# 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

Date of Report (Date of earliest event reported): September 9, 2019

## Lexicon Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

**Delaware**(State or other jurisdiction of incorporation or organization)

000-30111

(Commission File Number)

76-0474169 (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	w if the Form 8-K filing	is intended to simultane	ously satisfy the filing	g obligations of the registran	t under any of the
following provisions:					

	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-2(b))	
	Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))	
Securities registered pursuant to Section 12(b) of the Act:		

Title of each class Trading Symbol(s) Name of each exchange on which registered

Common Stock, par value \$0.001 LXRX The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company □

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.  $\Box$ 

## Item 1.01 Entry into a Material Definitive Agreement.

Effective as of September 9, 2019 (the "<u>Settlement Date</u>"), Lexicon Pharmaceuticals, Inc. entered into a Confidential Termination and Settlement Agreement and Mutual Releases (the "<u>Termination Agreement</u>") with Sanofi-Aventis Deutschland GmbH ("<u>Sanofi</u>"), pursuant to which the Collaboration and License Agreement, dated November 5, 2015, as amended (the "<u>Collaboration Agreement</u>") between Lexicon and Sanofi for the development and commercialization of sotagliflozin was terminated and certain disputes between Lexicon and Sanofi, as described in Lexicon's current report on Form 8-K filed on July 29, 2019 (the "<u>Disputes</u>"), were settled.

Under the terms of the Termination Agreement, Lexicon will regain all rights to sotagliflozin and assume full responsibility for the worldwide development and commercialization of sotagliflozin in both type 1 and type 2 diabetes. Sanofi will pay Lexicon \$260 million, of which 80% is payable upfront and 10% is payable within each of six and twelve months of the Settlement Date, and neither party will owe any additional payments pursuant to the Collaboration Agreement. The parties will cooperate in the transition of responsibility for ongoing clinical studies and other activities, and each party is responsible for its own expenses associated with such transition, subject to certain exceptions. Certain core Phase 3 clinical studies will transition to Lexicon immediately and certain other non-core clinical studies, including the SCORED Phase 3 cardiovascular outcomes study and the SOLOIST worsening heart failure study (the "Non-Core Studies"), will transition to Lexicon as of 120 days following the Settlement Date; *provided*, that Lexicon is responsible for payment under third party contracts associated with the Non-Core Studies during such 120-day period. Lexicon and Sanofi also agreed to a mutual release of all claims relating to the Disputes.

We issued a press release regarding our entry into the Termination Agreement on September 10, 2019, a copy of which is attached to this current report on Form 8-K as Exhibit 99.1.

A summary of the material terms of the Collaboration Agreement is included in our annual report on Form 10-K for the year ending December 31, 2018. The foregoing description of the Collaboration Agreement does not purport to be complete and is qualified in its entirety by reference to the Collaboration Agreement, which is filed as Exhibit 10.14 to our annual report on Form 10-K/A for the year ending December 31, 2015 and as Exhibit 10.1 to our quarterly report on Form 10-Q for the period ended September 30, 2017.

## Item 1.02 Termination of a Material Definitive Agreement.

The information contained in Item 1.01 of this current report on Form 8-K is incorporated herein by reference into this Item 1.02.

#### Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No. Description

99.1 — <u>Press Release of Lexicon Pharmaceuticals, Inc. dated September 10, 2019</u>

## 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: September 10, 2019 By: /s/ Brian T. Crum

Brian T. Crum

Vice President and General Counsel

## **Index to Exhibits**

Exhibit No.Description99.1— Press Release of Lexicon Pharmaceuticals, Inc. dated September 10, 2019

#### LEXICON PHARMACEUTICALS ANNOUNCES TERMINATION OF ALLIANCE AND SETTLEMENT WITH SANOFI

Conference Call and Webcast Today at 5:00 pm EDT / 4:00 pm CDT

**The Woodlands, Texas, September 10, 2019** - Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX), today announced the termination of its alliance with Sanofi for the development and commercialization of Zynquista<sup>TM</sup> (sotagliflozin) and the settlement of its related disputes with Sanofi, each effective September 9, 2019. In connection with the termination, Lexicon will regain all rights to Zynquista and assume full responsibility for the worldwide development and commercialization of Zynquista in both type 1 and type 2 diabetes. Under the terms of the settlement, Sanofi will pay Lexicon \$260 million, of which \$208 million is payable upfront and the remainder is payable within twelve months, and coordinate with Lexicon in the transition of responsibility for ongoing clinical studies and other activities.

