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): November 7, 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)

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

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:

☐ 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))

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 2.02 Results of Operations and Financial Condition

On November 7, 2019, we issued a press release to report our financial results for the three months ended September 30, 2019. A copy of the press release is attached to this current report on Form 8-K as Exhibit 99.1.

The information in this Form 8-K and the Exhibit attached to this Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.		Description
99.1	—	Press Release of Lexicon Pharmaceuticals, Inc. dated November 7, 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: November 7, 2019

By: /s/ Brian T. Crum

Brian T. Crum

Vice President and General Counsel

Index to Exhibits

Exhibit No.		Description
99.1	—	Press Release of Lexicon Pharmaceuticals, Inc. dated November 7, 2019

Exhibit 99.1

LEXICON PHARMACEUTICALS REPORTS THIRD QUARTER 2019 FINANCIAL RESULTS AND PROVIDES A BUSINESS UPDATE

The Woodlands, Texas, November 7, 2019 - Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX), today reported financial results and provided a business update for the three months ended September 30, 2019.

"We continue to make good progress on our XERMELO business, with XERMELO net sales growing more than 30% in the third quarter of 2019 versus the same period in 2018," said Lonnel Coats, Lexicon's president and chief executive officer. "We now have full rights for Zynquista. We expect to complete the core Phase 3 studies in type 2 diabetes in the near term and anticipate being in a position to file for regulatory approval for that indication in the U.S. and in Europe in the first half of 2020. We continue to have productive dialogue with the FDA on a path forward for Zynquista in type 1 diabetes in the U.S."

Third Quarter Product and Pipeline Highlights

XERMELO® (telotristat ethyl)

- XERMELO U.S. net sales were $8.4 million in the third quarter of 2019.
- The **Tel**otristat **E**thyl for **A**dvanced **B**iliary Tract **C**ancer, or TELE-ABC, study, a Phase 2a clinical study of telotristat ethyl in patients with biliary tract cancer, continues to enroll patients.

Zynquista™ (sotagliflozin)

- In September, Lexicon and Sanofi terminated their alliance for the development and commercialization of sotagliflozin. In connection with the termination, Lexicon regained all rights to sotagliflozin and assumed full responsibility for the worldwide development and commercialization of sotagliflozin in both type 1 and type 2 diabetes. Under the terms of the settlement, Sanofi will pay Lexicon $260 million, of which $208 million was paid in September and the remainder is payable within twelve months. Sanofi continues to coordinate with Lexicon in the transition of responsibility for ongoing clinical studies and other activities.

- Clinical data for sotagliflozin were highlighted in two oral presentations at the European Association for the Study of Diabetes (EASD) 55th annual meeting (September 16-20; Barcelona, Spain), demonstrating the effect of sotagliflozin on body weight and composition in adults with type 1 diabetes. In addition, five posters were presented, detailing the reductions in glucose variability and risk for hyperglycemia in adults with type 1 diabetes treated with sotagliflozin alone, improved treatment satisfaction in patients with type 1 diabetes treated with sotagliflozin and insulin versus insulin alone, lower rates of clinically relevant hypoglycemic events at any A1C level at 52 weeks in adults with type 1 diabetes, the positive impact of sotagliflozin on renal function, albuminuria and blood pressure in adults with type 1 diabetes and the reduction in markers of arterial stiffness in patients with type 1 diabetes.

- In September, a post-hoc analysis of hypoglycemia as a function of A1C in patients with type 1 diabetes receiving sotagliflozin or placebo in combination with optimized insulin therapy was published in *Diabetes Technology and Therapeutics*. The pooled analysis from inTandem1 and inTandem2 trials showed that at 52 weeks, level 1 and 2 hypoglycemia events were 22% to 30% less frequent with sotagliflozin added to optimized insulin therapy versus placebo in adults with type 1 diabetes at any A1C level, with greater differences at lower A1C values.

