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): March 13, 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 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 March 13, 2019, we issued a press release to report our financial results for the quarter and year ended December 31, 2018. 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 March 13. 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: March 13, 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 March 13, 2019

Exhibit 99.1

LEXICON PHARMACEUTICALS REPORTS FOURTH QUARTER AND FULL-YEAR 2018 FINANCIAL RESULTS AND PROVIDES A BUSINESS UPDATE

XERMELO® *(telotristat ethyl) 2018 U.S. Net Sales Reached $25.0 Million*

Sotagliflozin in Type 1 Diabetes: March 22 PDUFA Date in U.S., European Commission Decision Expected in Q2 2019 Following Recently-Received Positive CHMP Opinion

The Woodlands, Texas, March 13, 2019 - Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX), today reported financial results for the three months and full-year ended December 31, 2018 and provided a business update.

"In 2018, we achieved continued growth in XERMELO net sales and executed well against our strategic priorities," said Lonnel Coats, Lexicon's president and chief executive officer. "We made significant progress on our pipeline, which included Sanofi's submission of marketing applications for sotagliflozin in type 1 diabetes in the U.S. and Europe as well as advancement of our earlier-stage product candidates, LX2761 in diabetes and LX9211 in neuropathic pain. In 2019, our focus remains on creating long-term value for the company by executing on our strategic and financial objectives."

Fourth Quarter and Full-Year 2018 Product and Pipeline Highlights

XERMELO (telotristat ethyl) 250 mg

- XERMELO U.S. net sales reached $25.0 million in 2018.
- XERMELO received national reimbursement approval in Scotland, Denmark, Sweden, Greece, Luxemburg, Northern Ireland, Wales, Germany, Belgium and the Netherlands for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy.
- Positive analyses on time to sustained improvement in bowel movement frequency with XERMELO were presented at the American Society of Clinical Oncology's Gastrointestinal Cancers Symposium (ASCO GI) and the European Neuroendocrine Tumor Society Conference (ENETS).
- Favorable changes in weight in patients on XERMELO with neuroendocrine tumors (NETs) and carcinoid syndrome who participated in the TELESTAR study along with biochemical and metabolic improvements in diarrhea severity and nutritional status were published in *Clinical Therapeutics*.

Sotagliflozin
Type 1 Diabetes

- Additional positive 52-week data from the pivotal inTandem1 and inTandem2 studies for sotagliflozin in type 1 diabetes were presented at the 78th annual American Diabetes Association Scientific Sessions (ADA) and the European Association for the Study of Diabetes (EASD) 54th annual meeting and published in *Diabetes Care*.
- Lexicon's collaborator, Sanofi, submitted a New Drug Application (NDA) and a Marketing Authorization Application (MAA) for sotagliflozin in type 1 diabetes and the regulatory filings were accepted by the Food and Drug Administration (FDA) and European Medicines Agency (EMA), respectively.

- On January 17, 2019, the FDA Endocrinologic and Metabolic Drugs Advisory Committee voted eight to eight on the question of whether the overall benefits of sotagliflozin outweighed the risks to support approval in type 1 diabetes.
- On February 28, 2019, the EMA Committee for Medicinal Products for Human Use adopted a positive opinion recommending regulatory approval of sotagliflozin for use as an adjunct to insulin therapy to improve glycemic control in adults with type 1 diabetes with a body mass index of 27 kg/m^2 or greater, who have failed to achieve adequate glycemic control despite optimal insulin therapy.
- A target FDA action date under the Prescription Drug User Fee Act (PDUFA) is set for March 22, 2019 and a regulatory decision by the European Commission is expected in Q2 2019.

Type 2 Diabetes

- Patient enrollment continued for eleven Phase 3 sotagliflozin clinical trials in type 2 diabetes being conducted by Sanofi.
- Patient enrollment was completed in the nine Phase 3 clinical trials that support the planned filings for regulatory approval of sotagliflozin in type 2 diabetes.
- Sanofi initiated two additional Phase 3 studies for sotagliflozin in Chinese patients with type 2 diabetes (NCT03760965, NCT03761134).

LX2761

- Lexicon announced topline results from Phase 1 clinical studies of LX2761, an orally-administered, selective sodium-glucose cotransporter type 1 (SGLT1) inhibitor, in healthy subjects and patients with type 2 diabetes that confirmed the drug's unique preclinical profile as a potent gastrointestinal tract-selective SGLT1 inhibitor.

LX9211

- Lexicon announced positive topline results from a Phase 1a clinical study of LX9211, an orally-administered, selective adapter-associated kinase 1 (AAK1) inhibitor that is being developed for neuropathic pain. The Phase 1a study met its primary objectives, identifying a maximum tolerated dose and demonstrating a safety and tolerability profile in healthy human subjects supporting progression of the clinical program.

