

ACURA PHARMACEUTICALS, INC
Form 8-K
January 08, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D. C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the

Securities Exchange Act Of 1934

January 7, 2015

Date of Report (Date of earliest event reported)

ACURA PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

State of New York	1-10113	11-0853640
(State of Other Jurisdiction (Commission File Number) of Incorporation)		(I.R.S. Employer Identification Number)

616 N. North Court, Suite 120

Palatine, Illinois 60067

(Address of principal executive offices) (Zip Code)

(847) 705-7709

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-J(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17CFR 240.13e-L(c))

Item 1.01 Entry into a Material Definitive Agreement.

Collaboration and License Agreement with Egalet

On January 7, 2015, Acura Pharmaceuticals, Inc. (“we” or the “Company”) and Egalet US, Inc., a Delaware corporation (“Egalet US”), and Egalet Ltd., a company organized under the laws of England and Wales (“Egalet UK, and together with Egalet US, “Egalet”, subsidiaries of Egalet Corporation (Nasdaq Capital Market: EGLT), which is also a party to the Agreement with obligations thereunder) entered into a Collaboration and License Agreement, (the “Agreement”) to commercialize Oxaydo™ (oxycodone hydrochloride) tablets containing our Aversion® Technology. Oxaydo (formerly known as Oxecta®) is currently approved by the U.S. Food and Drug Administration (“FDA”) for marketing in the United States in 5 and 7.5 mg strengths. Under the terms of the Agreement, we are transferring the approved New Drug Application (“NDA”) for Oxaydo to Egalet and Egalet is granted an exclusive license under our intellectual property rights for development and commercialization of Oxaydo worldwide (the “Territory”) in all strengths, subject to our right to co-promote Oxaydo in the United States.

In accordance with the Agreement, we and Egalet will form a joint steering committee to coordinate commercialization strategies and the development of product line extensions. Egalet will pay a significant portion of the expenses relating to (i) annual NDA PDUFA product fees, (ii) expenses of the FDA required post-marketing study for Oxaydo and (iii) expenses of clinical studies for product line extensions (additional strengths) of Oxaydo for the United States and will bear all of the expenses of development and regulatory approval of Oxaydo for sale outside the United States.

Egalet is responsible for all manufacturing and commercialization activities in the Territory for Oxaydo. Subject to certain exceptions, Egalet will have final decision making authority with respect to all development and commercialization activities for Oxaydo, subject to our co-promotion right. Egalet may develop Oxaydo for other countries and in additional strengths in its discretion.

Egalet will pay us an upfront payment of \$5 million dollars upon signing of the Agreement and a \$2.5 million milestone on the earlier to occur of (A) the launch of Oxaydo and (B) January 1, 2016, but in no event earlier than June 30, 2015. In addition, we will be entitled to a one-time \$12.5 million milestone payment when Oxaydo net sales reach a specified level of \$150 million in a calendar year.

In addition, we will receive from Egalet a stepped royalty at percentage rates ranging from mid-single digits to double-digits on net sales during a calendar year based on Oxaydo net sales during such year (excluding net sales resulting from our co-promotion efforts). In any calendar year in which net sales exceed a specified threshold, we will receive a double digit royalty on all Oxaydo net sales in that year (excluding net sales resulting from our co-promotion

efforts). If we exercise our co-promotion rights, we will receive a share of the gross margin attributable to incremental Oxaydo net sales from our co-promotion activities. Egalet's royalty payment obligations commence on the first commercial sale of Oxaydo and expire, on a country-by-country basis, upon the expiration of the last to expire valid patent claim covering Oxaydo in such country (or if there are no patent claims in such country, then upon the expiration of the last valid claim in the United States or the date when no valid and enforceable listable patent in the FDA's Orange Book remains with respect to the Product). Royalties will be reduced upon the entry of generic equivalents, as well for payments required to be made by Egalet to acquire intellectual property rights to commercialize Oxaydo, with an aggregate minimum floor.

The Agreement expires upon the expiration of Egalet's royalty payment obligations in all countries. Either party may terminate the Agreement in its entirety if the other party breaches a payment obligation, or otherwise materially breaches the Agreement, subject to applicable cure periods, or in the event the other party makes an assignment for the benefit of creditors, files a petition in bankruptcy or otherwise seeks relief under applicable bankruptcy laws. Acura also may terminate the Agreement with respect to the U.S. and other countries if Egalet materially breaches its commercialization obligations. Egalet may terminate the Agreement for convenience on 120 days prior written notice, which termination may not occur prior to the second anniversary of Egalet's launch of Oxaydo. Egalet also may terminate the Agreement prior to the launch of Oxaydo on 30 days prior written notice upon the occurrence of serious safety issues, regulatory restrictions and intellectual property issues, in each case involving Oxaydo. Termination does not affect a party's rights accrued prior thereto, but there are no stated payments in connection with termination other than payments of obligations previously accrued. For all terminations (but not expiration), the Agreement provides for the transition of development and marketing of Oxaydo from Egalet to us, including the conveyance by Egalet to us of the trademarks and all regulatory filings and approvals relating to Oxaydo, and for Egalet's supply of Oxaydo for a transition period .

Amendment to Loan Agreement with Oxford Finance

On January 7, 2015, we, and our subsidiary, Acura Pharmaceutical Technologies, Inc. ("APT", and together with Acura, the "Borrowers") and Oxford Finance LLC ("Oxford" or the "Lender"), as collateral agent and as lender entered into an amendment (the "Amendment") to the Loan and Security Agreement (the "Loan Agreement") dated December 27, 2013 pursuant to which the Lender made a term loan to us in the principal amount of \$10.0 million (the "Term Loan"). Pursuant to the Amendment, (i) the exercise price of the warrant previously issued to the Lender to purchase 297,805 shares of our Common Stock was lowered from \$1.59 to \$0.504 per share (the average closing price of our common stock on Nasdaq for the 10 trading days preceding the date of the Amendment), (ii) the Borrowers agreed to maintain a \$2.5 million cash balance until such time as they repaid \$5 million in principal of the Term Loan, and (iii) the Lender consented to the terms of our Agreement with Egalet (as described above).

Item 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

The Section of Item 1.01 entitled "Amendment to Loan Agreement with Oxford Finance" is incorporated herein by reference.

This Report contains forward-looking statements about Oxaydo and Agreement between the Company and Egalet. However, substantial risks and uncertainties exist in the process of commercialization and further development and regulatory review with respect to such further development as well as our required post-marketing study. There can be no assurance that Oxaydo will prove to be commercially successful or that it will be developed in other strengths or for other countries Accordingly, investors in the Company should recognize that there is no assurance that the

Company will receive any of the milestone payments and royalties described above for Oxaydo tablets. For further discussion of these and other risks and uncertainties, see the Company's Annual Report on Form 10-K for the year ended December 31, 2013, under the heading "Risks Factors", and its most recent quarterly report on Form 10-Q and its other public disclosures filed with the U.S. Securities and Exchange Commission.

Item 9.01 Financial Statements and Exhibits

Exhibit Number Description

99.1 Press Release of the Registrant dated January 8, 2015.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ACURA PHARMACEUTICALS, INC.

By: /s/ Peter Clemens
Peter A. Clemens
Senior Vice President & Chief Financial Officer

Date: January 7, 2015

EXHIBIT INDEX

Exhibit Number Description

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