

18-03105-E

March 08 2018

US Securities & Exchange Commission  
Office of FOIA and Privacy Act Operations  
100 F Street, NE Mail Stop 5100  
Washington, DC 20549-5100



Dear FOIA Office:

Under the Freedom of Information Act (FOIA), please send a copy of the following:

**A copy of: Exhibit 10.1 to the form 10-Q filed by NOVEN PHARMACEUTICALS INC on August 8, 2007**

In the event confidential treatment has not expired provide the specific date for which confidential treatment is still in effect. I do not need a copy of the order. We authorize up to

\$61.00 in processing fees. Thank You,

**Paul D'Souza**  
Editor - Deals

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
STATION PLACE  
100 F STREET, NE  
WASHINGTON, DC 20549-2465

Office of FOIA Services

April 2, 2018

Mr. Paul D'Souza  
Clarivate Analytics  
160 Blackfriars Road  
London, SE18EZ  
United Kingdom

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552  
Request No. 18-03105-E

Dear Mr. D'Souza:

This letter is in response to your request, dated and received in this office on March 8, 2018, for access to Exhibit 10.1 to the Form 10-Q filed by Noven Pharmaceuticals Inc. on August 8, 2007.

The search for responsive records has resulted in the retrieval of seven (7) pages of records that may be responsive to your request. They are being provided to you with this letter.

No fees have been assessed for our processing of this request. If you have any questions, please contact me at [osbornes@sec.gov](mailto:osbornes@sec.gov) or (202) 551-8371. You may also contact me at [foiapa@sec.gov](mailto:foiapa@sec.gov) or (202) 551-7900. You also have the right to seek assistance from Ray J. McInerney as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or [Archives.gov](http://Archives.gov) or via e-mail at [ogis@nara.gov](mailto:ogis@nara.gov).

Sincerely,

A handwritten signature in cursive script that reads "Sonja Osborne".

Sonja Osborne  
FOIA Lead Research Specialist

Enclosure

June 15, 2004

Shire US Inc.  
One Riverfront Place  
Newport, Kentucky 41071

Attention: Gregory Flexter

Re: Development of Amphetamine Transdermal Delivery System

Dear Mr. Flexter:

This shall confirm the agreement of Noven Pharmaceuticals, Inc. ("Noven") and Shire US Inc. and/or its affiliate, Shire LLC (Shire US Inc. and Shire LLC collectively referred to as "Shire") to work together on a project (the "Project") to develop an Amphetamine Transdermal Delivery System (the "Product"). As we have discussed, the terms upon which the parties have agreed to proceed are as follows:

1. While subject to change by mutual agreement of the parties, ~~the activities that constitute the development plan for the Project are reflected in Exhibit A attached hereto (the "Plan"), and the target specifications for the Product are set forth in Exhibit B attached hereto (the "Target Specifications").~~

2. As consideration for the work to be performed by Noven hereunder, Shire shall make the following payments to Noven:

- a. \$250,000 upon execution of this letter agreement;
- b. \$250,000 upon ~~selection by Shire of up to 5 formulations that will yield a range of profiles to be advanced to animal PK and dermal toxicity work (to be completed within 8 months after Shire's selection of a preliminary Target Product Profile as described in Exhibit A provided that Noven has provided all appropriate formulation data to Shire within 6 months of Shire's selection of a preliminary Target Product Profile).~~ Shire shall select a target product profile within thirty (30) days after execution of this Agreement;
- c. \$1,125,000 upon ~~the expiration of the 30-day period following Shire's filing of an IND for the Product; provided that the FDA has not placed the Project on clinical hold (to be completed within 6 months after completion of (b) provided that Noven has delivered the applicable data, results and information pursuant to the guidelines set forth in Exhibit A);~~

- d. ~~\$1,125,000.00 upon Shire's successful completion of a human pharmacokinetic study, as determined in Shire's reasonable discretion in consideration of the Target Product Profile (to be completed within 6 to 9 months after completion of (c));~~
- e. ~~\$1,125,000.00 upon Shire's selection of a prototype formulation following completion of a Phase I pharmacokinetic study;~~
- f. ~~\$1,125,000.00 upon Noven's manufacture and Noven and Shire QA release of three 75 kg batches of the formulation selected by Shire for ICH stability (to be completed within 6 months of completion of (e)); provided however, that Noven shall not commence manufacture until Noven has received written authorization from Shire to commence such manufacture. Shire's QA release shall be completed within 30 days following Noven's QA release.~~

3. Each party shall conduct all tests, studies and other activities described in the Plan in a good scientific manner and in compliance in all material respects with all requirements of applicable laws, rules and regulations, including but not limited to cGMP and cGLP.

