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 12, 2020

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 March 12, 2020, we issued a press release to report our financial results for the quarter and year ended December 31, 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 March 12, 2020

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 12, 2020

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 12, 2020

Exhibit 99.1

LEXICON PHARMACEUTICALS REPORTS FOURTH QUARTER AND FULL-YEAR 2019 FINANCIAL RESULTS AND PROVIDES A BUSINESS UPDATE

XERMELO® (telotristat ethyl) 2019 U.S. Net Sales Reached $31.0 Million

The Woodlands, Texas, March 12, 2020 - Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX), today reported financial results for the three months and full-year ended December 31, 2019 and provided a business update.

“In 2019, we achieved continued growth in our XERMELO (telotristat ethyl) business of nearly 25% year-over-year and made significant strides in advancing pipeline initiatives such as telotristat ethyl in biliary tract cancer and LX9211 in neuropathic pain,” said Lonnel Coats, Lexicon’s president and chief executive officer. “We expect initial clinical efficacy data for telotristat ethyl in biliary tract cancer by the end of this year. As for LX9211, we are initiating a proof-of-concept study in diabetic peripheral neuropathic pain in the first half of this year.”

“We received a response yesterday from the Center for Drug Evaluation and Research (CDER) to our appeal of the FDA’s complete response letter (CRL) for sotagliflozin in type 1 diabetes,” continued Mr. Coats. “The response confirmed the CRL decision, and we are now evaluating the feedback they provided in their response."

“We are engaged in discussions around potential partnerships for sotagliflozin, which will be necessary to enable completion of the long-term outcomes studies, SCORED and SOLOIST, that are designed to demonstrate benefits in and support labeling for heart failure and chronic kidney disease.”

Fourth Quarter and Full-Year 2019 Product and Pipeline Highlights

XERMELO® (telotristat ethyl)

- XERMELO U.S. net sales were $31.0 million in 2019.
- In December, Lexicon completed a safety review of the initial safety run-in cohort of 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. Safety analysis from the first six patients who completed at least a 21-day cycle of treatment with telotristat ethyl in combination with cisplatin and gemcitabine supported the continuation of enrollment with no adjustment in the telotristat ethyl 500 mg three times daily dosing regimen.

Zynquista™ (sotagliflozin)

- In December, Lexicon announced topline data from the Phase 3 SOTA-EMPA study of sotagliflozin in type 2 diabetes. Sotagliflozin 400 mg achieved the primary endpoint of superiority on A1C reduction versus placebo at Week 26 in patients with inadequate glycemic control while on a dipeptidyl peptidase 4 inhibitor, with or without metformin therapy. Sotagliflozin 400mg also achieved the key secondary endpoint of noninferiority versus empagliflozin on A1C reduction from baseline at Week 26. Sotagliflozin was generally well tolerated, with safety results comparable to previously reported safety results in patients with type 2 diabetes.

- In December, Lexicon announced that the U.S. Food and Drug Administration’s (FDA) Office of New Drugs had reiterated the FDA's prior position that the New Drug Application for sotagliflozin in type 1 diabetes cannot be approved in its present form and denied the appeal of the previously issued CRL. Lexicon subsequently appealed the decision to CDER. As indicated above, CDER yesterday reaffirmed the FDA’s position.

LX9211

- Lexicon announced positive topline Phase 1 data for LX9211 in a multiple ascending dose study in healthy volunteers that demonstrated a favorable safety and pharmacokinetics profile supportive of once-daily dosing.

Fourth Quarter and Full-Year 2019 Financial Highlights

Unless otherwise stated, all comparisons are for the fourth quarter and full year of 2019 compared to the fourth quarter and full year of 2018.

Revenues: Revenues for the fourth quarter decreased to $8.7 million from $17.1 million for the corresponding period in 2018, primarily due to lower revenues recognized under collaboration and license agreements. Full-year 2019 revenues increased to $322.1 million from $63.2 million, primarily due to collaboration revenues recognized from the termination of the alliance with Sanofi and recognition of remaining amounts allocated to the performance obligations from the initial Sanofi collaboration agreement for development activities relating to sotagliflozin, as well as an increase from net product revenue. Net product revenues for full-year 2019 included $31.0 million and $1.3 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 $0.7 million and $0.6 million, respectively, for the fourth quarter of 2019 and 2018. Full-year 2019 and 2018 cost of sales was $3.2 million and $2.5 million, respectively.

Research and Development (R&D) Expenses: Research and development expenses for the fourth quarter increased to $40.6 million from $12.3 million for the corresponding period in 2018, primarily due to increases in external clinical development costs relating to sotagliflozin subsequent to Lexicon regaining the rights and responsibilities for development and commercialization of sotagliflozin pursuant to the termination of the Sanofi alliance. Full-year R&D expenses for 2019 decreased to $91.9 million from $100.2 million, due to decreases in professional and consulting fees and lower external clinical development costs.

