

EXHIBIT 10.7

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.

**MANUFACTURING AGREEMENT
(PTH and TEDUGLUTIDE)**

by and between

NPS PHARMACEUTICALS, INC.

and

SYNCO BIO PARTNERS B.V.

THIS MANUFACTURING AGREEMENT (the "Agreement") is made and entered into with an effective date of August 1, 2009 ("Effective Date"), by and between:

NPS Pharmaceuticals, Inc. with registered office at 550 Hills Drive, 3rd Floor, Bedminster, NJ, 07921 USA, (hereinafter: "NPS").

and

SynCo Bio Partners B.V., with its registered offices at Paasheuvelweg 30, 1105 BJ Amsterdam, The Netherlands, (hereinafter: "SYNCO").

Background

- NPS has developed PTH (as defined below) the proprietary recombinant human parathyroid hormone for the treatment of Hypoparathyroidism, and is currently in the process of completing its phase-III clinical studies in the U.S., Europe and Canada;
- NPS has developed TEDUGLUTIDE (as defined below) the proprietary recombinant glycine₂-human glucagon-like peptide for the treatment of short bowel syndrome, and is currently in the process of completing its phase-III clinical studies in the U.S., Europe and Canada;
- NPS is looking for a service provider to support pre-commercial launch production and commercial production of PTH and TEDUGLUTIDE.
- SYNCO operates as a biopharmaceutical service provider and has the experience with the manufacture processes of both Products in the past and SYNCO desires to manufacture the Products for NPS in accordance with NPS' requirements in order to facilitate NPS' commercial launch of each Product subsequent to NDA approval in the U.S.;
- NPS desires to have SYNCO conduct such manufacturing activities to facilitate the re-introduction of PTH and TEDUGLUTIDE in the Facility and the pre-launch and commercial manufacturing activities;
- The Parties have agreed that SYNCO will be the primary commercial manufacturer of PTH, subject to the provisions set forth hereinafter;

NOW, THEREFORE, in consideration of the premises, the mutual covenants, terms and conditions hereinafter set forth, THE PARTIES AGREE AS FOLLOWS:

ARTICLE 1 - DEFINITIONS

For the purpose of this Agreement the following terms shall be defined as follows:

- 1.1 "Affiliate" means: any person or legal entity which controls, or is controlled by or is under common control with either of the Parties. For the purpose of this definition, a person or legal entity shall be deemed to "control" another legal entity if it owns,

directly or indirectly, in excess of 50% of the outstanding voting securities or capital stock of such legal entity or any other comparable equity or ownership interest with respect to a legal entity.

- 1.2 "Batch" means: PTH or TEDUGLUTIDE, as applicable, from SYNCO's production thereof in a [*] fermenter which is intended to be GMP Grade as set out in the Specifications and the Batch Production Records.
- 1.3 "Batch Production Records" (BPRs) means: completed written records providing the history of a Batch required to be kept by the European Guide to Good Manufacturing Practices for Medicinal Products, the U.S. Code of Federal Regulations, and ICH Guideline Q7A.
- 1.4 "Campaign" means the manufacture without interruption (for cleaning or other purposes) of a number of Batches of PTH or TEDUGLUTIDE ordered by NPS pursuant to **Article 5** in a given calendar year.
- 1.5 "Conformance Lots" means the consecutive Batches of each of PTH and TEDUGLUTIDE, to validate the manufacturing process of such Products before market launch.
- 1.6 "Confidential Information" means any information and data disclosed by Parties in writing and designated confidential or, if disclosed orally, confirmed in writing and designated confidential within thirty (30) days after such disclosure.
- 1.7 "Engineering Run" means: the process performed by SYNCO concerning the reintroduction of the manufacturing process of PTH and TEDUGLUTIDE in SYNCO's Facility, which product will be tested to confirm the Reintroduction Objectives can be met.
- 1.8 "Excess Batch" means each Batch manufactured by SYNCO in excess of a Campaign of PTH or TEDUGLUTIDE in a given year.
- 1.9 "Facility" means SYNCO's manufacturing facility which will be used to manufacture, package and Product and all required documentation as provided for in this Agreement and is located at Paasheuvelweg 30, 1105 BJ Amsterdam, The Netherlands, licensed for manufacturing under licence number 108716 F.
- 1.10 "FDA" means the United States Food and Drug Administration or any successor agency having similar jurisdiction.
- 1.11 "GMP" means the current European Guide for Good Manufacturing Practices for Medicinal Products and, as of the date of receipt by SYNCO of a license to operate as commercial manufacturer issued by the FDA, the current Good Manufacturing Practices as described in the U.S. Code of Federal Regulations.
- 1.12 "GMP Grade" means Product that has been produced in accordance with the Regulatory Standards and the Specifications in all material respect.
- 1.13 "Material" means working cell banks and analytical standards as described in **Appendix B**. **Appendix B** will be updated if SYNCO requires further Material from NPS pursuant to **Article 3.1(i)**.
- 1.14 "NDA" means a New Drug Application as defined by the FDA for the marketing of the Product.

