LEXICON PHARMACEUTICALS, INC.
Form 8-K
November 06, 2015

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

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FORM 8-K

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CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 5, 2015

Lexicon Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	000-30111	76-0474169
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification Number)

8800 Technology Forest Place
The Woodlands, Texas 77381
(Address of principal executive offices and Zip Code)

(281) 863-3000
(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 obligations of the registrant under any of the following provisions:
o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a 12 under the Exchange Act (17 CFR 240.14a 12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d 2(b))
o Pre-commencement communications pursuant to Rule 13e 4(c) under the Exchange Act (17 CFR 240.13e 4(c))

Item 1.01 Entry into a Material Definitive Agreement.

On November 5, 2015, we entered into a Collaboration and License Agreement (the "Agreement") with Sanofi for the worldwide development and commercialization of our diabetes drug candidate sotagliflozin.

Under the Agreement, we granted Sanofi an exclusive, worldwide, royalty-bearing right and license under our patent rights and know-how to develop, manufacture and commercialize sotagliflozin. Subject to specified exceptions, neither party may (a) perform clinical development activities relating to any other compound which inhibits sodium-glucose cotransporters type 1 or type 2 or (b) commercialize any such compounds in the United States, countries of the European Union and certain other specified countries, in each case during the royalty terms applicable in such countries. Among the specified exceptions is a right we retained to pursue the development of our LX2761 drug candidate, with respect to which we granted Sanofi certain rights of first negotiation specified in the Agreement.

Under the Agreement, Sanofi will pay us an upfront payment of $300 million. In addition, we are eligible to receive from Sanofi (a) up to an aggregate of $430 million upon the achievement of specified development and regulatory milestones and (b) up to an aggregate of $990 million upon the achievement of specified sales milestones. We are also entitled to tiered, escalating royalties ranging from low double digit percentages to forty percent of net sales of sotagliflozin, based on indication and territory, with royalties for the higher band of such range attributable to net sales for type 1 diabetes in the United States, and subject in each case to customary royalty reduction provisions. Royalties payable with respect to net sales of sotagliflozin for type 1 diabetes in the United States will also be reduced in the event we do not exercise our co-promotion option described below.

We will continue to be responsible for all clinical development activities relating to type 1 diabetes and will retain an exclusive option to co-promote and have a significant role, in collaboration with Sanofi, in the commercialization of sotagliflozin for the treatment of type 1 diabetes in the United States. If we exercise our co promotion option, we will fund forty percent of the commercialization costs relating to such co-promotion activities. Sanofi will be responsible for all clinical development and commercialization of sotagliflozin for the treatment of type 2 diabetes worldwide and will be solely responsible for the commercialization of sotagliflozin for the treatment of type 1 diabetes outside the United States. We will share in the funding of a portion of the planned type 2 diabetes development costs over the next three years, up to an aggregate of $100 million. Sanofi will book sales worldwide in all indications.

The parties are responsible for using commercially reasonable efforts to perform their development and commercialization obligations pursuant to mutually approved development and commercialization plans.

The parties' activities under the Agreement are governed by a joint steering committee and certain other governance committees which reflect equal or other appropriate representation from both parties. If the applicable governance committee is not able to make a decision by consensus and the parties are not able to resolve the issue through escalation to specified senior executive officers of the parties, then Sanofi will have final decision-making authority, subject to limitations specified in the Agreement.

The Agreement will expire upon the expiration of all applicable royalty terms for all licensed products in all countries. The royalty term for each licensed product in each country is the period commencing on the effective date of the Agreement and ending on the latest of expiration of specified patent coverage, expiration of specified regulatory exclusivity and 10 years following the first commercial sale in the applicable country. Either party may terminate the Agreement in the event of an uncured material breach by the other party. Prior to completion of the core development activities for type 2 diabetes specified in the development plan, Sanofi may terminate the Agreement on a country-by-country and licensed product-by-licensed product basis, in the event of (a) notification of a material safety issue relating to the licensed product or the class of sodium-glucose cotransporters type 1 or type 2 inhibitors resulting in a recommendation or requirement that we or Sanofi cease development, (b) failure to achieve positive results with respect to certain clinical trial results, (c) the occurrence of specified fundamental adverse events or (d) the exploitation of the licensed product infringing third party intellectual property rights in specified major markets and Sanofi is unable to obtain a license to such third party intellectual property rights.

The effectiveness of the Agreement is contingent upon satisfaction of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

We issued a press release announcing the Agreement on November 6, 2015, a copy of which is attached to this current report on Form 8-K as Exhibit 99.1.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the Agreement, which we expect to file as an exhibit to our annual report on Form 10-K for the year ending December 31, 2015.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	— Press Release of Lexicon Pharmaceuticals, Inc. dated November 6, 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.

Lexicon Pharmaceuticals, Inc.

Date: November 6, 2015

By: /s/ Brian T. Crum
Brian T. Crum
Vice President and General Counsel

Index to Exhibits

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