4. ~~Noven shall use reasonable efforts to complete the Plan within the timeframe described in the Plan. Both parties shall use reasonable efforts to meet the timeframes included in paragraph 2, however, such timeframes are only goals and are not enforceable as dates by which the milestone payments shall be made should the milestone event set forth in each subparagraph of paragraph 2 not be completed. For purposes of clarity, except as specifically provided herein, payments to be made by Shire hereunder are not contingent upon successful completion of the Plan nor completion of the Plan within the timeframe described in the Plan, and no payment made by Shire for development work is reimbursable, whether or not the development is successful.~~

5. Each party agrees to keep the other informed as to (i) the status of the Plan, (ii) all available information reasonably requested by the other party relating to work completed or to be performed under the Plan and (iii) the results of pending and completed clinical studies. However, Noven shall not be required to disclose information which reveals materials, components, composition or construction of the transdermal system investigated or tested by Noven; provided that such information is not related to or being used in performance of the Plan.

6. ~~Within 60 days of the execution of this Agreement, Noven and Shire shall enter into a definitive license agreement ("Product License"), which shall include the material terms attached hereto as Exhibit C and other customary terms and conditions, wherein Noven grants Shire a license to exclusively develop the Product with Noven under Noven Intellectual Property Rights and Noven Arising Intellectual Property. If the parties jointly (through their respective employees, agents or consultants) make or conceive any inventions or discoveries or other intellectual property in the course of the work to be performed pursuant to the Project, the ownership of such inventions or discoveries or other intellectual property and any patent applications and patents obtained thereon shall be governed by Section 13 below. If Shire has not actively pursued the Project at any time for a period of more than ninety (90) days or if any~~

~~of the milestone events described in Section 2(b), (c) and (d) above are not completed within the period set forth therein, Noven shall provide Shire with written notice thereof. Within 30 days of receipt of such notice, Shire shall provide to Noven a written response detailing its activity during the 90 day period or making the applicable milestone, as the case may be, and, upon failure by Shire to timely provide such response, or if such response does not indicate that Shire has actively pursued the Project in that period, Shire shall be deemed to have terminated the Project. Notwithstanding the preceding sentence, Shire shall not be deemed to have terminated the Project if a Force Majeure Event has occurred. For purposes of this Agreement, a Force Majeure Event shall be any occurrence or circumstance beyond the reasonable control of Shire that prevents Shire from performing any or all of its obligations under this Agreement.~~

7. Either party may terminate the Project upon ~~thirty (30) days~~ written notice to the other in the event of a material breach by the other party of any of its obligations hereunder and failure to cure such breach within the ~~thirty (30) day~~ notice period. Shire may terminate the Project at any time without cause upon ~~thirty (30) days~~ written notice to Noven. Upon termination of the Project for any reason, the rights and obligations of both Parties shall cease immediately and no further payments shall be due under Section 2 above unless the activity upon which payment is based was (i) completed (with respect to payments due under Sections 2(a) through 2(e) above) prior to such termination or (ii) commenced (with respect to payments due under Section 2(f) above) prior to receipt of notice of termination. Sections 5, 6, 8, 9, 10, 11, 13 and 14 shall survive termination of the Project. Nothing in this Paragraph 7 shall limit the right of either party to seek to recover its actual damages resulting from a material breach of this Agreement by the other party.