- 1.15 "NDA Approval" means approval of a New Drug Application by FDA for the marketing of PTH and/or TEDUGLUTIDE as the context may require.
- 1.16 "Parties" and "Party" means SYNCO and NPS and SYNCO or NPS, respectively, as the context may require.
- 1.17 "Pre-Approval Inspection" means inspection of the Facility by FDA or corresponding European representatives in conjunction with the filing of an NDA or corresponding European application which may include among other things: verifying the accuracy and completeness of the manufacturing-related information submitted in the NDA or corresponding European application; evaluating manufacturing controls upon which information provided in the NDA or corresponding European application is based; evaluating GMP compliance; and collecting samples of GMP Grade Product.
- 1.18 "Product" means PTH or TEDUGLUTIDE, as the context requires, and "Products" means PTH and TEDUGLUTIDE.
- 1.19 "Regulatory Standards" means (i) the Facility license requirements, (ii) GMP regulations applicable to the manufacturing, storage and handling of Product at the Facility and (iii) any standards of any governmental authority that apply to the Facility or SYNCO's manufacturing, storage and handling of Product.
- 1.20 "PTH" means parathyroid hormone, which is a single-chain polypeptide containing 84 amino acids [*]. The amino acid sequence of PTH is identical to that of native parathyroid hormone. PTH molecular formula is [*], in the form of a drug substance.
- 1.21 "Reintroduction Objectives" means the objectives as specified in **Appendix D**.
- 1.22 "Specifications" means all specifications as described in **Appendix A**.
- 1.23 "TEDUGLUTIDE" means a recombinant glycine₂-human glucagon-like peptide- [*]. TEDUGLUTIDE's molecular Formula is [*], in the form of a drug substance.
- 1.24 "Yield" means grams of Product drug substance produced per Batch as indicated in the Batch Production Records approved by SYNCO'S Quality Assurance pursuant to **Article 6.5**.

ARTICLE 2 – SCOPE OF THE AGREEMENT

- 2.1 The scope of this Agreement is the reintroduction of the PTH process and the TEDUGLUTIDE process at SYNCO for the manufacture of bulk quantities of Product to support pre-commercial launch productions and commercial production. Parties acknowledge that SYNCO is presently [*] as a commercial manufacturer; and that NPS has [*] for the Products issued by the FDA. In view of this scope, SYNCO will be responsible for obtaining and complying with those requirements and licences as set forth in **Article 5**. In particular, SYNCO will file and maintain Drug Master Files as required by the FDA and, upon request by NPS, its European Union counterpart, provide NPS with relevant information and data to complete Section 7 of an NDA (including the chemistry, formulation, manufacturing and quality control information) and pass a Pre-Approval Inspection concerning its Facility as required

by the FDA. It is understood that each of PTH and TEDUGLUTIDE is classified as a 'drug' by the FDA and that SYNCO is considered a manufacturer of bulk active pharmaceutical ingredient under regulations issued by the FDA.

- 2.2 Parties agree that the manufacture and delivery of Products under this Agreement will be performed by SYNCO in two (2) distinct phases:

Phase I: Reintroduction of the PTH manufacturing process and the TEDUGLUTIDE manufacturing process [*].

Phase II: Commercial manufacture of Products pre and post NDA Approval.

Phase I and Phase II will be conducted in accordance with the timelines and deliverables set out in **Appendix D**.

- 2.3 The following Appendices are attached hereto and are incorporated in and are deemed to be an integral part of this Agreement.

| | | |
|------------|---|---|
| Appendix A | – | SYNCO Release Specifications |
| Appendix B | – | Material |
| Appendix C | – | Material and Equipment Purchased by SYNCO |
| Appendix D | – | Timelines and Deliverables |
| Appendix E | – | Financial Terms |
| Appendix F | – | Forecasting Schedule |
| Appendix G | – | NPS Release Specifications |

ARTICLE 3 – OBLIGATIONS OF THE PARTIES

- 3.1 Obligations of NPS. NPS shall at NPS' cost:

- (i) Have approved as from the Effective Date of the Agreement the table in Appendix A which lists the Specifications for each Batch of Product. If NPS desires a change to the Specifications as set out in **Appendix A**, it is NPS' obligation to provide the change in writing to SYNCO and to negotiate in good faith with SYNCO for inclusion of this change into **Appendix A**, provided that SYNCO will, subject to agreement by the Parties on the financial impact of such change, accept any change that is not prohibited under applicable law. Each agreed change including the financial impact thereof shall be put into writing. The Parties acknowledge and agree that depending on the nature of the change, a test Batch [*] may be necessary in order to verify the impact of the change on the manufacturing process of the Product.
- (ii) Provide SYNCO, free of charge, with Material in sufficient quantities, for the sole purpose of use by SYNCO in its manufacture of Product in Batch quantities in both Phase I and Phase II of this Agreement. The Material will remain the exclusive property of NPS. As of or promptly after the Effective Date of the Agreement, NPS shall provide the Material to SYNCO in sufficient quantities, including back-up Material, to manufacture the Batches in Phase I of this Agreement. NPS shall provide further Material to SYNCO on a timely basis for Phase II as required. NPS' Quality Assurance will release all Material and will supply SYNCO with a certificate of

analysis of the Material.

