



September 29, 2014

Jeffrey P. Riedler
Assistant Director
Securities and Exchange Commission
100 F Street, N.E.
Washington D.C. 20549

**Re: Acura Pharmaceuticals, Inc.
Annual Report on Form 10-K
Filed March 3, 2014
File No. 001-10113**

Dear Mr. Riedler:

On behalf of Acura Pharmaceuticals, Inc. (the "Company") we are transmitting the following responses to the Staff's letter dated September 23, 2014 containing comments to Company's Annual Report on Form 10-K for the year ended December 31, 2013 as filed with the Securities and Exchange Commission on March 3, 2014. For your convenience the full text of each of the Staff's comments is set forth in bold below, and the Company's response to each comment directly follows the applicable text.

COMMENT: General

- 1. We note that you have not filed the settlement agreements you entered into in 2013 with Par Pharmaceutical, Inc., and Impax Laboratories, Inc. as exhibits to your 2013 Annual Report on Form 10-K and that you have not filed the settlement agreements you entered into with Sandoz Inc. and Ranbaxy, Inc. during the second quarter of 2014 in your Quarterly Report on Form 10-Q for the quarter ended June 30, 2014. Please file the agreements with your next Quarterly Report on Form 10-Q. Alternatively, provide us with an analysis as to why none of these agreements is a material contract required to be filed pursuant to Item 601(b)(10) of Regulation S-K.**

RESPONSE:

Item 601(b)(10)(ii) provides that registrants need not file a contract, if "the contract is such as ordinarily accompanies the kind of business conducted by the registrant" unless it falls into one or more of the categories specified therein. The settlement agreements with each of Par Pharmaceutical Inc. ("Par"), Impax Laboratories, Inc. ("Impax"), Ranbaxy Inc. ("Ranbaxy") and Sandoz Inc. ("Sandoz") are of a type that ordinarily accompanies the kind of business conducted by the Company. These types of patent infringement settlements are routine for branded pharmaceutical companies, such as the Company, and it is the Company's expectation that it will enter into similar agreements on an ongoing basis as part of its normal business operations. In addition, the Company's Aversion® Oxycodone product had only nominal sales during the period it was licensed to Pfizer, Inc., and since the termination of that license agreement and return of the product to the Company, it has not been marketed and generates no revenue. Accordingly, unless it falls into one of the specified categories listed in Item 601(b)(10)(ii), the settlement agreements do not need to be filed. The only category that could be relevant is Item (B), which requires the filing of any contract "upon which the registrant's business is substantially dependent, as in the case of continuing contracts to sale the major part of the registrant's products or services."

Under the settlement agreement with Par, Par will be permitted to commence marketing of a generic equivalent product to Aversion® Oxycodone in the U.S. on January 1, 2022. The material fact related to the Par settlement agreement is that Par has the right to market a generic equivalent to Aversion® Oxycodone prior to the expiration of the Patent covering Acura's product, which expires in November 2023. This fact was promptly disclosed in the Company's Current Report on Form 8-K filed on October 9, 2013 and again in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2013. No upfront payment was made by Par and any royalty revenue the Company receives under the Par settlement agreement is not expected to be material to the Company, and is not material at present since none is payable until Par commences marketing its generic equivalent in 2022. Accordingly, as the Company currently derives no revenue pursuant to the Par settlement agreement and does not expect in the future to derive revenue material to its business under the Par settlement agreement, the Company has determined that its business is not "substantially dependent" on the Par settlement agreement and has therefore not filed the Par settlement agreement as a material contract.

Under the settlement agreements with Impax and Sandoz, each of Impax and Sandoz will be permitted to commence marketing a generic equivalent product to Aversion® Oxycodone in the U.S. commencing 180 days following the first sale of a generic Aversion® Oxycodone product in the U.S. by any entity that is entitled to the 180 first-filer exclusivity provisions under applicable FDA regulations (or if no entity is entitled to such exclusivity, the date on which a generic Aversion® Oxycodone product is first sold in the U.S., or November 27, 2021, whichever date occurs first). The material fact related to each of the Impax and Sandoz' settlement agreements is that each entity has the right to market a generic equivalent product prior to the expiration of the patent covering the Company's Aversion® Oxycodone product. This fact was promptly disclosed by the Company in its Current Reports on Form 8-K filed on each of October 9, 2013 and May 21, 2014 and again in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2013 and in the Company's Form 10-Q for the fiscal quarter ended June 30, 2014. Neither of such settlement agreements provide for any payments or royalty to the Company provided such parties' generic formulations remain unchanged, and in the case of Sandoz settlement, contemplates a de minimus royalty on sales a revised formulation of their generic product. The Company expects that it will not generate any revenue under either of the Impax or Sandoz settlement agreements. Accordingly, the Company has determined that its business is not "substantially dependent" on either the Impax or the Sandoz settlement agreements and has therefore not filed such settlement agreements as material contracts.

