
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): July 31, 2019

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 July 31, 2019, we issued a press release to report our financial results for the three months ended June 30, 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	— Press Release of Lexicon Pharmaceuticals, Inc. dated July 31, 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: July 31, 2019

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

Index to Exhibits

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99.1	— Press Release of Lexicon Pharmaceuticals, Inc. dated July 31, 2019

LEXICON PHARMACEUTICALS REPORTS SECOND QUARTER 2019 FINANCIAL RESULTS AND PROVIDES A BUSINESS UPDATE

The Woodlands, Texas, July 31, 2019 - Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX), today reported financial results and provided a business update for the three months ended June 30, 2019.

“We are pleased that recent preliminary results of three Phase 3 clinical trials support the potential benefits Zynquista may bring to people with type 2 diabetes and particularly those with chronic kidney disease,” said Lonnel Coats, Lexicon’s president and chief executive officer. “We are disappointed in Sanofi’s announcement of its purported termination of our alliance but are encouraged by the results that we have received thus far. We expect the balance of the core Phase 3 studies will be completed this year. As for our XERMELO business, we saw 24% growth in XERMELO net sales in the U.S. in the second quarter of 2019 versus the same period in 2018 and continue to make good progress on that front while effectively managing our resources and spend.”

Second Quarter Product and Pipeline Highlights

XERMELO® (telotristat ethyl)

- XERMELO U.S. net sales were \$7.4 million in the second quarter of 2019.
- 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, continues to enroll patients.

Zynquista™ (sotagliflozin)

- In April, the European Commission granted marketing authorization for Zynquista in both a 200-mg and 400-mg dose for use as an adjunct to insulin therapy to improve blood sugar (glycemic) control in adults with type 1 diabetes (T1D) mellitus with a body mass index (BMI) \geq 27 kg/m², who have failed to achieve adequate glycemic control despite optimal insulin therapy.

Second Quarter 2019 Financial Highlights

Revenues: Revenues for the three months ended June 30, 2019 decreased to \$9.7 million from \$13.8 million for the corresponding period in 2018, primarily due to lower revenues recognized from our collaboration and license agreement with Sanofi, partially offset by an increase in net product revenues. Net product revenues for the three months ended June 30, 2019 included \$7.4 million from net sales of XERMELO in the U.S. and \$1.3 million from the sales of bulk XERMELO tablets to Ipsen, cumulatively up 19% from the prior year quarter.

Cost of Sales: Cost of sales related to sales of XERMELO for the three months ended June 30, 2019 and 2018 was \$1.3 million and \$0.8 million, respectively.

Research and Development (R&D) Expenses: Research and development expenses for the three months ended June 30, 2019 decreased to \$12.6 million from \$26.5 million for the corresponding period in 2018, primarily due to lower external clinical development costs relating to Zynquista.

Selling, General and Administrative (SG&A) Expenses: Selling, general and administrative expenses for the three months ended June 30, 2019 decreased to \$14.3 million from \$16.8 million for the corresponding period in 2018, primarily due to decreased marketing costs.

Net Loss: Net loss for the three months ended June 30, 2019 was \$23.0 million, or \$0.22 per share, compared to a net loss of \$34.5 million, or \$0.33 per share, in the corresponding period in 2018. For the three months ended June 30, 2019 and 2018, net loss included non-cash, stock-based compensation expense of \$3.8 million and \$2.9 million, respectively.

Cash and Investments: As of June 30, 2019, Lexicon had \$106.0 million in cash and investments, as compared to \$160.1 million as of December 31, 2018.

Anticipated Near-Term Milestones

- September 2019 – Presentation of new analyses from pivotal studies of Zynquista in type 1 diabetes at the 55th Annual Meeting of the European Association for the Study of Diabetes (EASD)
- 2H 2019 – Topline Phase 1b data for LX9211
- 2H 2019 – Topline results from core Phase 3 studies for Zynquista in type 2 diabetes
- 2H 2019 – Completion of patient enrollment of the initial safety cohort in 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 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 5789855. 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. XERMELO is approved in the United States, the European Union and certain additional countries 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.

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 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/m², 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.

Lexicon has granted Sanofi an exclusive worldwide (excluding Japan) license to develop, manufacture and commercialize Zynquista. Lexicon remains responsible for all clinical development activities relating to type 1 diabetes and Sanofi is responsible for all clinical development activities of Zynquista for the treatment of type 2 diabetes. Sanofi has delivered to Lexicon a notice purporting to terminate the alliance. Lexicon has notified Sanofi that it considers the notice invalid and Sanofi to be in breach of contract.

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 status of its alliance with Sanofi, the commercialization of XERMELO (telotristat ethyl) and Zynquista (sotagliflozin), and 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, 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.

Lexicon Pharmaceuticals, Inc.

Selected Financial Data

Consolidated Statements of Operations Data

(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(Unaudited)		(Unaudited)	
Revenues:				
Net product revenue.....	\$ 8,672	\$ 7,316	\$ 15,412	\$ 12,776
Collaborative agreements.....	860	6,404	3,299	26,236
Royalties and other revenue.....	150	78	187	160
Total revenues.....	9,682	13,798	18,898	39,172
Operating expenses:				
Cost of sales (including finite-lived intangible asset amortization).....	1,327	838	1,880	1,371
Research and development, including stock-based compensation of \$1,903, \$1,395, \$3,671 and \$3,050, respectively.....	12,637	26,477	24,659	74,173
Selling, general and administrative, including stock-based compensation of \$1,863, \$1,503, \$3,506 and \$2,922, respectively.....	14,263	16,755	28,373	31,612
Total operating expenses	28,227	44,070	54,912	107,156
Loss from operations	(18,545)	(30,272)	(36,014)	(67,984)
Interest expense	(5,164)	(5,187)	(10,281)	(10,300)
Interest and other income, net.....	691	910	1,480	1,915
Net loss	\$ (23,018)	\$ (34,549)	\$ (44,815)	\$ (76,369)
Net loss per common share, basic and diluted.....	\$ (0.22)	\$ (0.33)	\$ (0.42)	\$ (0.72)
Shares used in computing net loss per common share, basic and diluted.....	106,272	105,848	106,164	105,758

Consolidated Balance Sheet Data

(In thousands)

	As of June 30, 2019	As of December 31, 2018
	(Unaudited)	
Cash and investments.....	\$ 105,977	\$ 160,052
Property and equipment, net.....	15,007	15,865
Goodwill.....	44,543	44,543
Other intangible assets.....	49,236	50,119
Total assets.....	233,143	284,136
Deferred revenue.....	26,511	27,046
Current and long-term debt.....	245,068	245,002
Accumulated deficit.....	(1,516,392)	(1,471,577)
Total stockholders' equity (deficit).....	(64,886)	(26,405)

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