
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): May 3, 2018

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)

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 May 3, 2018, we issued a press release to report our financial results for the three months ended March 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	— Press Release of Lexicon Pharmaceuticals, Inc. dated May 3, 2018

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: May 3, 2018

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

Index to Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	— Press Release of Lexicon Pharmaceuticals, Inc. dated May 3, 2018

LEXICON PHARMACEUTICALS REPORTS FIRST QUARTER 2018 FINANCIAL RESULTS AND PROVIDES A BUSINESS UPDATE

XERMELO® (telotristat ethyl) Quarterly U.S. Net Sales Reach \$5.4 Million

Filings Submitted for Regulatory Approval of Sotagliflozin in Type 1 Diabetes

The Woodlands, Texas, May 3, 2018 - Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX), today reported financial results for the three months ended March 31, 2018 and highlighted progress with the company's first commercial product, XERMELO® (telotristat ethyl), its pipeline drug candidates and its overall business. The company will conduct a conference call and webcast today at 8:00 am EDT / 7:00 am CDT to discuss the financial results and to provide a business update.

"Although we are treating more people affected with carcinoid syndrome diarrhea than ever before, we still have much work to do," said Lonnel Coats, Lexicon's president and chief executive officer. "We continue to position the company for future growth and to build long-term sustainable value for shareholders. As such, we are excited about exploring the investigational use of telotristat ethyl in oncology indications this year. For sotagliflozin, we are a step closer to making the therapy available to people with type 1 diabetes, with the recent regulatory submissions in the U.S. and in Europe and the European Medicines Agency's acceptance of the filing in Europe. Finally, we look forward to reporting clinical data later this year from our earlier-stage product candidates, LX2761 and LX9211, in diabetes and neuropathic pain, respectively, which we believe will create long-term value for the company."

First Quarter Product and Pipeline Highlights

XERMELO (telotristat ethyl) 250 mg

- Data from a poster highlighting time to sustained improvement in bowel movement frequency with XERMELO were presented at the 2018 American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO GI; San Francisco) in January.

Sotagliflozin

- Lexicon's collaborator Sanofi submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in March for sotagliflozin, for use in combination with insulin therapy to improve glycemic control in adults with type 1 diabetes mellitus.
- Sanofi submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in March for sotagliflozin, for use in combination with insulin therapy to improve glycemic control in adults with type 1 diabetes mellitus, and the review of the MAA under the Centralized Procedure began on March 29.

LX2761

- A Phase 1b clinical trial of LX2761, an orally administered drug candidate selectively targeted to inhibit SGLT1 (sodium-glucose cotransporter type 1) in the gastrointestinal tract, remains ongoing in people with type 2 diabetes.

LX9211

- A Phase 1a clinical trial of LX9211, an orally-administered drug candidate selectively targeted to inhibit AAK1 (adapter-associated kinase 1), remains ongoing in healthy volunteers.

First Quarter 2018 Financial Highlights

Revenues: Revenues for the first quarter of 2018 increased 38% to \$25.2 million from \$18.3 million for the corresponding period in 2017, primarily due to an increase in net product revenues recognized from the sale of XERMELO in the U.S. to \$5.4 million from \$0.7 million and increased revenue from collaborative agreements.

Cost of Sales: Cost of sales related to sales of XERMELO for the first quarter of 2018 increased 137% to \$0.5 million from \$0.2 million for the corresponding period in 2017.

Research and Development (R&D) Expenses: Research and development expenses increased 10% to \$47.8 million for the first quarter of 2018 from \$43.6 million for the corresponding period in 2017, primarily due to higher external clinical development expenses relating in substantial part to development of sotagliflozin in type 2 diabetes and professional and consulting fees related to sotagliflozin NDA preparation.

Selling, General and Administrative (SG&A) Expenses: Selling, general and administrative expenses for the first quarter of 2018 were flat year-over-year at \$14.9 million.

Consolidated Net Loss: Net loss for the first quarter of 2018 was \$42.1 million, or \$0.40 per share, compared to a net loss of \$34.9 million, or \$0.33 per share, in the corresponding period in 2017. For the first quarter 2018 and 2017, net loss included non-cash, stock-based compensation expense of \$3.1 million and \$2.2 million, respectively.

Cash and Investments: As of March 31, 2018, Lexicon had \$262.3 million in cash and investments, as compared to \$310.8 million as of December 31, 2017.

Anticipated Upcoming Milestones

- 2Q 2018 - Initiation of additional Phase 3 sotagliflozin study in type 2 diabetes by Sanofi
- 3Q 2018 - Phase 1b data for LX2761 in type 2 diabetes
- June 2018 - Sotagliflozin data presentations at the American Diabetes Association 78th Scientific Sessions (ADA; June 22-26, 2018; Orlando, FL)
- October 2018 - Sotagliflozin data presentations at the 54th Annual Meeting of the European Association for the Study of Diabetes (EASD; October 1-5, 2018; Berlin, Germany)
- 2H 2018 - Initiation of clinical studies for telotristat ethyl in neuroendocrine tumors and biliary tract cancers
- 2H 2018 - Phase 1a data for LX9211 in neuropathic pain
- 2018 - Manuscript publications for XERMELO and sotagliflozin
- 2018 - Launch of XERMELO by Ipsen in additional European countries

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 3191269. The live webcast and replay may be accessed by visiting Lexicon's website at www.lexipharma.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 somatostatin analog (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 ($\geq 5\%$) 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 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 and regulatory filings for sotagliflozin, LX2761 and LX9211 and the potential therapeutic and commercial potential of XERMELO, 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 obtain regulatory approvals of sotagliflozin and successfully conduct preclinical and clinical development and obtain necessary regulatory approvals of 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.

Lexicon Pharmaceuticals, Inc.

Selected Financial Data

Consolidated Statements of Operations Data

(In thousands, except per share data)

	Three Months Ended	
	March 31,	
	2018	2017
	(unaudited)	
Revenues:		
Net product revenue	\$ 5,460	\$ 721
Collaborative agreements	19,665	17,565
Royalties and other revenue	82	7
Total revenues	25,207	18,293
Operating expenses:		
Cost of sales (including finite-lived intangible asset amortization)	533	225
Research and development, including stock-based compensation of \$1,655 and \$1,184, respectively	47,783	43,581
Increase in fair value of Symphony Icon purchase liability	—	2,101
Selling, general and administrative, including stock-based compensation of \$1,419 and \$1,047, respectively	14,857	14,871
Total operating expenses	63,173	60,778
Loss from operations	(37,966)	(42,485)
Interest expense	(5,114)	(1,588)
Interest and other income, net	1,005	530
Net loss before income taxes	(42,075)	(43,543)
Income tax benefit	—	8,652
Consolidated net loss	\$ (42,075)	\$ (34,891)
Consolidated net loss per common share, basic and diluted	\$ (0.40)	\$ (0.33)
Shares used in computing consolidated net loss per common share, basic and diluted	105,668	104,461

Consolidated Balance Sheet Data

(In thousands)

	March 31, 2018	December 31, 2017
	(unaudited)	
Cash and investments	\$ 262,272	\$ 310,788
Property and equipment, net	17,244	17,687
Goodwill	44,543	44,543
Other intangible assets	51,444	51,885
Total assets	386,813	436,539
Deferred revenue	29,514	62,527
Current and long-term debt	245,396	245,670
Accumulated deficit	(1,409,267)	(1,381,404)
Total stockholders' equity	26,194	52,102

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