Under the settlement agreement with Ranbaxy, the Company dismissed its litigation alleging that a generic of our Aversion® Oxycodone product for which Ranbaxy is seeking approval to market in the U.S. infringed the Company's Patents. The settlement agreement provides that Ranbaxy's current generic formulation of Aversion® Oxycodone does not infringe the Company's patents listed in the FDA's Orange Book. We have not provided Ranbaxy with a license to patents as part of the settlement agreement. The material fact related to the Ranbaxy settlement agreement is that we agreed with Ranbaxy that their generic formulation of our Aversion® Oxycodone product does not infringe our patents listed in the FDA's Orange Book. This fact was promptly disclosed in the Company's Current Report on Form 8-K filed on May 8, 2014 and again in the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2014. Additionally, since no license grant was made by the Company to Ranbaxy as part of the Ranbaxy settlement agreement, and the Company will not derive any revenue from such agreement, it has determined that its business is not "substantially dependent" on the Ranbaxy settlement agreement and has therefore not filed the Ranbaxy settlement agreement as a material contract.

The Company has described each of the settlement agreements with Par Pharmaceutical, Impax Laboratories, Ranbaxy Inc. and Sandoz Inc. in its 2013 Form 10-K under the captions "Item 3. Legal Proceedings – Paragraph IV ANDA Litigation" and "Item IA. Risk Factors – Generics manufacturers are using litigation and regulatory means to seek approval for generic versions of Oxecta, which could cause our and our licenses sales to suffer," and in each of the Company's Form 10-Qs for the quarters ended March 31, 2014 and June 30, 2014 under the caption "Note 2 – License, Development and Commercialization Agreement – Paragraph IV ANDA Litigation."

COMMENT:

Item 1. Business

Patents and Patent Applications, page 13

- 2. Please amend your disclosure to provide the expiration dates for each of your seven material patents. Also, please advise us as to whether any of these seven patents were challenged by any of the four filers of ANDAs for Oxecta (i.e. Par, Impax, Ranbaxy or Sandoz) and whether any of them were subsequently invalidated. If any of these patents were subject to pending unresolved challenges as of December 31, 2013 and such challenges remain unresolved, please provide appropriate disclosure as to their status.**
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RESPONSE:

We respectfully request that the Staff permit the Company to address the disclosure sought in this Comment 2 in the Company's upcoming Form 10-Q for the quarter ending September 30, 2014 under the caption "Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations – Company Overview." Below is the text of the proposed disclosure (marked against the disclosure contained in the Company's 10-K) which (i) includes the expiration dates of each of the Company's seven material patents, (ii) identifies those patents that were challenged by the filers of ANDAs for a generic of the Company's Aversion® Oxycodone (formerly known as Oxceta®), and (iii) clarifies that the Company's patents remain valid and enforceable following the settlement of the patent litigation with such generic sponsors. We also wish to advise the Staff that the identity of the Company's Patents challenged by the ANDA filers, and the settlements with each of Par Pharmaceutical Inc. and Impax Laboratories Inc., were described in the Form 10-K on page 36 under the caption "Item 1A. Risk Factors – Generic manufacturers are using litigation and regulatory means to seek approval for generic versions of Oxecta, which would cause our and our licensee's sales to suffer" and on page 42 under the caption "Item 3. Legal Proceedings – Paragraph IV ANDA Litigation", and that the subsequent settlements with each of Ranbaxy Inc. and Sandoz Inc. were described in the Company's Form 10-Q for the quarter ended June 30, 2014 under the caption "Note 2 – License, Development and Commercialization Agreement – Paragraph IV ANDA Litigation."

**[Proposed text to be included in Company's Form 10-A
for the quarter ending September 30, 2014]**

Patents and Patent Applications

In April 2007, the United States Patent and Trademark Office, or USPTO, issued to us U.S. Patent No. 7,201,920 titled "Methods and Compositions for Deterring Abuse of Opioid Containing Dosage Forms," or the 920 Patent. The 54 allowed claims in the 920 Patent encompass certain pharmaceutical compositions intended to deter the most common methods of prescription opioid analgesic product misuse and abuse. These patented pharmaceutical compositions include the mixture of functional inactive ingredients and specific opioid analgesics such as oxycodone HCl and hydrocodone bitartrate among others. [The 920 Patent expires in March, 2025.](#)

In January 2009, the USPTO issued to us U.S. Patent No. 7,476,402, or the 402 Patent, with 18 allowed claims. The 402 Patent encompasses certain combinations of kappa and mu opioid receptor agonists and other ingredients intended to deter opioid analgesic product misuse and abuse. [The 402 Patent expires in November, 2023.](#)

In March 2009, the USPTO issued to us U.S. Patent No. 7,510,726, or the 726 Patent, with 20 allowed claims. The '726 Patent encompasses a wider range of abuse deterrent compositions than our '920 Patent. [The 726 Patent expires in November, 2023.](#)