- (iii) Reimburse SYNCO the purchase price [*] of any and all raw materials purchased by SYNCO for use in phase I (see Article 4 of this Agreement).
- (iv) Accept delivery and perform required testing and evaluation in a timely manner (other than what SYNCO is responsible for) for release of each Batch of Product manufactured by SYNCO as set out in **Article 6.6**.
- (v) Perform in a timely manner its obligations reflected in or to be reflected in and pursuant to the provisions hereof and of **Appendix D**.
- (vi) Review and when acceptable notify SYNCO of NPS' approval of all documents and changes thereto written by SYNCO specific for production of either of the Products.
- (vii) Retain title in the Material and Batches which NPS has paid for in full pursuant to **Article 8.2**. NPS shall hold appropriate insurance for the Material and Batches which NPS has paid for pursuant to **Article 8.2**.
- (viii) Be responsible for registering its title to the Material under the appropriate legislation. NPS is responsible for registering a security interest in the Batches which NPS has partially paid for pursuant to **Article 8.2**, if such security interest is desired by NPS.
- (ix) Accept the delivery within [*] upon notification by SYNCO of all Batches which are ready to be delivered by SYNCO. In the absence of such (explicit) acceptance by NPS, the relevant Batches shall be deemed to have been accepted for delivery by NPS on the [*] from the notification by SYNCO. The risk in a Batch and, subject to **Article 3.2 (xv)**, title to a Batch shall transfer to NPS upon the acceptance (or deemed acceptance) of the delivery of such Batch and NPS shall ensure that as from such moment such Batch is insured. Without prejudice to the first and second full sentence of this **Article 3.1 (ix)**, SYNCO will store Batches for a maximum period of [*] after the production of the Product. NPS and SYNCO agree that the Batches will be collected by NPS before the end of the [*] storage at SYNCO. Storage of materials beyond the agree [*] period will be addressed as the need arises and a mutually agreed upon system will be implemented.

3.2 Obligations of SYNCO. SYNCO shall:

- (i) Not transfer the Material to any third party and, at the request of NPS, return to NPS any unused quantities of the Material at the termination of this Agreement.
- (ii) Confirm that the Material is satisfactory for the manufacture of Products. SYNCO will notify NPS prior to production of each Batch if the Material is not satisfactory and can not be used for the

manufacture of GMP Grade Product in accordance with this Agreement. SYNCO will maintain records of usage of the Material, and will inform NPS of needs for additional quantities or changes in characteristics thereof in a timely manner.

- (iii) Purchase all raw materials and consumables required for the manufacture of Products other than the Material under the terms as described in **Appendix B**.
- (iv) Perform quality control and assurance release procedures for the release of Products in accordance with **Article 6**.
- (v) Purchase the equipment as described in **Appendix C** for production of Products.
- (vi) Provide all equipment necessary for the manufacture, testing, storage, release, and delivery of Products in accordance with this Agreement. All of the equipment shall be validated and maintained by SYNCO for the manufacture of Products in accordance with this Agreement and as provided for in the Specifications in all material respect. SYNCO shall be and remain the owner of such equipment.
- (vii) Perform the manufacturing process for the production of Batches of Product as outlined in the Batch Production Records and in accordance with the Specifications in **Appendix A** and the Regulatory Standards in all material respect.
- (viii) Prepare and maintain the Batch Production Records and related control, distribution and other records required to comply with Specifications in all material respect.
- (ix) Perform quality control and assurance review of process raw materials and in-process materials, and Batches.
- (x) Write all documents specific for the production of the Products in the English language. Any changes to these documents shall follow a change of control procedure in accordance with GMP in all material respect. In addition, SYNCO shall provide NPS with its Specification document of the Specifications as described in **Appendix A**.
- (xi) Ensure that the manufacture of Batches of Product complies with all process requirements including quality in-process control limits of acceptance as found in the agreed Batch Production Records and the master formulation sheet in all material respect.
- (xii) Provide and maintain appropriate personnel, facilities, equipment, the Facility, and support documents to carry out the manufacture of Batches of GMP Grade Product as required by this Agreement.
- (xiii) Be responsible for all actions and activities at the Facility required for GMP compliance.
- (xiv) Perform its obligations in a timely manner and pursuant to the schedule in **Appendix D**.

- (xv) Retain title to the work-in-progress and to any Batch which has not yet been paid for in full by NPS pursuant to **Article 8.2**.
- (xvi) Co-operate with NPS as reasonably required by NPS in registering NPS' title under the appropriate legislation to the Material and in registering NPS' security interest, if requested by NPS, in the Batches which NPS has partially paid for pursuant to **Article 8.2**.
- (xvii) Support pre approval inspections or regulatory inspections by the competent European Union, U.S. or Canadian authorities in order to support the registration of the Products. The support of inspections by any other authorities shall be agreed to and governed by a separate agreement between the Parties.
- (xviii) Provide support for the relevant manufacturing sections of a CMC report.

ARTICLE 4 – PHASE I: REINTRODUCTION OF PTH MANUFACTURE PROCESS AND TEDUGLUTIDE MANUFACTURE PROCESS

- 4.1 Phase I will comprise of the reintroduction of the PTH manufacturing process and the TEDUGLUTIDE manufacturing process at SYNCO and will include [*] for each Product and the agreed number of Conformance Lots, as specified in **Appendix E**, for each of Product. Phase I will end as to PTH when SYNCO has manufactured [*] and NPS' Quality Assurance has released the Batches, pursuant to **Article 6.6**, and Phase I will end as to TEDUGLUTIDE when SYNCO has manufactured [*] and NPS' Quality Assurance has released the Batches, pursuant to **Article 6.6**.
- 4.2 For the Batches manufactured during Phase I, SYNCO will charge NPS and NPS will pay to SYNCO the amounts as described in **Appendix E**.
- 4.3 SYNCO and NPS have agreed that SYNCO will perform its best efforts to establish a minimum Yield for the Engineering Run as indicated in **Appendix D**.