Fourth Quarter and Full-Year 2018 Financial Highlights

Unless otherwise stated, all comparisons are for the fourth quarter and full year of 2018 compared to the fourth quarter and full year of 2017.

Revenues: Revenues for the fourth quarter decreased to $17.1 million from $34.0 million for the corresponding period in 2017, primarily due to lower revenues recognized under collaboration and license agreements. Full-year 2018 revenues decreased to $63.2 million from $91.7 million, primarily due to timing of revenues recognized from clinical trial activities under the collaboration and license agreements with Sanofi and decreases in milestone payments from Ipsen, partially offset by an increase in net product revenue. Net product revenues for full-year 2018 included $25.0 million and $1.6 million, respectively, from net sales of XERMELO in the U.S. and the sale of bulk tablets to Lexicon's collaborator, Ipsen.

Cost of Sales: Cost of sales related to sales of XERMELO was $0.6 million and $0.5 million, respectively, for the fourth quarter of 2018 and 2017. Full-year 2018 and 2017 cost of sales was $2.5 million and $1.9 million, respectively.

Research and Development (R&D) Expenses: Research and development expenses for the fourth quarter decreased to $12.3 million from $46.3 million for the corresponding period in 2017, primarily due to decreases in our external clinical development costs relating to sotagliflozin. Full-year 2018 R&D expenses decreased to $100.2 million from $152.2 million, primarily due to lower external clinical development costs relating to sotagliflozin and professional and consulting fees.

Selling, General and Administrative (SG&A) Expenses: Selling, general and administrative expenses for the fourth quarter were $16.6 million compared to $16.1 million for the same period in 2017. Full-year 2018 SG&A expenses decreased to $63.8 million from $66.1 million, primarily due to lower salaries and benefits, and decreased marketing costs.

Income Tax Benefit: During 2018, there was no income tax benefit. During 2017, Lexicon recognized an $8.7 million income tax benefit when the intangible assets relating to XERMELO were reclassified from indefinite-lived to finite-lived assets. The income tax benefit was remeasured to $12.7 million for full year 2017.

Net Loss: Net loss for the fourth quarter was $16.8 million, or $0.16 per share, compared to a net loss of $26.6 million, or $0.25 per share, in the corresponding period in 2017. For the fourth quarter 2018, net loss included non-cash, stock-based compensation expense of $2.8 million. For the fourth quarter 2017, net loss included non-cash, stock-based compensation expense of $2.3 million. Net loss for the full-year 2018 was $120.5 million, or $1.14 per share, compared to a net loss of $123.0 million, or $1.17 per share, in 2017. For the full-year 2018, net loss included non-cash, stock-based compensation expense of $11.7 million. For the full-year 2017, net loss included non-cash, stock-based compensation expense of $9.5 million.

Cash and Investments: As of December 31, 2018, Lexicon had $160.1 million in cash and investments, as compared to $310.8 million as of December 31, 2017.

Anticipated Upcoming Milestones

- Q1 2019 – Manuscript publications for XERMELO in carcinoid syndrome diarrhea
- Q1 2019 – Initiation of a Phase 1b study for LX9211
- March 22, 2019 – PDUFA date for sotagliflozin in type 1 diabetes in the U.S.
- Q2 2019 – European Commission decision on marketing application for sotagliflozin in type 1 diabetes in the EU
- June, September 2019 – Presentation of new analyses from pivotal studies of sotagliflozin in type 1 diabetes at the annual ADA and EASD meetings
- 2H 2019 – Topline Phase 1b data for LX9211
- 2019 – Topline data from core Phase 3 studies for sotagliflozin in type 2 diabetes
- 2019 – Patient enrollment in a Phase 2 study for 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 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 6598765. 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 in combination with SSA therapy in adults inadequately controlled by SSAs. XERMELO targets tryptophan hydroxylase, an enzyme that mediates the excess serotonin production within metastatic neuroendocrine tumor (mNET) cells. Lexicon has built the in-house capability and infrastructure to launch and market XERMELO in the U.S., where it retains all commercialization rights. Lexicon also retains rights to market XERMELO in Japan. Lexicon has established a license and collaboration agreement with Ipsen to commercialize XERMELO in Europe and other countries outside of U.S. and Japan.

XERMELO was approved by the U.S. Food and Drug Administration on February 28, 2017 and by the European Commission on September 19, 2017 for the treatment of carcinoid syndrome diarrhea in combination with SSA therapy in adults inadequately controlled by SSA therapy. Carcinoid syndrome is a rare condition that occurs in patients living with metastatic NETs (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.

