIDENTIAL**

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 [\*].
- (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

**CONFIDENTIAL**

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.

**CONFIDENTIAL**

## 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.

**CONFIDENTIAL**

## 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 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

**CONFIDENTIAL**

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

**CONFIDENTIAL**

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.

\* \* \* \* \*

**CONFIDENTIAL**

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.:

VETTER PHARMA  
INTERNATIONAL GmbH  
& Co. KG

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

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

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

**CONFIDENTIAL**

**APPENDIX 1: PRODUCT**

**INTENTIONALLY LEFT BLANK**

**CONFIDENTIAL**

**APPENDIX 2:**

**YIELD**

[\*]

**CONFIDENTIAL**

## APPENDIX 3: TERRITORY

[\*]

**CONFIDENTIAL**

**APPENDIX 4: INTENTIONALLY OMITTED**

**CONFIDENTIAL**

**APPENDIX 5: INTENTIONALLY OMITTED**

**CONFIDENTIAL**

**APPENDIX 6: INTENTIONALLY OMITTED**

**CONFIDENTIAL**

## APPENDIX 7: PRICES

[\*]

**CONFIDENTIAL**

**APPENDIX 8A: TRADEMARKS OF VPI and AFFILIATES**

**NONE LISTED**

**APPENDIX 8B: \_TRADEMARKS OF NPS**

**NPS**

**NPS**

**PREOS**

**CONFIDENTIAL**

**APPENDIX 9: AGREED VALUE OF NPS' RAW MATERIALS**

[\*]

**CONFIDENTIAL**

**APPENDIX 10: CONFIDENTIALITY AGREEMENT**

**CONFIDENTIAL**

## APPENDIX 11 QUALITY AGREEMENT

**CONFIDENTIAL**

## APPENDIX 12: ROLLING FORECASTS AND PURCHASE ORDERS

[\*]

**CONFIDENTIAL**