ARTICLE 5 – PHASE II: PRE-LAUNCH AND COMMERCIAL MANUFACTURE OF PTH AND TEDUGLUTIDE

PRE-LAUNCH MANUFACTURE

- 5.1 Phase II will start with respect to relevant Product after completion of Phase I with respect to such Product pursuant to **Article 4.1** or earlier upon agreement between the Parties.
- 5.2 Concerning the pre-launch Batches NPS will provide SynCo with [*] notice in writing with a binding order [*]. The manufacturing, release and delivery of GMP Grade Product for the pre-launch Campaign shall be done according to SYNCO's manufacturing schedule. Notwithstanding anything to the contrary in this **Article 5.2**, SYNCO will have the obligation to deliver the Batches at the delivery date to be agreed upon between the Parties upon placement of the order by NPS and acceptance of the order by SYNCO.
- 5.3 Concerning the manufacture of initial commercial Batches before the actual launch

date or approval date of either of the Products, NPS can place a binding order for the initial commercial batches [*] before the actual launch date or approval date.

5.4 For each Batch manufactured during the pre-launch period under Phase II, SYNCO will charge NPS and NPS shall pay to SYNCO the amount as indicated in **Appendix E**.

5.5 The prices in **Appendix E** are based on [*].

COMMERCIAL MANUFACTURE

5.6 SYNCO will manufacture Batches of Product on a Campaign basis during the commercial manufacture phase. The (preliminary) planning of the manufacturing of Batches at the Facility will be based on [*] in order to minimize [*]; provided, however, that if NPS want [*].

5.7 Notwithstanding Article 5.6, SYNCO has the right to adjust the planning of the Batches as it deems fit, provided it observes the delivery dates agreed with NPS.

5.8 SYNCO ensures that it will be able to produce a combined maximum of [*] Batches of Product per calendar year, provided that NPS has observed its obligations as to forecasting and ordering pursuant to Article 5.9 and 5.10 of this Agreement.

5.9 [*]

5.10 NPS may amend the [*] by written notice to SYNCO until and including the last date on which a firm and binding order in respect of the relevant calendar year must be made.

5.11 NPS agrees to provide SYNCO with [*] of their market research related to the Products (including volumes of each of the Products ordered or anticipated to be ordered by NPS' clients) when they become available.

5.12 For each Batch manufactured during Phase II, SYNCO will charge NPS and NPS shall pay to SYNCO the amount as indicated in **Appendix E**. The prices in **Appendix E** are based on [*].

5.13 The manufacturing, release and delivery of GMP Grade Product for each Campaign shall be done according to an agreed schedule between the Parties confirmed in writing. Notwithstanding anything to the contrary in this **Article 5.13** SYNCO will, if SYNCO elects to do so, [*], provided that the allowed and appropriate stability time periods will be observed and such Batches will not be invoiced earlier than if such Batches would have been manufactured according to the initial schedule.

5.14 NPS acknowledges and agrees that SYNCO shall supply up to [*] Batches of Product per calendar year for the combined manufacture of both PTH and TEDUGLUTIDE in such calendar year. In the event NPS would only produce one Product, either PTH or TEDUGLUTIDE in a specific calendar year, SYNCO shall supply up to [*] batches of the selected Product in such calendar year. If NPS requires Batches in excess of such quantity, NPS shall first provide SYNCO the opportunity to supply such additional Batches to NPS under the terms of this Agreement, [*].