Selling, General and Administrative (SG&A) Expenses: Selling, general and administrative expenses for the fourth quarter were $14.6 million compared to $16.6 million for the same period in 2018. Full-year 2019 SG&A expenses decreased to $56.8 million from $63.8 million, primarily due to lower marketing expenses and professional and consulting costs.

Impairment Loss on Intangible Asset: An impairment loss in 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 in 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. During 2018, there was no income tax benefit.

Net Income (Loss): Net loss for the fourth quarter was $51.1 million, or $0.48 per share, as compared to a net loss of $16.8 million, or $0.16 per share, in the corresponding period in 2018. For the fourth quarter 2019, net loss included non-cash, stock-based compensation expense of $3.5 million. For the fourth quarter 2018, net loss included non-cash, stock-based compensation expense of $2.8 million. Net income for the full-year 2019 was $130.1 million, or $1.16 per diluted share, as compared to a net loss of $120.5 million, or $1.14 per share, in 2018. For the full-year 2019, net income included non-cash, stock-based compensation expense of $14.2 million. For the full-year 2018, net loss included non-cash, stock-based compensation expense of $11.7 million.

Cash and Investments: As of December 31, 2019, Lexicon had $271.7 million in cash and investments, as compared to $160.1 million as of December 31, 2018.

Anticipated Near-Term Milestones

- H1 2020 – Initiation of a Phase 2 study for LX9211 in diabetic peripheral neuropathic pain
- H1 2020 – Completion of patient enrollment in the first efficacy cohort of the Phase 2 study of telotristat ethyl in biliary tract cancer
- H1 2020 – Topline results from core Phase 3 sotagliflozin studies in type 2 diabetes
- June 2020 – Presentation of Phase 3 data for sotagliflozin in type 2 diabetes at the 80th Scientific Sessions of the American Diabetes Association (ADA)
- September 2020 – Presentation of Phase 3 data for sotagliflozin in type 2 diabetes at the 56th Annual Meeting of the European Association for the Study of Diabetes (EASD)
- Q4 2020 – Data from the first efficacy cohort of 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 ET / 7:00 am CT 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 4187725. 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/m^2, 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 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.

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)	**2019**	**2018**	**2019**	**2018**
	(Unaudited)		**(Unaudited)**	
Revenues				
Net product revenue	$ 8,568	$ 7,521	$ 32,331	$ 26,583
Collaborative agreements	22	9,479	289,231	36,271
Royalties and other revenue	137	71	511	355
Total revenues	8,727	17,071	322,073	63,209
Operating expenses:				
Cost of sales (including finite-lived intangible asset amortization)	774	569	3,231	2,491
Research and development, including stock-based compensation of $1,727, $1,488, $7,096 and $6,010, respectively	40,606	12,307	91,924	100,243
Selling, general and administrative, including stock-based compensation of $1,752, $1,359, $7,122 and $5,686, respectively	14,564	16,562	56,835	63,754
Impairment loss on intangible asset	—	—	28,638	—
Total operating expenses	55,944	29,438	180,628	166,488
Income (loss) from operations	(47,217)	(12,367)	141,445	(103,279)
Interest expense	(5,191)	(5,224)	(20,676)	(20,777)
Interest and other income, net	1,270	810	3,350	3,508
Net income (loss) before income taxes	(51,138)	(16,781)	124,119	(120,548)
Income tax benefit	—	—	6,014	—
Net income (loss)	$ (51,138)	$ (16,781)	$ 130,133	$ (120,548)
Net income (loss) per common share, basic	$ (0.48)	$ (0.16)	$ 1.23	$ (1.14)
Net income (loss) per common share, diluted	$ (0.48)	$ (0.16)	$ 1.16	$ (1.14)
Shares used in computing net income (loss) per common share, basic	106,272	105,920	106,218	105,830
Shares used in computing net income (loss) per common share, diluted	106,272	105,920	116,747	105,830

	As of December 31, 2019	**As of December 31, 2018**
	(Unaudited)	
Consolidated Balance Sheet Data		
(In thousands)		
Cash and investments	$ 271,659	$ 160,052
Property and equipment, net	14,047	15,865
Goodwill	44,543	44,543
Other intangible assets	19,716	50,119
Total assets	417,715	284,136
Deferred revenue	—	25,990
Current and long-term debt	245,183	245,002
Accumulated deficit	(1,341,444)	(1,471,577)
Total stockholders' equity (deficit)	117,101	(26,405)

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