- In August, 52-week cardiorenal results from a pooled analysis from the inTandem1 and inTandem2 studies of sotagliflozin in adults with type 1 diabetes were published in *Diabetes Care*. Sotagliflozin demonstrated changes in clinical biomarkers such as estimated glomerular filtration rate (eGFR), hematocrit, serum albumin, uric acid, systolic blood pressure and urinary albumin-to-creatinine ratio (UACR) that suggest sotagliflozin may reduce cardiovascular risk and progression of chronic kidney disease. Sotagliflozin was associated with short- and long-

term renal hemodynamic changes. After cessation of 52 weeks of therapy, eGFR was comparable to baseline and significantly higher than placebo in sotagliflozin-treated patients.

- In July, Lexicon announced the preliminary topline results received from Sanofi from SOTA-MET, SOTA-CKD3 and SOTA-CKD4, the first three of a total of nine clinical trials included in the core Phase 3 development program for sotagliflozin in type 2 diabetes.

Third Quarter 2019 Financial Highlights

Revenues: Revenues for the three months ended September 30, 2019 increased to $294.4 million from $7.0 million for the corresponding period in 2018, primarily due to an increase of collaborative revenues of $260 million from the termination of the alliance with Sanofi and recognition of the remaining amount of $23.5 million allocated to performance obligations from the initial agreement with Sanofi and an increase in net product revenue. Net product revenues for the three months ended September 30, 2019 consisted of $8.4 million from net sales of XERMELO in the U.S., which were up 33% from the prior year quarter.

Cost of Sales: Cost of sales related to sales of XERMELO for each of the three months ended September 30, 2019 and 2018 was $0.6 million.

Research and Development (R&D) Expenses: Research and development expenses for the three months ended September 30, 2019 increased to $26.7 million from $13.8 million for the corresponding period in 2018, primarily due to an increase in external clinical development costs related to sotagliflozin subsequent to the termination of the alliance with Sanofi, in which Lexicon regained the rights and responsibilities for development and commercialization for sotagliflozin.

Selling, General and Administrative (SG&A) Expenses: Selling, general and administrative expenses for the three months ended September 30, 2019 decreased to $13.9 million from $15.6 million for the corresponding period in 2018, primarily due to decreased marketing costs.

Impairment Loss on Intangible Asset: An impairment loss for the three months ended September 30, 2019 of $28.6 million was recognized to an indefinite lived intangible asset associated with Lexicon's 2010 acquisition of Symphony Icon, due to the decision to terminate research and development activities related to a program for irritable bowel syndrome that was among the assets acquired.

Income Tax Benefit: An income tax benefit of $6.0 million for the three months ended September 30, 2019 was recognized in connection with the impairment loss on the indefinite lived intangible asset, which resulted in a decrease to the deferred tax liability and created an income tax benefit.

Net Income (Loss): Net income for the three months ended September 30, 2019 was $226.1 million, or $1.95 per diluted share, as compared to a net loss of $27.4 million, or a loss of $0.26 per share, in the corresponding period in 2018. For the three months ended September 30, 2019 and 2018, net income included non-cash, stock-based compensation expense of $3.6 million and $2.9 million, respectively.

Cash and Investments: As of September 30, 2019, Lexicon had $296.3 million in cash and investments, as compared to $160.1 million as of December 31, 2018. The cash position as of September 30, 2019 includes proceeds of $208 million in connection with the termination of the alliance with Sanofi.

Anticipated Near-Term Milestones

- Q4 2019 - Topline Phase 1 data for LX9211
- Q4 2019 / early 2020 - Topline results from core Phase 3 studies for sotagliflozin in type 2 diabetes
- Q4 2019 - Completion of patient enrollment of the initial safety cohort in the Phase 2 study of telotristat ethyl in biliary tract cancer

Conference Call and Webcast Information

Lexicon management will hold a live conference call and webcast today at 8:00 am EST / 7:00 am CST 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 8189178. 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 XERMELO (telotristat ethyl)

Discovered using Lexicon's unique approach to gene science, XERMELO (telotristat ethyl) is the first and only approved oral therapy for carcinoid syndrome diarrhea. XERMELO targets tryptophan hydroxylase, an enzyme that mediates the excess serotonin production within metastatic neuroendocrine tumor (mNET) cells. XERMELO is approved in the United States, the European Union and certain additional countries for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy. Carcinoid syndrome is a rare condition that occurs in patients living with mNETs and is characterized by frequent and debilitating diarrhea. XERMELO targets the overproduction of serotonin inside mNET cells, providing an additional treatment option for patients suffering from carcinoid syndrome diarrhea.