ARTICLE 6 - REGULATORY AFFAIRS AND QUALITY ASSURANCE

- 6.1 SYNCO will exercise all reasonable skill, care and diligence customary in the industry in the performance of its duties under this Agreement and in accordance with the requirements of GMP in all material respect. SYNCO shall obtain and maintain all permits required under Dutch legislation in order to manufacture PTH and TEDUGLUTIDE. SYNCO will inform NPS of all permits filed under Dutch legislation or otherwise and their status with respect to approval insofar as these relate to the manufacture of PTH or TEDUGLUTIDE.
- 6.2 The parties acknowledge that the manufacture of PTH and TEDUGLUTIDE in accordance with this Agreement and the Specifications is believed to correspond to GMP requirements in all material respects. However, NPS will cooperate with SYNCO, in obtaining full and complete compliance with the relevant U.S. Code of Federal Regulations.
- 6.3 SYNCO will file and maintain for the Facility a Site Master File ("SMF") with the regulatory agency in The Netherlands.
- 6.4 Subject to reasonable prior notice, NPS or its designated representatives may audit and inspect the Facility for the purpose of reviewing manufacturing of PTH and/or TEDUGLUTIDE and quality assurance standards and for determining compliance with GMP at reasonable times during the term of this Agreement, to the extent that such inspections relate solely to SYNCO's manufacture of PTH and/or TEDUGLUTIDE for NPS and subject to SYNCO's obligations of confidentiality to third parties. SYNCO will provide full cooperation for these inspections.
- 6.5 Subject to Article 12.1, any Batches (except for Engineering Batches) manufactured during Phase I and II (see Article 4 and 5 of this Agreement), shall on the date of delivery to NPS conform to the agreed Specifications as attached hereto in **Appendix A**, and when manufacturing the Batches SYNCO shall conform to GMP in all material respect.
- 6.6 SYNCO will supply NPS with one (1) copy of all Batch Production Records, deviation reports and test results (including out of specification test results) for each Batch produced at the time of invoice or as otherwise agreed between the Parties. NPS will have final responsibility for confirming Quality Assurance and for the release of each Batch of GMP Grade PTH and TEDUGLUTIDE manufactured by SYNCO for commercial use.
- 6.7 SYNCO will retain raw material samples as required under GMP.
- 6.8 SYNCO will obtain NPS' written approval, not to be unreasonably withheld, in advance of any modifications to the raw materials, facility, utilities, process, procedures, production or Facility equipment used in the manufacture of PTH or TEDUGLUTIDE. None of these modifications will be inconsistent with maintaining compliance with the Specifications or to the applicable law or regulations to the extent required under this Agreement for producing GMP Grade PTH and TEDUGLUTIDE.
- 6.9 SYNCO will cooperate fully with recognised regulatory authorities of the European Union and Canada and with the FDA during inspections related to the manufacture of PTH and TEDUGLUTIDE in the Facility. The expected timeline for Pre-Approval Inspection is set out in **Appendix D**. SYNCO will notify NPS immediately of any

such inspections and will make arrangements, where feasible, for NPS to attend any such inspections.

ARTICLE 7 - WARRANTIES AND LIABILITY

7.1 In addition to other warranties provided for in this Agreement, SYNCO warrants that:

- (a) SYNCO has and will maintain all permits under Dutch legislation in order to manufacture Products.
- (b) The Material, when received, will be stored in accordance with the relevant Specifications, GMP and cGMP in all material respect;
- (c) Products produced by SYNCO under this Agreement will comply with the Specifications and Regulatory Standards in all material respect, it will be GMP Grade, will have been manufactured, packed, stored and delivered in compliance with this Agreement and applicable laws, orders and regulations, including GMP and cGMP in all material respect, and that the Facility, equipment and personnel used to produce Products will be at all times qualified to manufacture GMP Grade Products in all material respect;
- (d) For the term of this Agreement, the Facility will be operated and maintained in accordance with all applicable laws, rules, orders and regulations, including GMP and cGMP in all material respect.
- (e) SYNCO agrees that it will not carry on activities in the Facility that could reasonably prevent Products from being manufactured, packed and stored in accordance with applicable laws, rules and regulations, including GMP and cGMP in all material respect.
- (f) The manufacturing, release and delivery of GMP Grade Products for each Campaign shall be done according to the agreed schedules during the ordering procedure of the Batches, unless otherwise agreed to by the Parties.

7.2 EXCEPT AS OTHERWISE EXPRESSLY PROVIDED HEREIN, SYNCO MAKES NO WARRANTIES EXPRESS OR IMPLIED AND EXPRESSLY DISCLAIMS WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, AND SYNCO SHALL NOT BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES IN ANY CASE OF NONCONFORMITY. SYNCO SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING FROM ANY ALLEGED OR ACTUAL BREACH OF THIS AGREEMENT. SYNCO'S LIABILITY FOR DIRECT DAMAGE – IN ADDITION TO SYNCO'S OBLIGATIONS TO PROVIDE NPS WITH REPLACEMENT BATCH(ES) IN THE EVENT OF NON-CONFORMING BATCH(ES) - IS LIMITED TO [*].

7.3 SYNCO shall promptly replace, free of charge, any quantity of Product which is not GMP Grade provided that NPS notifies SYNCO in writing upon discovery of the defect or non-conformity within a period of [*] after receipt of all documentation and information from SYNCO by NPS pursuant to **Article 6.5 and Article 6.6**, and provided that NPS allows SYNCO to evaluate the claim and to test the said quantity of PTH or TEDUGLUTIDE, as applicable, within a reasonable period of time, not to exceed [*]. Products which are determined not to be GMP Grade (either by agreement between the Parties or by an independent qualified expert pursuant to

Article 7.4), shall be replaced during the current or next Campaign with GMP Grade Product. If such Product is not replaced with GMP Grade Product as provided for in this **Article 7.3**, NPS shall receive a full refund for any payment made for such quantity of Product [*]