8. All disclosures relating to the Project shall be subject to the confidentiality provisions of the Transaction Agreement by and among Noven, Shire and Shire Pharmaceuticals Group PLC, dated as of February 26, 2003 (the "Transaction Agreement"); provided that the term "Agreement" as used in the confidentiality section of the Transaction Agreement shall mean this letter Agreement and refer to the Confidential Information disclosed pursuant hereto. ~~Additionally, during the term of this Agreement, neither party shall, independently nor with any third party, (i) engage in the research, development, manufacturing, marketing or sales of any products or projects relating to any amphetamine transdermal delivery systems; or (ii) discuss, negotiate or enter into any agreement or any other arrangement with any third party with respect to any products or projects relating to any amphetamine transdermal delivery systems.~~

9. It is understood that the Parties may wish to publish or otherwise disclose information generated under the Project to a third party for publication in a reputable scientific forum (for example, as an abstract, poster presentation, lecture, article, book, or any other means of dissemination to the public). Such disclosures may be made to a third party upon consent by the other party, such consent not to be unreasonably withheld. No such disclosure shall be made to a third party until a patent application has been filed adequately describing and claiming any invention believed to be patentable embodied in such disclosure. A party wishing to make any such disclosure shall submit a complete written draft of the disclosure to the other party at least ~~forty five (45) days~~ prior to submission for publication of such draft, or an abstract of a proposed oral disclosure at least ~~forty five (45) days~~ prior to submission of such abstract or the oral disclosure, whichever is earlier. In the event that patent filings are necessary, public disclosure shall be delayed until said patent filings have been made. The other party shall have the right

(i) to propose modifications to the publication for patent reasons, (ii) to request a delay in publication or presentation in order to protect patentable information or (iii) to request that the information be maintained as a trade secret and, in such case, the other party shall not make such publication.

10. Shire agrees to defend, indemnify and hold harmless Noven and its officers, directors and employees from and against any and all liability, damage, loss, cost or expense (including reasonable attorney's fees and expenses) arising out of or resulting from any third party claims made or suits brought against such parties which arise or result from activities conducted by Shire under the Plan; provided, however, Shire shall not be obligated to defend, indemnify and hold harmless Noven from or against any liability, damage, loss, cost or expense which results from the negligence or other wrongdoing of Noven.

11. Noven agrees to defend, indemnify and hold harmless Shire and its officers, directors and employees from and against any and all liability, damage, loss, cost or expense (including reasonable attorney's fees and expenses) arising out of or resulting from any third party claims made or suits brought against such parties which arise or result from activities conducted by Noven under the Plan; provided, however, Noven shall not be obligated to defend, indemnify and hold harmless Shire from or against any liability, damage, loss, cost or expense which results from the negligence or other wrongdoing of Shire.

12. Each party represents that neither it nor any of its employees has been debarred or is subject to debarment proceedings by the FDA. If any such proceedings are commenced against a party hereto (or any of its employees) during the term of this Agreement, such party will notify the other party in writing within five business days of the commencement of such proceedings and will keep the other party informed, on a regular basis, of the status of such proceedings. Neither Noven nor Shire will employ any persons or entities that have been debarred, or that are subject to debarment proceedings, for any aspect of the development, manufacturing or testing of the Product.

13. (i) Each party will retain and own its respective intellectual property existing prior to the date of this Agreement (respectively, "Shire Intellectual Property" and "Noven Intellectual Property").

(ii) ~~All information, data, inventions, improvements, know-how and technology learned, made, conceived or developed by either party, alone or jointly with the other, in developing the Product during the term of the Project ("Arising Intellectual Property"); (a) relating solely to transdermal delivery systems and pharmaceutical compositions including pharmacokinetic and clinical data and the like generated therefrom, packaging technology, manufacturing processes, and the like for use to deliver or manufacture drugs including amphetamines, shall belong to Noven (collectively, "Noven Arising Intellectual Property"); (b) relating solely to amphetamine drugs themselves and their pharmaceutical treatments, indications and uses, shall belong to Shire (collectively, "Shire Arising Intellectual Property");~~

(iii) Noven will take responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents relating to Noven Intellectual Property and Noven Arising Intellectual Property, together with any and all reissues, modification by

means of certificates of correction or reexamination certificates, extensions and patents of addition, continuations, divisionals, and continuations-in-parts related to such patents and patent applications ("Noven Patents"). Shire will take responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents relating to Shire Intellectual Property and Shire Arising Intellectual Property, together with any and all reissues, modification by means of certificates of correction or reexamination certificates, extensions and patents of addition, continuations, divisionals, and continuations-in-parts related to such patents and patent applications ("Shire Patents").

