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): July 25, 2019

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 obligation of the registrant 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	Name of each exchange on which registered
Common stock	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. ☐

Item 1.02 Termination of a Material Definitive Agreement.

On July 25, 2019, Lexicon Pharmaceuticals, Inc. received written notice (the "Letter") from Sanofi-Aventis Deutschland GmbH ("Sanofi"), informing the Company of Sanofi's intention to terminate the Collaboration and License Agreement, dated November 5, 2015 (the "CLA," and as amended by Amendment No. 1 to the Agreement, dated as of July 1, 2017 (the "Amendment"), the "Agreement"), entered into between the Company and Sanofi for the worldwide development and commercialization of the Company's diabetes drug candidate sotagliflozin. Capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the Agreement.

The Letter purports to provide notice of Sanofi's decision to terminate the Agreement for a Positive Results Failure pursuant to Section 12.3.2(i)(b) thereof, relating to Study EFC14837 (the "CKD-3 Study") and Study EFC 15166 (the "CKD-4 Study"). We disagree that Sanofi has the right to so terminate the Agreement and consider Sanofi's notice to such effect to be invalid and such purported termination to constitute a breach of the Agreement and a breach of Sanofi's implied duty and covenant of good faith and fair dealing under New York law.

Section 12.3.2(i)(b) of the Agreement provides that Sanofi may terminate the Agreement upon thirty (30) days' written notice if, with respect to any Decision Point, Positive Results are not achieved in all material respects, as determined in accordance with Section 3.1.3 of the Agreement. Section 3.1.3 of the Agreement provides that the JSC determines whether or not Positive Results have been achieved. The timing of that determination is to be "within thirty (30) days after the earlier of (i) completion of the final study report for the applicable clinical study and, if applicable, delivery of such report to Sanofi and (ii) one hundred twenty (120) days after the first database lock for the applicable clinical study." In the event that the JSC is unable to agree, the determination of Positive Results is subject to the dispute resolution procedures of the Agreement. In no case is Sanofi entitled to unilaterally make a Positive Results determination.

Sanofi first provided Lexicon with a summary of topline results from the CKD-3 Study and the CKD-4 Study on July 23, 2019. Sanofi did not provide at that time, and still has not provided, the clinical data underlying Sanofi's summary topline results. Having not received that data, the Lexicon members of the JSC have not had a reasonable opportunity to evaluate the clinical data and the statistical analysis thereof. The earliest date under the Agreement for a JSC determination of Positive Results is in October 2019. Contrary to these terms of the Agreement, Sanofi claims to have taken upon itself, bypassing the JSC, without providing access to the underlying data, ignoring contractually-specified timelines, and disregarding the dispute resolution provisions of the Agreement, the right to unilaterally determine Positive Results so that it declare them not to have been achieved (which we dispute and/or are not yet in a position to assess) and report at its previously scheduled earnings call on July 29, 2019 that it had "terminated" the Agreement.

In addition, we believe that Sanofi has breached Section 3.1.1 of the Agreement, which provides that Sanofi's Development activities for T2DM "shall be conducted in accordance with and pursuant to the Development Plan," by defining the "primary endpoint" of the CKD-3 Study as six successively statistically tested endpoints, including several subgroups, rather than a single primary endpoint as required in the Development Plan. As a result, we disagree with Sanofi's assertion that the primary endpoint of the CKD-3 Study was not met.

In the event of a termination of the Agreement, Sanofi has certain obligations including, at Lexicon's request, transferring to Lexicon control of all clinical studies involving sotagliflozin being conducted by Sanofi as of the effective date of termination; provided that Sanofi shall remain obligated to continue to fund, to the extent of Sanofi's funding obligations under the Agreement, the costs of such clinical studies then being conducted by Sanofi for Development Costs incurred twelve (12) months after the effective date of termination.

We issued a press release regarding the topline results and the disputed termination notice on July 26, 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 Agreement is included in our annual report on Form 10-K for the year ending December 31, 2018. The foregoing description of the CLA and the Amendment does not purport to be complete and is qualified in its entirety by reference to the CLA, which is filed as Exhibit 10.14 to our annual report on Form 10-K/A for the year ending December 31, 2015, and the Amendment, which is filed as Exhibit 10.1 to our quarterly report on Form 10-Q for the period ended September 30, 2017.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.		Description
99.1	—	Press Release of Lexicon Pharmaceuticals, Inc. dated July 26, 2019

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: July 26, 2019

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

Exhibit 99.1

LEXICON PHARMACEUTICALS PROVIDES PRELIMINARY UPDATE FOR ZYNQUISTA™ (SOTAGLIFLOZIN) TYPE 2 DIABETES PHASE 3 PROGRAM

Sanofi Provides Disputed Termination Notice

The Woodlands, Texas – July 26, 2019 – Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX) received preliminary topline results from Sanofi for three Phase 3 trials of Zynquista™ (sotagliflozin) in adults living with type 2 diabetes from the InSynchrony clinical program. Lexicon has not yet received the underlying data, and expects to conduct its own review and validation and statistical analysis of the data when they are received.