- 7.4 If the Parties disagree as to whether or not the said quantity of Product is GMP Grade, then a qualified independent party, acceptable to both parties, will determine if the quantity of Product is GMP Grade. The resulting determination will be final and binding on SYNCO and NPS. SYNCO will bear the cost of the third party evaluation if the testing demonstrates that the PTH or TEDUGLUTIDE, as applicable, is not GMP Grade. If the Product is determined to be GMP Grade, then NPS shall bear all costs of the third party evaluation.
- 7.5 NPS will indemnify and hold SYNCO and its Affiliates harmless from and against any and all losses, claims, damages or liabilities (including but not limited to reasonable attorney's fees), arising from (a) any use, including clinical trials, or sale by NPS or any third party of any Product supplied by SYNCO hereunder; (b) any allegation by any third party of infringement of its intellectual property rights by reason of the manufacture, use or sale of Product by SYNCO, NPS or any third party; (c) breach by NPS of its representations, warranties or covenants under this Agreement; or (d) any negligence or intentional wrongdoing of NPS. However, NPS shall not indemnify SYNCO for such losses, claims, damages or liabilities that are due to the gross negligence or wilful misconduct of SYNCO.
- 7.6 SYNCO will indemnify and hold NPS and its Affiliates harmless from and against any and all losses, claims, damages or liabilities (including but not limited to reasonable attorney's fees), arising (a) any allegation by any third party of infringement of its intellectual property rights by reason of the use in the manufacture of the Product by SYNCO of methods and processes generally used by SYNCO in the manufacture of products and which methods and/or processes are not provided by NPS to SYNCO; (b) breach by SYNCO of its representations, warranties or covenants under this Agreement; or (c) SYNCO's gross negligence or wilful misconduct. [*]
- 7.7 If any claim is made for which a Party may seek indemnification from the other, the Party seeking indemnity shall promptly notify the other Party of the nature and basis of such claims and amounts thereof, to the extent known. In the event any action, suit or proceeding is brought against a Party with respect to which the other Party may have liability hereunder, the other Party may, at its option and at its own expense, elect to assume the defence of any such action, suit or proceeding itself, and if it does not so elect, the Party having the action, suit or proceeding brought against it will assume the defence thereof. Neither Party shall make any settlement of claims without the written consent of the other party, which consent shall not be unreasonably withheld.

ARTICLE 8 - PAYMENTS

- 8.1 For the manufacture and delivery of GMP Grade Product, NPS shall pay SYNCO the amounts as specified in **Appendix E**. SYNCO will supply NPS with copies of all Batch Production Records, deviation reports and test results (including out of specification test results) for each Batch produced at the time of invoice or as otherwise agreed between the Parties.
- 8.2 Invoices will be in Euro's and all payments to SYNCO shall be made in Euro's. All payments shall be made within [*] of the date of receipt by NPS of a copy of the

invoice sent by e-mail. All invoices will be sent by regular mail with a copy by e-mail. Title will pass to NPS according to **Article 3.1 (vii)**.

- 8.3 Any amounts to be paid under this Agreement that are not paid within the relevant payment terms shall bear interest at a rate of [*] per month or part of a month that such amount remains unpaid. Interest shall be compounded on a monthly basis.
- 8.4 Batch prices will be updated on an annual basis beginning [*] further described in **Appendix E**. The adjustment factor will be the official national price index factor (Dutch "CPI") prior to the calendar year for which the price adjustment will become effective, as published by the Government of the Netherlands plus a mutually agreed raw material basket increase, when appropriate. The pricing of this raw material basket will be evaluated on a periodic base, but in any case before [*] of each new calendar year.
- 8.5 Liability For Payment. Termination of this Agreement under this Article, shall not release any Party from any liability for payment accrued or accruing to the other Party prior to the termination date.
- 8.6 Neither Party is entitled to any set-off, compensation of payments, withholding or similar action in respect of any monetary payments to be made under this Agreement

ARTICLE 9 - CONFIDENTIALITY AND INTELLECTUAL PROPERTY

- 9.1 A Party receiving Confidential Information (including, without limitation, Specifications, information related to the Facility and other data designated as confidential in writing by either Party) from the other or developing such information hereunder shall not disclose such information to any third party or any Affiliates and shall keep it in strict confidence, use it solely for the purposes authorized under this Agreement during the term hereof and shall not disclose such information, for a period extending nine (9) years following termination, except as follows:
- (a) to the extent such information is or becomes general public knowledge through no fault of the recipient Party; or
 - (b) to the extent such information can be shown by contemporaneous documentation of the recipient Party to have been in its possession prior to receipt thereof hereunder; or
 - (c) to the extent such information is received by the recipient Party from a third party without any breach of an obligation by the disclosing Party; or
 - (d) to the extent required by law, by local authorities for regulatory purposes or is necessary to perform its obligations under this Agreement, in which case, the recipient Party may disclose the information if the recipient Party gives the other Party prior notice of such disclosure and an opportunity to comment upon the content of the disclosure. However, SYNCO shall have the right, at all times and without the obligation to give notice to NPS, to use information related to its Facility for its own business purposes and NPS shall have the right, at all times and without the obligation to give notice to SYNCO, to use the information related to the Products for its own business purposes.

