18-02531-E

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From: Mark Edwards <medwards@biosciadvisors.com>
Sent: Friday, February 16, 2018 7:29 PM
To: foiapa
Subject: FOIA Request

I would like to request access to Exhibit 10.1 to the Form 8-K filed by Accentia Biopharmaceuticals, Inc. on 10/19/2006. Confidential treatment was sought as to certain portions when initially filed with the Commission.

In the event that confidential treatment has not expired or has been extended, I further request that you send me the expiration date(s) from the relevant CT order(s) so I will know when I should resubmit my request.

I authorize up to $61 in search and retrieval fees. Please send the exhibit(s) by PDF if possible.

Sincerely,
Mark
Mark G Edwards
Managing Director
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598
medwards@biosciadvisors.com
925 954-1397

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

Office of FOIA Services

March 16, 2018

Mr. Mark G. Edwards
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-02531-E

Dear Mr. Edwards:

This letter is in response to your request, dated February 16, 2018 and received in this office on February 20, 2018, for access to Exhibit 10.1 to the Form 8-K filed by Accentia Biopharmaceuticals, Inc. on October 19, 2006.

In connection with a previous request, access was granted to the subject exhibit. Therefore, we have determined to release the same exhibit (copy enclosed) to you. No fees have been assessed in this instance.

If you have any questions, please contact me at reidk@sec.gov or (202) 551-3504. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Lizzette Katilius 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 or via e-mail at ogis@nara.gov.

Sincerely,

Kay Reid

Kay Reid
FOIA Lead Research Specialist

Enclosures

10.1

* Areas highlighted in YELLOW are requesting CONFIDENTIAL TREATMENT PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

AMENDMENT NO. 1
TO THE FIRST AMENDED AND RESTATED ROYALTY STREAM PURCHASE AGREEMENT

THIS AMENDMENT NO. 1 (the "Amendment"), dated as of September 26, 2006, is by and between Accentia Biopharmaceuticals, Inc., a Florida corporation ("Accentia"), and Pharmaco Investments, Inc., a Delaware corporation ("PPD").

WHEREAS, Accentia and Pharmaceutical Product Development, Inc. ("PPDI") entered into that certain Royalty Stream Purchase Agreement dated September 7, 2004 (the "Original Agreement"); and

WHEREAS, Accentia and PPDI subsequently entered into that certain First Amended and Restated Royalty Stream Purchase Agreement dated August 11, 2005 (the "Restated Agreement"); and

WHEREAS, PPDI assigned its rights and obligations under the Restated Agreement to PPD, its wholly-owned subsidiary; and

WHEREAS, the first Amended and Restated Royalty purchase Agreement provided for a termination of PPD's obligations under Schedule 2 of the Restated Agreement on December 31, 2005 in the event a first patient had not been dosed in a Clinical Trial by December 31, 2005; and

WHEREAS, despite the fact that a first patient was not dosed in a Clinical Trial by December 31, 2005 and the provision providing for termination of PPD's obligations under Schedule 2, the parties have continued to operate under the Restated Agreement and Accentia has continued to progress the development of the SinuNase Formulation and now desires to amend the Restated Agreement to provide for ongoing limited clinical trial services for the SinuNase Formulation for the treatment of chronic sinusitis; and

WHEREAS, PPD is providing clinical trial services for Accentia's Study Protocol ACC-QS-06-01 entitled "A Qualitative Study of the Cardinal Symptoms in Patients With Chronic Sinusitis" (the "Qualitative Study") through its affiliate PPD Development, LP under the Master Services Agreement between Accentia and PPD Development, LP dated April 10, 2006 ("MSA");

WHEREAS, PPD is willing to provide other limited clinical trial services on the terms and conditions set forth in this Amendment in exchange for the increase in certain royalty payments due under the Original Agreement and as set forth in Section 1(l) of the Restated Agreement; and

WHEREAS, the parties further desire to provide each other with the option to terminate PPD's obligation under Section 9(a) and Schedule 2 hereof on the terms and conditions as hereinafter provided.

NOW, THEREFORE, that for and in consideration of the foregoing premises, the mutual covenants herein contained, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Defined Terms. Capitalized terms not otherwise defined herein shall have the meaning given to them in the Restated Agreement.