(iv) Noven and Shire shall immediately create a Patent Steering Committee comprised of at least one, and not more than two, participants from Noven and at least one, and not more than two, participants from Shire to oversee the Arising Intellectual Property that pertains to the Product. The Patent Steering Committee shall meet at least three times a year. The Patent Steering Committee shall agree on patent strategy including claim and patent application structure, third party issues, and prosecution. In the rare event that the Patent Steering Committee cannot agree on a material issue of patent strategy, the issue will be submitted to the Chief Executive Officers or their designees of Noven and Shire to together reach agreement. In the event that no agreement is reached, Noven shall make the final decision if it pertains to Noven Arising Intellectual Property and Shire shall make the final decision if it pertains to Shire Arising Intellectual Property.

14. Except as otherwise set forth herein, no right or license is granted under this Agreement by either Party to the other Party except as may be necessary to allow the other party to perform its obligations under the Plan. For the avoidance of doubt, all materials and inventions, technologies, trade secrets, know-how, Confidential Information and other intellectual property and proprietary rights of the other party that are provided to a party by the other party in connection with the Project or otherwise hereunder shall, as between the parties, remain the property of the providing party and the receiving party shall not acquire any right, title or interest therein or thereto.

15. Neither Shire nor Noven shall be liable for failure of or delay in performing obligations set forth in this Agreement, and neither shall be deemed in breach of its obligations, if such failure or delay is due to natural disasters or any causes reasonably beyond the control of Shire or Noven.

16. Both Shire and Noven shall comply in all material respects with the requirements of all applicable laws, rules, regulations and orders of any government authority in handling or disposing of the compounds to be studied hereunder.

17. The terms of this letter shall not be amended, modified, varied or supplemented except in writing signed by the duly authorized representatives of the parties.

18. Each party will provide a project manager, who will be the principal contact for communication between the parties.

19. In making and performing this Agreement, the parties are acting and shall act as independent contractors. Nothing in this Agreement shall be deemed to create an agency, joint

venture or partnership relationship between the parties hereto. Neither party shall have the authority to obligate the other party in any respect, and neither party shall hold itself out as having any such authority.

20. If any provision of this letter shall be found by any court or administrative body of competent jurisdiction to be invalid or unenforceable, the invalidity or unenforceability of that provision shall not affect the other provisions of this letter and all provisions not affected by the invalidity or unenforceability shall remain in full force and effect.

21. No party shall have a right to assign this Agreement or delegate any of its rights, interests, duties or obligations hereunder without the prior written consent of the other party (which consent may be granted in such party's sole discretion); provided, however, that any party may assign this Agreement to any of its affiliates without the prior written consent of the other party; and provided, further that no such assignment of this Agreement shall relieve the assignor of any of its obligations or liabilities under this Agreement. Notwithstanding the foregoing, any party may assign this Agreement without the other parties' prior written consent in connection with the transfer or sale of all or substantially all of its assets or business or its merger or consolidation with another Person upon written notice to the other parties.

22. Except as required by law or applicable stock exchange rules, neither party shall, without the prior written consent of the other party, disclose to any other person or entity (including, without limitation, by issuing a press release or otherwise making any public statement) the fact that confidential information has been exchanged between Shire and Noven, the fact that this letter has been executed and delivered, the fact that the Project or discussions or negotiations regarding the Project are taking place, or any of the terms, conditions or other facts with respect thereto.

23. This letter, together with the Transaction Agreement, represents the entire agreement between the parties relating to the Project and the Plan. Neither party shall have obligations to the other party hereunder other than as expressly set forth in this letter and the Transaction Agreement.

24. Any disputes arising hereunder shall be resolved pursuant to the dispute resolution provisions of the Transaction Agreement.

25. This letter shall be governed by, and construed in accordance with, the laws of the State of Delaware, without giving effect to the choice of law provisions thereof.

If you are in agreement with the foregoing arrangement, please so indicate by signing where indicated below and return an executed copy to me.

Sincerely,

NOVEN PHARMACEUTICALS, INC.

By: /s/ Robert C. Strauss

Robert C. Strauss

President, Chief Executive Officer and  
Chairman

**Accepted and Agreed**

SHIRE US INC.

By: /s/ Gregory Flexter

Gregory Flexter

Title: EVP and GM, North America

Date: 6-15-04