- 9.2 NPS hereby grants to SYNCO a royalty-free, non-transferable, non-exclusive license, without the rights to sub-license, under all patent rights and know-how owned or controlled by NPS, required to manufacture PTH and TEDUGLUTIDE for NPS in accordance with this Agreement for the term of this Agreement. NPS has granted no license, express or implied, to SYNCO to use NPS's proprietary technology, know-how or other intellectual or proprietary rights other than for the purposes of this Agreement and the fulfilment by SYNCO of its obligations hereunder.
- 9.3 SYNCO has granted no license, express or implied, to NPS to use SYNCO proprietary technology, know-how or other intellectual or proprietary rights (i) existing as of the Effective Date, or (ii) developed by or for SYNCO on or after the Effective Date outside the scope of any project undertaken by SYNCO pursuant to this Agreement. SYNCO shall be the sole owner of any proprietary technology, know-how or other proprietary rights developed by or for SYNCO pursuant to or under this Agreement or, directly or indirectly, related to this Agreement, including the manufacture and supply of Products hereunder (all the foregoing intellectual property rights collectively referred to as "SYNCO Intellectual Property"). SYNCO shall grant to NPS, and does hereby grant to NPS a royalty-free, non-exclusive license on any ideas, innovations or inventions developed by or for SYNCO pursuant to or under this Agreement which are related to or useful to the manufacture of PTH and/or TEDUGLUTIDE and to negotiate in good faith an exclusive license at NPS' request. This non-exclusive license can be sub-licensed. SYNCO covenants, represents and warrants that it will not, during this Agreement and for two years after the termination of this Agreement, use or license SYNCO Intellectual Property to make, have made, use, offer for sale, sell or import (i) any product that would compete with a Product in the Field or (ii) any PTH Related Compound or TEDUGLUTIDE Related Compound. "PTH Related Compound" means a compound that: [*]. "TEDUGLUTIDE Related Compound" means a compound that: [*].
- 9.4 This Agreement supersedes all other agreements, express or implied, between the parties concerning confidentiality.

ARTICLE 10 - TERM OF AGREEMENT AND TERMINATION

- 10.1 **Term.** This Agreement shall upon signature by both Parties become effective on the Date of Agreement and remain in effect until terminated in accordance with this Article 10. This Agreement may be terminated at any time after December 31, 2016 by either Party by providing the other Party with at least [*] prior written notice of termination. Binding orders shall not be affected by any termination and therefore, NPS shall remain bound by such binding orders even if the manufacturing dates of the Batches covered by such orders go beyond the date on which the Agreement terminates.
- 10.2 **Termination for Insolvency or Breach.** A Party shall have the right without prejudice to any rights exercisable, damages accrued or claims for damages or other relief, to terminate this Agreement by written notice to the other Party upon occurrence of any of the following events:
- (a) if such Party becomes insolvent in that liabilities exceed assets, is adjudged bankrupt or insolvent, applies for judicial or extra-judicial settlement with its creditors, makes an assignment for the benefit of its creditors, voluntarily files for bankruptcy or has a receiver or trustee (or the like) in bankruptcy

appointed over its business, property or assets, or if a Party becomes the subject of liquidation or dissolution (except for reconstruction purposes such as mergers etc.) or involuntary bankruptcy proceedings or otherwise discontinues business;

- (b) if such Party breaches any material term or condition of this Agreement and the defaulting Party, having received [*] written notice of such default from the Party asserting the breach, fails to fully cure such breach within [*] of receipt of such notice from the Party asserting the breach.

10.3 **NPS Termination.** If SYNCO (i) is required to replace and/or reimburse NPS in accordance with **Article 7.2** for Product which is not GMP Grade in all material respect equal to [*] percent of the total amount of such Product invoiced by SYNCO cumulatively in any calendar year; or (ii) is required to replace and/or reimburse NPS in accordance with **Article 7.2** for Product which is not GMP Grade in all material respect equal to [*] percent of the total amount of such Product invoiced by SYNCO cumulatively during the term of the Agreement, NPS may terminate this Agreement by giving SYNCO [*] written notice.

10.4 **Liability For Payment.** Termination of this Agreement under this Article, shall not release any Party from any liability for payment accrued or accruing to the other Party prior to the termination date and as further agreed in **Appendix E section 5**.

10.5 **Survival of Termination.**

- (a) **Article 9.3** shall survive termination or expiration of this Agreement (as the case may be) and shall remain in full force and effect.
- (b) The provisions of **Articles 7.4, 7.5, 8.1, 8.5, 12.7 and 12.9** shall survive termination or expiration of this Agreement (as the case may be) and shall remain in full force and effect for five (5) years after termination or expiration of this Agreement.
- (c) The provisions of **Articles 3.2(xii, xiii, xiv, xvi), 6.3, 6.4, 6.6, 6.7, 6.9 and 6.10** shall survive termination or expiration of this Agreement (as the case may be) and shall remain in full force and effect for two (2) years after termination or expiration of this Agreement.

ARTICLE 11 - NOTICES

11.1 Any notices or other communications to be served on or sent to either Party shall be sufficiently served or sent if sent by fax and confirmed by registered return receipt prepaid mail within twenty-four (24) hours after dispatch of the fax to such Party at its address as set out below or such other address as such Party may notify in writing to the other Party from time to time.

Notices to SYNCO shall be to:

Attn: CEO
SynCo Bio Partners B.V.
Paasheuvelweg 30
1105 BJ Amsterdam

The Netherlands

Notices to NPS shall be to:

Attn: General Counsel
550 Hills Drive
3rd Floor
Bedminster, 07921 NJ
USA

or to such other address as a Party may designate.