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 Sotagliflozin

Sotagliflozin is an investigational 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.

Lexicon entered into a collaboration and license agreement with Sanofi in November 2015 under which Lexicon granted Sanofi an exclusive, worldwide (excluding Japan), royalty-bearing right and license to develop, manufacture and commercialize sotagliflozin. Lexicon is responsible for all clinical development activities relating to type 1 diabetes and has exercised 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 U.S. Sanofi is responsible for all clinical development and commercialization of sotagliflozin for the treatment of type 2 diabetes worldwide (excluding Japan) and is solely responsible for the commercialization of sotagliflozin for the treatment of type 1 diabetes outside the U.S. (excluding Japan). A New Drug Application and Marketing Authorization Application for sotagliflozin in type 1 diabetes are currently under review at the U.S. Food and Drug Administration and European Medicines Agency, respectively. The product has not yet been approved for use in the U.S., European Union or any other jurisdiction.

About Lexicon Pharmaceuticals

Lexicon is a fully integrated biopharmaceutical company that is applying a unique approach to gene science based on Nobel Prize-winning technology to discover and develop precise medicines for patients with serious, chronic conditions. Through its Genome5000™ program, Lexicon scientists have studied the role and function of nearly 5,000 genes over the last 20 years and have 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 for carcinoid syndrome diarrhea, Lexicon has a pipeline of promising drug candidates in clinical and pre-clinical development in diabetes and metabolism 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 commercialization of XERMELO (telotristat ethyl), 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, 2017, 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.

Exhibit 99.1

Lexicon Pharmaceuticals, Inc.

Selected Financial Data

Consolidated Statements of Operations Data	**Three Months Ended December 31,**		**Year Ended December 31,**	
(In thousands, except per share data)	**2018**	**2017**	**2018**	**2017**
		(Restated)		**(Restated)**
	(Unaudited)		**(Unaudited)**	
Revenues:				
Net product revenue	$ 7,521	$ 5,447	$ 26,583	$ 15,890
Collaborative agreements	9,479	28,405	36,271	75,621
Royalties and other revenue	71	114	355	178
Total revenues	17,071	33,966	63,209	91,689
Operating expenses:				
Cost of sales (including finite-lived intangible asset amortization)	569	538	2,491	1,899
Research and development, including stock-based compensation of $1,488, $1,207, $6,010 and $4,905, respectively	12,306	46,311	100,243	152,223
Increase in fair value of Symphony Icon purchase liability	-	-	-	2,101
Selling, general and administrative, including stock-based compensation of $1,359, $1,051, $5,686 and $4,567, respectively	16,563	16,133	63,754	66,090
Total operating expenses	29,438	62,982	166,488	222,313
Loss from operations	(12,367)	(29,016)	(103,279)	(130,624)
Interest expense	(5,224)	(2,163)	(20,777)	(6,984)
Interest and other income, net	810	561	3,508	1,954
Net loss before income taxes	(16,781)	(30,618)	(120,548)	(135,654)
Income tax benefit	-	4,009	-	12,661
Net loss	$ (16,781)	$ (26,609)	$ (120,548)	$ (122,993)
Net loss per common share, basic and diluted	$ (0.16)	$ (0.25)	$ (1.14)	$ (1.17)
Shares used in computing net loss per common share, basic and diluted	105,920	105,588	105,830	105,237

Consolidated Balance Sheet Data	**As of December 31, 2018**	**As of December 31, 2017**
(In thousands)		**(Restated)**
	(Unaudited)	
Cash and investments	$ 160,052	$ 310,788
Property and equipment, net	15,865	17,687
Goodwill	44,543	44,543
Other intangible assets	50,119	51,885
Total assets	284,136	436,539
Deferred revenue	27,046	65,254
Current and long-term debt	245,002	245,670
Accumulated deficit	(1,471,577)	(1,365,241)
Total stockholders' (deficit) equity	(26,405)	68,265

Restatement of Previously Issued Financial Statements: During the financial close for fiscal year 2018, the Company determined that the research and development expenses from prior periods were overstated. The financial information for prior periods has been restated to reflect these adjustments.

Exhibit 99.1

For Investor Inquiries:

Kimberly Lee, D.O.
Head of Investor Relations and Corporate Strategy
Lexicon Pharmaceuticals
(281) 863-3383
klee@lexpharma.com

For Media Inquiries:

Chas Schultz
Executive Director, Corporate Communications and Advocacy
Lexicon Pharmaceuticals
(281) 863-3421
cschultz@lexpharma.com