In July 2011, the USPTO issued to us U.S. Patent No. 7,981,439, or the 439 Patent, with 7 allowed claims. The 439 Patent encompasses certain compositions including any water soluble drug of abuse intended to deter the most common methods of prescription opioid analgesic product misuse and abuse. [The 439 Patent expires in August, 2024.](#)

In January 2012, the USPTO issued to us U.S. Patent No. 8,101,630, or the 630 Patent with a single claim that encompasses an extended release abuse deterrent dosage form of oxycodone or a pharmaceutically acceptable salt thereof. [The 630 Patent expires in August, 2024.](#)

In April 2013, the USPTO issued to us U.S. Patent No. 8,409,616, or the 616 Patent, that encompasses certain immediate-release abuse deterrent dosage forms. [The 616 Patent expires in November, 2023.](#)

In January 2014, the USPTO issued to us U.S. Patent No. 8,637,540, or the 540 Patent, that encompasses certain immediate-release abuse deterrent opioid products. [The 540 Patent expires in November, 2023.](#)

In addition to our issued U.S. patents, we have filed multiple U.S. patent applications and international patent applications relating to compositions containing abusable active pharmaceutical ingredients as well as applications covering our Impede Technology. ~~Except for those rights conferred in the Pfizer Agreement, we~~ We have retained all intellectual property rights to our Aversion Technology, Impede Technology, and related product candidates. ~~See below under the caption Legal Proceedings contained in Item 3 of this Report for a discussion of our pending patent infringement actions against two generic sponsors of ANDAs for generic drugs listing Oxecta as the reference drug.~~

[In 2012 and 2013, we received Paragraph IV Certification Notices from five generic sponsors of an ANDA for a generic drug listing our Aversion® Oxycodone product as the reference listed drug. The Paragraph IV Notices referred to our 920, 726 and 439 Patents, which cover our Aversion® Technology and our Aversion® Oxycodone product. We filed suit against each of such generic sponsors, Watson Laboratories, Inc., Par Pharmaceutical, Inc., Impax Laboratories, Inc., Sandoz Inc. and Ranbaxy Inc., in the United States District Court for the District of Delaware alleging infringement of our 726 Patent listed in the FDA's Orange Book. Our litigation against Watson Laboratories was dismissed by us following Watson Laboratories' change of its Paragraph IV Certification to a Paragraph III Certification, indicating it would not launch its generic product until the expiry of our applicable Patents. Our litigation against the remaining generic sponsors was settled during the period October 2013 through May 2014 on an individual basis, upon mutual agreement between us and such generic sponsors. None of such settlements impacted the validity or enforceability of our Patents. See "Item 3. Legal Proceedings. Paragraph IV ANDA Litigation" for a discussion of the settlements relating to such patent litigation.](#)

Reference is made to the Risk Factors contained in item 1A of this Report for a discussion, among other things, of patent applications and patents owned by third parties, including claims that may encompass our Aversion Technology and Oxecta tablets.

COMMENT

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters, page 56

3. We note [you have not] disclosed the name(s) of the natural person(s) who have voting, investment and/or dispositive power over the shares held by Care Capital II, LLC. Please amend your disclosure to include this information.

RESPONSE:

Instruction 3 of Item 403 of Regulation S-K, pursuant to which security ownership is mandated in Item 12 of Form 10-K, allows the Company to rely on the information set forth in any statements filed with the Securities and Exchange Commission on a Schedule 13D unless the Company knows or has reason to believe that such information is not complete or accurate or that a statement or amendment should have been filed and was not.

Care Capital II, LLC and others jointly filed Amendment No.1 to Schedule 13D on December 27, 2012 with respect to the Company's securities held by them. Item 2 thereof ("Identity and Background"), which unlike certain other Items in such Schedule 13D has not been subsequently amended, provides that **"Care Capital II, LLC is managed by three or more members and accordingly none of the managing members is deemed to have voting or dispositive control over the securities."**

As the Company is entitled to rely on this statement pursuant to Instruction 3 to Item 403 of Regulation S-K, we respectfully submit that no amendment to Item 12 to the Company's 10-K is needed, as there are no other persons who have voting or dispositive control over the Company's securities held by Care Capital II, LLC. As part of the preparation of the Company's Form 10-K for the fiscal year ending December 31, 2014, the Company will undertake to inquire of Care Capital II, LLC to determine the natural persons who have voting, investment and/or dispositive power over the shares held by it and, if made available to the Company, will make such disclosure in such Form 10-K.

On behalf of the Company it is acknowledged that:

- the Company is responsible for the adequacy and accuracy of the disclosure in the filing;
- Staff comments or changes to disclosure in response to staff comments do not foreclose the Commission from taking any action with respect to the filing; and
- the Company may not assert Staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Please contact me at (973) 491-3354, or in my absence, Stanley Brener at (973)-491-3367 with any other questions.

Sincerely,

/s/ John Reilly

John P. Reilly
Attorney at Law

Cc: Scott Foley