ARTICLE 12 - ADDITIONAL TERMS

- 12.1 **Force Majeure.** A Party shall not be held liable to the other for any delay in performance or non-performance of that Party directly or indirectly caused by reason of force majeure including, but not limited to, industrial disputes, strike, lockouts, riots, mobs, fires, floods, or other natural disasters, wars declared or undeclared, civil strife, embargo, lack or failure of transport facilities, currency restrictions, or events caused by reason of laws, regulations or orders by any government, governmental agency or instrumentality or by any other supervening circumstances beyond the control of either Party. Provided, however, that the Party affected shall: give prompt written notice to the other Party of the date of commencement of the force majeure, the nature thereof, and expected duration; and shall use its best efforts to avoid or remove the force majeure to the extent it is able to do so; and shall make up, continue on and complete performance when such cause is removed to the extent it is able to do so. Either Party has the right to terminate the Agreement with immediate effect, upon written notice to the other Party, should the force majeure continue after three (3) months following the first notification. For the purpose of this Agreement, termination of the clinical development of the PTH will not be considered force majeure.
- 12.2 **Non-Waiver.** The failure by any Party at any time to enforce any of the terms or provisions or conditions of this Agreement or exercise any right hereunder shall not constitute a waiver of the same or affect the validity of this Agreement or any part hereof, or that Party's rights thereafter to enforce or exercise the same. No waiver by a Party shall be valid or binding, except if in writing and signed by a duly authorized representative of the waiving Party.
- 12.3 **Severability.** In case one or more of the provisions contained in this Agreement shall, for any reason, be held invalid, illegal or unenforceable in any respect, such holding shall not affect any other provisions of this Agreement, but this Agreement shall be construed by limiting such provision to such extent as would nearly as possible reflect the intent, purpose and economic effect of such provision, or, if such is not possible, by deleting such provision from this Agreement, provided that the remaining provisions reflect the intent of the Parties, as evidenced by this Agreement as a whole.
- 12.4 **Assignment.** This Agreement is deemed personal to SYNCO. Neither Party shall sell, assign, transfer, encumber or otherwise dispose of its interest in this Agreement or any of its rights or obligations, except to an Affiliate, without the prior written consent of the other, which consent shall not unreasonably be withheld, provided that NPS may assign this Agreement (in whole and not in part)

without SYNCO's prior written consent to a third party that acquires all or substantially all of NPS' Hypoparathyroidism business.

- 12.5 **Enurement.** This Agreement is binding on all successors and permitted assignees.
- 12.6 **Captions.** All titles and captions in this Agreement are for convenience only and shall not affect its interpretation.
- 12.7 **Law and Arbitration.** This Agreement shall be governed, construed and interpreted by the laws of the Netherlands. The Parties agree that all disputes between them arising out of or relating to this Agreement shall be settled by arbitration in accordance with the Rules of Conciliation and Arbitration of the International Chamber of Commerce by three arbitrators appointed in accordance with such Rules. The Parties shall not be entitled to terminate this Agreement during the pendency of any claim or dispute between them under this Agreement. The arbitration proceedings shall take place in Amsterdam, The Netherlands and shall be conducted in the English language. Judgement on the award may be issued by and enforced by any court of competent jurisdiction.
- 12.8 **Entire Understanding.** This Agreement (including appendices) is the entire understanding and agreement between the Parties relating to the subject matter hereof and supersedes (except as provided herein) any and all prior arrangements, understandings, and agreements between the Parties whether written or oral relating thereto. No amendments, changes, or modifications of the terms of this Agreement shall be valid or binding unless made in writing and signed by the duly authorized representatives of each Party.
- 12.9 **Independent Status of Parties.** Each Party is an independent trader acting in its own name and for its own account. Neither Party has any authority to act as an agent or representative of the other, or to contract in the name of, or create or assume any obligation against, or otherwise legally bind, the other Party in any way for any purpose, unless agreed separately in writing. All costs and expenses connected with each Party's activities and performance under this Agreement unless otherwise separately agreed or provided for in this Agreement are to be borne solely by the Party incurring such costs and expenses.
- 12.10 **Duplicate Originals.** This Agreement is executed in duplicate originals one being retained by each Party hereto.

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

NPS Pharmaceuticals, Inc.,

SynCo Bio Partners B.V.:

/s/ Francois Nader

By: Francois Nader

Title: President & CEO

/s/ Pierre Warffemius

Pierre Warffemius

CEO

APPENDIX A - SYNCO RELEASE SPECIFICATIONS

Specification of PTH Batches

SYNCO release Specifications concerning a manufactured PTH Batch

Table A.1: Acceptance criteria for test methods as performed for SYNCO release testing

| Test | Test Method | Acceptance Criteria | Sample ID |
|------|-------------|---------------------|-----------|
| [*] | [*] | [*] | [*] |
| [*] | [*] | [*] | [*] |
| [*] | [*] | [*] | [*] |
| [*] | [*] | [*] | [*] |
| [*] | [*] | [*] | [*] |
| [*] | [*] | [*] | [*] |
| [*] | [*] | [*] | [*] |
| [*] | [*] | [*] | [*] |
| [*] | [*] | [*] | [*] |

Specification of TEDUGLUTIDE Batches

SYNCO's release Specifications for TEDUGLUTIDE

Table A.2: Acceptance criteria for test methods as performed for SYNCO release testing

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

APPENDIX B - MATERIAL

[*]

APPENDIX C – RAW MATERIALS AND EQUIPMENT PURCHASED BY SYNCO

[*]

APPENDIX D – TIMELINES AND DELIVERABLES

[*]

APPENDIX E – FINANCIAL TERMS

[*]

APPENDIX F – FORECAST SCHEDULE

[*]

APPENDIX G – NPS Release Specifications

[*]