
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): April 27, 2020

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)

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	LXX	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 April 27, 2020, we issued a press release to report our financial results for the quarter ended March 31, 2020. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	— Press Release of Lexicon Pharmaceuticals, Inc. dated April 27, 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: April 27, 2020

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

Index to Exhibits

Exhibit No.

Description

99.1

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[Press Release of Lexicon Pharmaceuticals, Inc. dated April 27, 2020](#)

LEXICON PHARMACEUTICALS REPORTS FIRST QUARTER 2020 FINANCIAL RESULTS AND PROVIDES A BUSINESS UPDATE*17% Increase in XERMELO® U.S. Net Sales*

The Woodlands, Texas, April 27, 2020 - Lexicon Pharmaceuticals, Inc (Nasdaq: LXRX), today reported financial results and provided a business update for the three months ended March 31, 2020.

“We achieved 17% growth in XERMELO net sales for the first quarter of 2020 compared to the prior-year period, and we see favorable growth dynamics going forward,” said Lonnel Coats, Lexicon’s president and chief executive officer. “We have made good progress on our pipeline, having fully enrolled the first efficacy cohort of 20 patients in the Phase 2 telotristat ethyl study in biliary tract cancer from which we expect top-line data later this year. Importantly, we are steps closer to advancing our next major innovation, LX9211, into a proof-of-concept study in diabetic peripheral neuropathic pain, which we expect to initiate mid-year. Finally, we are making progress on the close-out of the two sotagliflozin outcome studies, SCORED and SOLOIST, which we expect to conclude in the near term.”

First Quarter Product and Pipeline Highlights**XERMELO® (telotristat ethyl)**

- XERMELO U.S. net sales were \$7.9 million in the first quarter of 2020.
- Medical record data on XERMELO’s antiproliferative effects were presented at the American Society for Clinical Oncology (ASCO) 2020 Symposium in gastrointestinal cancers, showing that, among 200 patients with metastatic neuroendocrine tumors on standard background therapies, the mean tumor size was 0.59 cm smaller (p=0.006) in scans obtained after initiation of XERMELO.
- Medical record data on XERMELO’s antiproliferative effects in patients with carcinoid syndrome presented at the European Neuroendocrine Tumor Society (ENETS) meeting demonstrated that most patients with metastatic neuroendocrine tumors on standard background therapies had no tumor progression at 6, 12 and 18 months following initiation of XERMELO, with a median time to tumor progression (TTP) of 39.8 months. The majority of patients also experienced progression-free survival (PFS) in the period following initiation of XERMELO, with a median PFS of 23.7 months. In addition, in a subset of 22 patients with recorded biomarker data, mean serotonin levels decreased significantly in the period following initiation of XERMELO. Patients also improved on carcinoid syndrome (CS) symptoms, body weight and performance status.
- The **Telotristat Ethyl for Advanced Biliary Tract Cancer**, or TELE-ABC, study, a Phase 2a clinical study of telotristat ethyl in patients with biliary tract cancer, completed enrollment of 20 patients in the first efficacy cohort.

Sotagliflozin

- In March, Lexicon announced the early close-out of the two long-term outcomes studies of sotagliflozin, SCORED and SOLOIST, that were originally designed to demonstrate benefits in and support labeling for heart failure and chronic kidney disease.

First Quarter 2020 Financial Highlights

Revenues: Revenues for the three months ended March 31, 2020 decreased to \$8.0 million from \$9.2 million for the corresponding period in 2019, primarily due to a decrease of collaborative revenues, partially offset by an increase in net product revenue. Net product revenues for the three months ended March 31, 2020 consisted of \$7.9 million from net sales of XERMELO in the U.S., up 17% from the prior year quarter.

Cost of Sales: Cost of sales related to sales of XERMELO for each of the three months ended March 31, 2020 and 2019 was \$0.6 million.

Research and Development (R&D) Expenses: Research and development expenses for the three months ended March 31, 2020 increased to \$55.2 million from \$12.0 million for the corresponding period in 2019, primarily due to increases in external clinical development costs related to sotagliflozin subsequent to the termination of the alliance with Sanofi.

Selling, General and Administrative (SG&A) Expenses: Selling, general and administrative expenses for the three months ended March 31, 2020 were \$14.7 million as compared to \$14.1 million for the corresponding period in 2019.

Net Loss: Net loss for the three months ended March 31, 2020 was \$66.6 million, or \$0.63 per share, as compared to a net loss of \$21.8 million, or \$0.21 per share, in the corresponding period in 2019. For the three months ended March 31, 2020 and 2019, net income included non-cash, stock-based compensation expense of \$4.4 million and \$3.4 million, respectively.

Cash and Investments: As of March 31, 2020, Lexicon had \$249.1 million in cash and investments, as compared to \$271.7 million as of December 31, 2019.

Anticipated Near-Term Milestones

- Mid-2020 – Initiation of the Phase 2 study for LX9211 in diabetic peripheral neuropathic pain
- Q4 2020 – Data from the first efficacy cohort of the Phase 2 study of telotristat ethyl in biliary tract cancer
- 2020 – Manuscript publications for XERMELO in carcinoid syndrome diarrhea

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 9403118. 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 ($\geq 5\%$) 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

Discovered using Lexicon's unique approach to gene science, sotagliflozin 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. Sotagliflozin 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.

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.lexipharma.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), 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, 2019, 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

(In thousands, except per share data)

	Three Months Ended March 31,	
	2020	2019
	(Unaudited)	
Revenues		
Net product revenue	\$ 7,877	\$ 6,740
Collaborative agreements	8	2,439
Royalties and other revenue	114	37
Total revenues	7,999	9,216
Operating expenses:		
Cost of sales (including finite-lived intangible asset amortization)	568	553
Research and development, including stock-based compensation of \$2,176 and \$1,768, respectively	55,181	12,022
Selling, general and administrative, including stock-based compensation of \$2,256 and \$1,643, respectively	14,688	14,110
Total operating expenses	70,437	26,685
Loss from operations	(62,438)	(17,469)
Interest expense	(5,131)	(5,117)
Interest and other income, net	958	789
Net loss	\$ (66,611)	\$ (21,797)
Net loss per common share, basic and diluted	\$ (0.63)	\$ (0.21)
Shares used in computing net loss per common share, basic and diluted	106,536	106,054

Consolidated Balance Sheet Data

(In thousands)

	As of March 31, 2020	As of December 31,
	(Unaudited)	2019
Cash and investments	\$ 249,137	\$ 271,659
Property and equipment, net	13,582	14,047
Goodwill	44,543	44,543
Intangible assets	19,275	19,716
Total assets	370,567	417,715
Current and long-term debt	245,222	245,183
Accumulated deficit	(1,408,055)	(1,341,444)
Total stockholders' equity	54,777	117,101

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