The preliminary topline results received from Sanofi for the three studies are as follows:

- In SOTA-MET, Zynquista 400 mg demonstrated a statistically significant reduction in blood sugar control (A1C) compared to placebo at 26 weeks in patients on metformin.
- In SOTA-CKD3, Zynquista 400 mg showed a statistically significant reduction in A1C in the entire population of patients with moderate (stage 3) chronic kidney disease (CKD) and in the subpopulation of patients with a glomerular filtration rate of 45-<60 mL/min/1.73m2 (stage 3A CKD) compared to placebo at 26 weeks. Although Zynquista demonstrated numerical improvement on A1C, a statistically significant reduction in A1C was not achieved in the subpopulation of patients with a glomerular filtration rate of 30-<45 mL/min/1.73m2 (stage 3B CKD).
- In SOTA-CKD4, Zynquista 400 mg achieved a clinically meaningful effect but narrowly missed statistical significance on A1C reduction versus placebo in patients with severe (stage 4) CKD at 26 weeks.

Zynquista was well tolerated in all three studies. The data from these studies is planned to be presented at upcoming medical conferences.

“We are pleased that today’s results support the potential benefits Zynquista may bring to adults living with type 2 diabetes, particularly for those living with chronic kidney disease,” said Pablo Lapuerta, M.D., executive vice president and chief medical officer at Lexicon. “Although the SOTA-CKD4 study appears to have narrowly missed statistical significance on A1C, we are very encouraged by the overall results in that study and look forward to Phase 3 data from the remainder of the core studies from the InSynchrony program later this year.”

Separately, Sanofi has delivered to Lexicon a notice purporting to terminate the alliance. Lexicon has notified Sanofi that it considers the notice invalid and Sanofi to be in breach of contract. The collaboration and license agreement provides that, even if a valid termination of the alliance had been delivered, Sanofi has continuing contractual obligations to transition rights to sotagliflozin and continue to fund ongoing clinical trials for a contractually-specified period of time following termination.

“While we are disappointed in the position taken by Sanofi, we are confident in the strength of the data we have seen thus far in the type 2 diabetes program and are optimistic about achieving continued success in the balance of the core Phase 3 program, which we expect will be completed in the coming months,” said Lonnel Coats, Lexicon’s president and chief executive officer. “In the event of a valid termination of the Sanofi alliance, we will also look forward to regaining full rights to Zynquista in type 1 diabetes in the United States, as well as rights in the remainder of the world, notably including the European Union, in which Zynquista has already received approval.”

Lexicon will be hosting a live conference call and webcast on Thursday, August 1, 2019 at 8:00 am EDT / 7:00 am CDT to review its financial and operating results and to provide a general business update. 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 5789855. The live webcast and replay may be accessed by visiting Lexicon’s website at www.lexpharma.com/investors. An archived version of the webcast will be available on the website for 14 days.

About the InSynchrony Type 2 Diabetes Phase 3 Clinical Trial Program

The InSynchrony program consists of 11 Phase 3 clinical trials to evaluate the efficacy and safety of Zynquista in adults with type 2 diabetes on various therapeutic backgrounds (i.e., diet and exercise alone, metformin, a sulfonylurea, a dipeptidyl peptidase 4 inhibitor, or basal insulin). These trials include placebo and active comparators (i.e., glimepiride and empagliflozin) and also is evaluating patients with CKD, cardiovascular risk factors, and heart failure, as well as patients age 55 and older.

SOTA-MET, SOTA-CKD3 and SOTA-CKD4 are the first trials to report data from the program:

SOTA-MET is evaluating the efficacy and safety of Zynquista (400 mg once daily) in adults with type 2 diabetes with inadequate blood sugar control on metformin, compared to placebo.

SOTA-CKD3 and SOTA-CKD4 are evaluating the efficacy and safety of two doses of Zynquista (200 mg and 400 mg once daily) in adults with type 2 diabetes and moderate to severe CKD with inadequate blood sugar control receiving standard of care treatment, compared to placebo.

About Zynquista™ (sotagliflozin)

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 ³ 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.

Lexicon has granted Sanofi an exclusive worldwide (excluding Japan) license to develop, manufacture and commercialize Zynquista. Lexicon remains responsible for all clinical development activities relating to type 1 diabetes and Sanofi is responsible for all clinical development activities of Zynquista for the treatment of 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™ 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® (telotristat ethyl), Lexicon has a pipeline of promising drug candidates in clinical and preclinical development in diabetes, metabolism, oncology and neuropathic pain. For additional information, please visit www.lexpharma.com.

Safe Harbor Statement

This press release contains "forward-looking statements," including statements relating to Lexicon's long-term outlook on its business, including the clinical development of, the regulatory filings for, and the potential therapeutic and commercial potential of sotagliflozin. 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.

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