
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 01, 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 November 1, 2018, we issued a press release to report our financial results for the three months ended September 30, 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 November 01, 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: November 01, 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 November 01, 2018

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

The Woodlands, Texas, November 1, 2018 - [Lexicon Pharmaceuticals, Inc.](#) (Nasdaq: LXX), today reported financial results and provided a business update for the three months ended September 30, 2018.

“In the third quarter, we and our collaborator, Sanofi, have been working diligently with regulatory agencies to make sotagliflozin available for patients with type 1 diabetes as quickly as possible and we continue to make progress in growing XERMELO for its current indication,” said Lonnel Coats, Lexicon’s president and chief executive officer. “Our collaborator, Ipsen, continues to gain approvals and market authorizations for XERMELO in Europe. We are making good progress on our pipeline. By end of year, we expect to start a clinical trial for telotristat ethyl, the investigational form of XERMELO, in biliary tract cancer as well as announce data for LX2761 in diabetes and LX9211, a neuropathic pain candidate, in healthy volunteers.”

Third Quarter Product and Pipeline Highlights

XERMELO (telotristat ethyl) 250 mg

- XERMELO was approved in Australia in September for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by somatostatin analog (SSA) therapy.
- In the third quarter, Ipsen launched XERMELO in several European countries including Sweden and Switzerland.

Sotagliflozin

- In September, clinical data for sotagliflozin were presented at the European Association for the Study of Diabetes (EASD) 54th annual meeting. Data from patient exit interviews from a sotagliflozin Phase 3 study were also presented, reporting meaningful improvements in patient reported outcomes.

Third Quarter 2018 Financial Highlights

Revenues: Revenues for the three months ended September 30, 2018 decreased to \$6.9 million from \$26.9 million for the corresponding period in 2017, primarily due to lower revenues recognized from the collaboration and license agreement with Sanofi, partially offset by an increase in net product revenues. Net product revenues for the three months ended September 30, 2018 included \$6.3 million from net sales of XERMELO in the U.S., up 19% from the prior year quarter and 5% from the second quarter of 2018.

Cost of Sales: Cost of sales related to sales of XERMELO for each of the three months ended September 30, 2018 and 2017 was \$0.6 million.

Research and Development (R&D) Expenses: Research and development expenses for the three months ended September 30, 2018 decreased to \$13.8 million from \$39.1 million for the corresponding period in 2017, primarily due to lower external clinical development costs relating to sotagliflozin.

Selling, General and Administrative (SG&A) Expenses: Selling, general and administrative expenses for the three months ended September 30, 2018 decreased to \$15.6 million from \$16.7 million for the corresponding period in 2017, primarily due to decreased marketing costs.

Net Loss: Net loss for the three months ended September 30, 2018 was \$27.5 million, or \$0.26 per share, compared to a net loss of \$30.7 million, or \$0.29 per share, in the corresponding period in 2017. For the three months ended

September 30, 2018 and 2017, net loss included non-cash, stock-based compensation expense of \$2.9 million and \$2.6 million, respectively.

Cash and Investments: As of September 30, 2018, Lexicon had \$187.3 million in cash and investments, as compared to \$310.8 million as of December 31, 2017.

Anticipated Near-Term Milestones

- 4Q 2018 - Phase 1b data for LX2761 in type 2 diabetes
- 4Q 2018 - Phase 1a data for LX9211 (neuropathic pain candidate) in healthy volunteers
- 4Q 2018 - Initiation of clinical development of telotristat ethyl in biliary tract cancer
- March 22, 2019 - PDUFA date for sotagliflozin in type 1 diabetes

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 6394419. 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 ($\geq 5\%$) 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 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 a Marketing Authorization Application for sotagliflozin are currently under review at the U.S. Food and Drug Administration and the European Medicines Agency, respectively, and the product has not yet been approved for use in the U.S. or in Europe.

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 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		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	
Revenues:				
Net product revenue	\$ 6,286	\$ 5,830	\$ 19,062	\$ 10,443
Collaborative agreements	446	21,112	26,470	46,781
Royalties and other revenue	124	—	284	64
Total revenues	6,856	26,942	45,816	57,288
Operating expenses:				
Cost of sales (including finite-lived intangible asset amortization)	551	599	1,922	1,361
Research and development, including stock-based compensation of \$1,472, \$1,345, \$4,522 and \$3,698, respectively	13,769	39,137	88,141	109,653
Increase in fair value of Symphony Icon purchase liability	—	—	—	2,101
Selling, general and administrative, including stock-based compensation of \$1,405, \$1,235, \$4,327 and \$3,516, respectively	15,579	16,724	47,191	50,069
Total operating expenses	29,899	56,460	137,254	163,184
Loss from operations	(23,043)	(29,518)	(91,438)	(105,896)
Interest expense	(5,252)	(1,619)	(15,553)	(4,821)
Interest and other income, net	783	415	2,698	1,393
Net loss before income taxes	(27,512)	(30,722)	(104,293)	(109,324)
Income tax benefit	—	—	—	8,652
Net loss	\$ (27,512)	\$ (30,722)	\$ (104,293)	\$ (100,672)
Net loss per common share, basic and diluted	\$ (0.26)	\$ (0.29)	\$ (0.99)	\$ (0.96)
Shares used in computing net loss per common share, basic and diluted	105,881	105,582	105,800	105,119

Consolidated Balance Sheet Data

(In thousands)

	September 30, 2018	December 31, 2017
	(unaudited)	
Cash and investments	\$ 187,297	\$ 310,788
Property and equipment, net	16,299	17,687
Goodwill	44,543	44,543
Other intangible assets	50,561	51,885
Total assets	310,192	436,539
Deferred revenue	23,108	62,527
Current and long-term debt	244,945	245,670
Accumulated deficit	(1,471,485)	(1,381,404)
Total stockholders' equity	(29,401)	52,102

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