"Our four-year alliance with Sanofi has been a productive one, with Zynquista receiving marketing approval in Europe in type 1 diabetes and advancing into late-stage studies in type 2 diabetes," said Lonnel Coats, president and chief executive officer of Lexicon. "Regaining worldwide rights allows us to advance our efforts to realize the full value of the Zynquista program as we prepare for regulatory filings in the U.S. and in Europe in type 2 diabetes, with data coming over the next few months from the remainder of the core Phase 3 studies and over the longer term from two outcomes studies with potential for demonstrating cardiovascular and renal benefits. We believe that this potential, along with a European approval in type 1 diabetes, offer an attractive opportunity for potential collaborators as we work to maximize the global potential for Zynquista and to achieve greater operational flexibility."

#### **Conference Call and Webcast Information**

Lexicon management will hold a live conference call and webcast today at 5:00 pm EDT / 4:00 pm CDT to discuss today's announcement. The dial-in number for the conference call is 888-645-5785 (U.S./Canada) or 970-300-1531 (international). The conference ID for all callers is 7376526. The live webcast and replay may be accessed by visiting Lexicon's website at <a href="https://www.lexpharma.com/investors">www.lexpharma.com/investors</a>. An archived version of the webcast will be available on the website for 14 days.

#### About Zynquista (sotagliflozin)

Discovered using Lexicon's unique approach to gene science, Zynquista is an oral dual inhibitor of two proteins responsible for glucose regulation known as sodium-glucose co-transporter types 1 and 2 (SGLT1 and SGLT2). SGLT1 is responsible for glucose absorption in the gastrointestinal tract, and SGLT2 is responsible for glucose reabsorption by the kidney. Zynquista is approved in the European Union (EU) for use as an adjunct to insulin therapy to improve blood sugar (glycemic) control in adults with type 1 diabetes with a body mass index  $\geq$  27 kg/m2, who could not achieve adequate glycemic control despite optimal insulin therapy. Outside of such approval, Zynquista is investigational and has not been approved by any other regulatory authority for type 1 or type 2 diabetes.

## **About Lexicon Pharmaceuticals**

Lexicon is a fully integrated biopharmaceutical company with a mission of pioneering medicines that transform patients' lives. Through its Genome5000<sup>TM</sup> program, Lexicon scientists studied the role and function of nearly 5,000 genes and identified more than 100 protein targets with significant therapeutic potential in a range of diseases. Through the precise targeting of these proteins, Lexicon is pioneering the discovery and development of innovative medicines to safely and effectively treat disease. In addition to its first commercial product, XERMELO, Lexicon has a pipeline of promising drug candidates in clinical and preclinical development in diabetes and metabolism, oncology and neuropathic pain. For additional information, please visit <a href="https://www.lexpharma.com">www.lexpharma.com</a>.

#### **Safe Harbor Statement**

This press release contains "forward-looking statements," including statements relating to Lexicon's long-term outlook on its business, the commercialization of XERMELO (telotristat ethyl) and Zynquista (sotagliflozin), and the clinical development of, the regulatory filings for, and the potential therapeutic and commercial potential of telotristat ethyl, sotagliflozin, LX2761 and LX9211. In addition, this press release also contains forward looking statements relating to Lexicon's growth and future operating results, discovery, development and commercialization of products, strategic alliances and intellectual property, as well as other matters that are not historical facts or information. All forward-looking statements are based on management's current assumptions and expectations and involve risks, uncertainties and other important factors, specifically including Lexicon's ability to meet its capital requirements, successfully commercialize XERMELO, successfully conduct preclinical and clinical development and obtain necessary regulatory approvals of telotristat ethyl, sotagliflozin, LX2761, LX9211 and its other potential drug candidates on its anticipated timelines, achieve its operational objectives, obtain patent protection for its discoveries and establish strategic alliances, as well as additional factors relating to manufacturing, intellectual property rights, and the therapeutic or commercial value of its drug candidates. Any of these risks, uncertainties and other factors may cause Lexicon's actual results to be materially different from any future results expressed or implied by such forward-looking statements. Information identifying such important factors is contained under "Risk Factors" in Lexicon's annual report on Form 10-K for the year ended December 31, 2018, as filed with the Securities and Exchange Commission. Lexicon undertakes no obligation to update or revise any such forward-looking statements, whether as a result of new information, future events or otherwise.

## For Investor Inquiries:

Kimberly Lee, D.O.
Head of Investor Relations and Corporate Strategy
Lexicon Pharmaceuticals
(281) 863-3383
<a href="mailto:klee@lexpharma.com">klee@lexpharma.com</a>

## For Media Inquiries:

Chas Schultz
Senior Director, Corporate Communications and Advocacy
Lexicon Pharmaceuticals
(281) 863-3421
<a href="mailto:cschultz@lexpharma.com">cschultz@lexpharma.com</a>