Lexicon has granted Ipsen an exclusive royalty-bearing right and license to commercialize XERMELO outside of the United States and Japan. We are commercializing XERMELO in the United States and Ipsen is commercializing XERMELO in multiple countries, including the United Kingdom and Germany.

XERMELO (telotristat ethyl) Important Safety Information

- ***Warnings and Precautions:*** XERMELO may cause constipation, which can be serious. Monitor for signs and symptoms of constipation and/or severe, persistent, or worsening abdominal pain in patients taking XERMELO. Discontinue XERMELO if severe constipation or severe, persistent, or worsening abdominal pain develops.
- ***Adverse Reactions:*** The most common adverse reactions (≥5%) include nausea, headache, increased gamma-glutamyl-transferase, depression, flatulence, decreased appetite, peripheral edema, and pyrexia.
- ***Drug Interactions:*** If necessary, consider increasing the dose of concomitant CYP3A4 substrates, as XERMELO may decrease their systemic exposure. If combination treatment with XERMELO and short-acting octreotide is needed, administer short-acting octreotide at least 30 minutes after administering XERMELO.

For more information about XERMELO, see Full Prescribing Information at www.xermelo.com.

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 ≥ 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™ 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 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 XERMELO (telotristat ethyl), Zynquista (sotagliflozin), 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 complete the transition from Sanofi of responsibility for ongoing clinical studies and other activities relating to sotagliflozin, successfully conduct preclinical and clinical development and obtain necessary regulatory approvals of telotristat ethyl, sotagliflozin, 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.

Lexicon Pharmaceuticals, Inc.
Selected Financial Data

Consolidated Statements of Operations Data	**Three Months Ended September 30,**		**Nine Months Ended September 30,**	
(In thousands, except per share data)	**2019**	**2018**	**2019**	**2018**
	(Unaudited)		**(Unaudited)**	
Revenues				
Net product revenue	$ 8,351	$ 6,286	$ 23,763	$ 19,062
Collaborative agreements	285,910	556	289,209	26,792
Royalties and other revenue	187	124	374	284
Total revenues	294,448	6,966	313,346	46,138
Operating expenses:				
Cost of sales (including finite-lived intangible asset amortization)	577	551	2,457	1,922
Research and development, including stock-based compensation of $1,698, $1,472, $5,369 and $4,522, respectively	26,659	13,763	51,318	87,936
Selling, general and administrative, including stock-based compensation of $1,864, $1,405, $5,370 and $4,327, respectively	13,898	15,579	42,271	47,191
Impairment loss on intangible asset	28,638	—	28,638	—
Total operating expenses	69,772	29,893	124,684	137,049
Income (loss) from operations	224,676	(22,927)	188,662	(90,911)
Interest expense	(5,204)	(5,252)	(15,485)	(15,552)
Interest and other income, net	600	783	2,080	2,698
Net income (loss) before income taxes	220,072	(27,396)	175,257	(103,765)
Income tax benefit	6,014	—	6,014	—
Net income (loss)	$ 226,086	$ (27,396)	$ 181,271	$ (103,765)
Net income (loss) per common share, basic	$ 2.13	$ (0.26)	$ 1.71	$ (0.98)
Net income (loss) per common share, diluted	$ 1.95	$ (0.26)	$ 1.59	$ (0.98)
Shares used in computing net income (loss) per common share, basic	106,272	105,881	106,200	105,800
Shares used in computing net income (loss) per common share, diluted	116,640	105,881	116,742	105,800

	As of September 30, 2019	**As of December 31, 2018**
	(Unaudited)	
Consolidated Balance Sheet Data		
(In thousands)		
Cash and investments	$ 296,304	$ 160,052
Property and equipment, net	14,540	15,865
Goodwill	44,543	44,543
Other intangible assets	20,157	50,119
Total assets	444,588	284,136
Deferred revenue	1,117	27,046
Current and long-term debt	245,126	245,002
Accumulated deficit	(1,290,306)	(1,471,577)
Total stockholders' equity (deficit)	164,712	(26,405)

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