2. Section 9(a). Section 9(a) of the Agreement is hereby stricken and replaced in its entirety by the following:

"(a) Services. PPD will cause PPD Development, LP ("PPD Development") and other Affiliates to provide certain limited Services (as defined in Schedule 2 attached hereto and made a part hereof) to Accentia with respect to clinical trials for the SinuNase Formulation for the treatment of chronic sinusitis. Notwithstanding anything herein to the contrary, the respective rights and obligations of each party with respect to the Services are as set forth in Schedule 2. With respect to the performance of the Services, in the event of any conflict between a term or condition set forth in Schedule 2 and a term or condition set forth elsewhere in this Agreement, the term or condition in Schedule 2 shall control."

3. Section 1.1 of Schedule 2. Section 1.1 of Schedule 2 is hereby stricken and replaced in its entirety by the following:

"1.1 Services to be Provided by PPD. PPD shall cause PPD Development, LP ("PPD Development") and other Affiliates, as appropriate, to provide the CRO services set forth below with respect to clinical trials to test the safety and efficacy of the SinuNase Formulation in refractory surgical patients with chronic sinusitis ("Clinical Trials") pursuant to the terms and conditions set forth in this Schedule 2 ("Services"). PPD Development's obligation to provide Services is subject to the following conditions precedent, both of which must be satisfied before PPD Development shall be obligated to provide all or any part of the Services: (a) Accentia's completion of the Qualitative Study to the reasonable satisfaction of PPD; (b) receipt by Accentia of written documentation from the FDA that evidences the FDA's agreement to (i) specific clinical endpoints that will enable Accentia to market the SinuNase Formulation for chronic sinusitis in refractory surgical patients and (ii) specific criteria for demonstrating efficacy of the SinuNase Formulation; and (c) PPD's acceptance of the FDA's clinical endpoints and efficacy criteria for the SinuNase Formulation and the written documentation therefor, which acceptance by PPD shall be in PPD's sole discretion and evidenced by written notification to Accentia. In the event that PPD does not agree with the endpoints or efficacy levels agreed upon by the FDA, PPD shall provide written notice to Accentia thereof and PPD Development's obligations to provide Services to Accentia under this Schedule 2 shall terminate immediately upon such notice.

Provided the conditions precedents set forth above are met in full, and subject to the dollar limitation on the amount of Services PPD Development is obligated to provide

hereunder, the Services to be provided by PPD Development shall be limited to providing the direct labor support (i.e., PPD personnel) for the following tasks and activities:

(a) Review and identification of clinical trial sites and/or investigators to participate in the Clinical Trials.
(b) Assistance in signing up of clinical trial sites (see Section 2 below).
(c) Seeking Investigational Review Board (IRB) approval.
(d) Data capture and patient randomization.
(e) Monitoring of clinical trial sites.
(f) Collection of safety data and safety reporting to the FDA.
(g) Production of individual clinical trial study reports.
(h) Production of Integrated Safety Summary (ISS).
(i) Production of New Drug Application

The Services shall exclude any services with respect to the Clinical Trials not listed above. Without limiting the generality of the foregoing, the Services shall not include any of the following:

(j) Any Services related to clinical trial material (CTM) including, but not limited to, chemistry, manufacturing and controls (CMC), regulatory services, stability and release of CTM, and depoting and distribution of CTM to sites.
(k) Bioanalytical analysis of biological samples.
(l) Laboratory analysis of endoscopy samples.
(m) Measurement of fungal load in biological samples.
(n) Analysis of CT scans.
(o) Validation of the Rhinoqol Questionnaire.
(p) Performance of clinical studies using a pump spray.
(q) Any Services related to bioavailability, pharmacokinetics, or safety related studies such as animal toxicity and carcinogenicity.

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Notwithstanding anything herein to the contrary, PPD Development's obligation to provide the Services shall be limited to providing direct labor support having a Fully-Loaded Cost to PPD of up to a maximum of four million dollars ($4,000,000). The term "Fully-Loaded Cost" shall mean the sum of (i) the aggregate cost incurred by PPD of employee compensation (including without limitation salaries, bonuses and other forms of compensation), employee benefits and overhead with respect to all employees providing direct labor support for the Services, all as determined by PPD in its reasonable discretion and in accordance with its accounting methods and practices, (ii) the aggregate cost incurred by PPD for any independent contractors providing labor for the performance of the Services and (iii) any unreimbursed out-of-pocket expenses that PPD has incurred in connection with the performance of the Services. Once the Fully-Loaded Cost equals $4,000,000, PPD Development shall have no further liability or obligation to provide any further Services to Accentia, even if the Services identified above have not been performed or completed in whole or in part. For clarity, the cost for clinical trial

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services performed under the MSA for the Qualitative Study shall be paid to PPD Development in cash and are not included in PPD's obligation to provide Services as stated in this Section 1.1. PPD Development shall provide Services in compliance with this Schedule 2, PPD Development's Standard Operating Procedures ("SOPs"), and all applicable laws, rules, and regulations. SOPs are subject to revision by PPD Development in which case PPD Development shall notify Accentia of such revision. The current SOPs for conducting and monitoring clinical trials are available for review upon request by Accentia."

4. Section 2 of Schedule 2. The first sentence of Section 2 of Schedule 2 is hereby stricken and replaced in its entirety by the following two sentences:

"Accentia shall reimburse PPD for all out-of-pocket expenses incurred in connection with the performance of Services, including, without limitation, travel expenses, printing fees and other "pass through" expenses reasonably expected to be incurred in connection with performing the Services (collectively, the "Pass Through Costs"). Notwithstanding anything herein to the contrary, PPD shall have no obligation to advance, pay for or finance the payment of grants or other payments to clinical trial sites or investigators participating in any Clinical Trial under agreements with such investigators or otherwise."

5. Option To Terminate Services. Accentia and PPD shall each have the option to terminate PPD and PPD Development's obligations under Section 9(a) and Schedule 2 of this Agreement (the "Option"), each in their sole and absolute discretion, at any time prior to 5 PM Eastern time on December 31, 2006 by delivering written notice thereof (the "Termination Notice") to the other party on or before December 31, 2006. The Termination Notice shall be delivered to the other party in accordance with Section 10(e) of this Agreement and the date on which it is deemed given and received under Section 10(e) shall be the "Termination Date" for purposes of this Section 5. Upon termination by either party under this Section 5, Accentia shall pay PPD an amount in cash equal to the Fully-Loaded Cost through the Termination Date plus any additional obligations that PPD has incurred in performing the Services that are not cancelable or terminable by PPD (the "Full Cash Payment"). Following the Termination Date, PPD shall send Accentia an invoice for the Full Cash Payment, which shall be due and payable in full within ten (10) days of the date on which PPD sent such invoice to Accentia. Upon receipt by PPD of the Full Cash Payment, the term "Royalty Stream" as used in the Restated Agreement shall mean Royalty Stream as defined in the Original Agreement. For clarification, upon receipt by PPD of the Full Cash Payment from Accentia, the royalty payable to PPD on the SinuNase Formation shall be reduced from 14% to 7%.

6. Remaining Terms and Conditions of Agreement. Except as specifically amended herein, all other terms and conditions of the Restated Agreement are in full force and effect, including, without limitation, the payment of the Royalty Stream as defined in Section 1(l) of the Restated Agreement.

IN WITNESS WHEREOF, Accentia and PPD have, by their duly authorized officers, executed this Amendment No. 1 as of the date first above written.

Accentia Biopharmaceuticals, Inc.

By: /s/Frank E. O'Donnell 10/09/06
Frank E. O'Donnell
Chairman and CEO

Pharmco Investments, Inc.

By: /s/ B. Judd Hartman
B. Judd Hartman
President

PPD Development, LP executes and delivers this Amendment for the sole and limited purpose of agreeing to be bound by the provisions of Section 3 and 4 hereof and the amendments to Schedule 2 set forth therein.

PPD Development, LP
By: PPD GP, LLC, its General Partner

By: /s/ Fred N. Eschelman
Fred N. Eshelman
Chief Executive Officer

F:d/l/g/investments/accentia/royaltystreampurchase/amendmentno.1(v3)