
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): February 22, 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 February 22, 2018, we issued a press release to report our financial results for the quarter and year ended December 31, 2017. 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 February 22, 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: February 22, 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 February 22, 2018

LEXICON PHARMACEUTICALS REPORTS FOURTH QUARTER AND FULL-YEAR 2017 FINANCIAL RESULTS AND PROVIDES A BUSINESS UPDATE

XERMELO® (telotristat ethyl) U.S. Net Sales Since March 2017 Launch Reach \$15.1 Million

Regulatory Filings for Sotagliflozin in Patients with Type 1 Diabetes Expected in First Quarter of 2018

The Woodlands, Texas, February 22, 2018 - [Lexicon Pharmaceuticals, Inc.](#) (Nasdaq: LXX), today reported financial results for the three months and full-year ended December 31, 2017 and highlighted progress with the company's 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 EST / 7:00 am CST to discuss the financial results and to provide a business update.

"2017 was a historic inflection point for Lexicon as we became a fully-integrated, commercial-stage biopharmaceutical company with the launch of our first product, XERMELO, bringing a novel, oral tryptophan hydroxylase inhibitor to market," said Lonnel Coats, Lexicon's president and chief executive officer."

Accomplishments in 2017 included:

- The approval and launch of XERMELO in the U.S and Europe,
- Completion of the registrational sotagliflozin clinical program in type 1 diabetes, encompassing three successful Phase 3 clinical trials which delivered the largest body of safety and efficacy data ever for a potential oral adjunct to insulin therapy for type 1 diabetes and the broadest range of adult patients,
- Initiation of Phase 3 studies for sotagliflozin scheduled to enroll more than 15,000 patients with type 2 diabetes by our collaborator, Sanofi, including dedicated studies in patients with stage 3 and 4 chronic kidney disease (SOTA-CKD3 and SOTA-CKD4) and a 10,500-patient cardiovascular and renal outcomes trial (SCORE), and
- Advancement of our earlier-stage pipeline, including initiation of human clinical trials of LX2761 and LX9211 in diabetes and neuropathic pain, respectively.

"We enter 2018 with a well-defined strategy to position the company for future growth and to build long-term sustainable value for shareholders," continued Mr. Coats. "XERMELO remains a significant franchise for us, and we are extremely excited about exploring the use of telotristat ethyl in additional therapeutic indications where the role of serotonin inhibition has shown preclinical promise. In parallel, we and Sanofi look forward to filing for regulatory approval in the U.S. and in Europe for sotagliflozin in type 1 diabetes in the upcoming weeks. Lastly, we continue to advance our earlier-stage product candidates in areas we believe will create long-term value for the company."

Fourth Quarter and Full-Year 2017 Product and Pipeline Highlights

XERMELO (telotristat ethyl) 250 mg

In 2017, XERMELO was approved and launched in the U.S. and in the European Union as the first and only oral treatment for carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adult cancer patients with metastatic neuroendocrine tumors (NETs) inadequately controlled by SSA therapy. Within three months of the U.S. launch, XERMELO was included in NCCN guidelines in oncology.

- The FDA and EMA approved XERMELO 250 mg in the U.S. and in the European Union in February and September, respectively.
- XERMELO was launched in the U.S. shortly after approval and was included as a recommended treatment option in the latest National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for NET patients with carcinoid syndrome diarrhea. The NCCN designated XERMELO together with SSA therapy as a

category 2A treatment for adults inadequately controlled by SSA therapy. XERMELO was also included in the NCCN Drugs & Biologics Compendium.

- Ipsen, Lexicon's collaborator, launched XERMELO for the treatment of carcinoid syndrome diarrhea in combination with SSA therapy in adults inadequately controlled by SSA therapy in the United Kingdom, Germany and Austria.

Sotagliflozin

Type 1 Diabetes

In 2017, sotagliflozin achieved favorable results from the inTandem Phase 3 clinical program in type 1 diabetes, with the publication of inTandem3 results in the September issue of New England Journal of Medicine, and U.S. and European Union regulatory filings expected in 1Q 2018.

- Lexicon announced statistically significant 24-week inTandem1 and inTandem2 primary endpoint data and outcomes on secondary endpoints at 24 weeks (presented at the 77th American Diabetes Association (ADA) Scientific Sessions and the European Association for the Study of Diabetes (EASD) 53rd annual meeting), as well as maintenance of benefit and favorable safety results at 52 weeks.
- Lexicon exercised its option under its collaboration and license agreement with Sanofi to co-promote sotagliflozin for the treatment of type 1 diabetes in the U.S.
- Lexicon announced positive pooled continuous glucose monitoring data from the pivotal Phase 3 inTandem1 and inTandem2 studies of sotagliflozin.
- The company announced positive top-line inTandem3 results which were published in the *New England Journal of Medicine*.

Type 2 Diabetes

Sanofi launched a robust type 2 diabetes clinical program for sotagliflozin, encompassing more than 15,000 patients and including dedicated studies in patients with stage 3 and 4 chronic kidney disease and a 10,500-patient cardiovascular and renal impairment outcomes study. Lexicon expects data from core studies in 2019 followed by regulatory filings in Europe and U.S. in 2H 2019 and 1H 2020, respectively.

- Sanofi initiated the following Phase 3 sotagliflozin studies in type 2 diabetes:
 - Efficacy and safety of sotagliflozin versus placebo in patients with type 2 diabetes mellitus on background of sulfonylurea alone or with metformin (NCT03066830)
 - Safety and efficacy study of sotagliflozin on glucose control in patients with type 2 diabetes, moderate impairment of kidney function, and inadequate blood sugar control (SOTA-CKD3; NCT03242252)
 - Safety and effects of sotagliflozin dose 1 and dose 2 on glucose control in patients with type 2 diabetes, severe impairment of kidney function and inadequate blood sugar control (SOTA-CKD4; NCT03242018)
 - Efficacy and safety of sotagliflozin versus placebo in subjects with type 2 diabetes mellitus who have inadequate glycemic control while taking insulin alone or with other oral antidiabetic agents (SOTA-INS; NCT03285594)
 - Effect of sotagliflozin on cardiovascular and renal events in patients with type 2 diabetes and moderate renal impairment who are at cardiovascular risk (SCORED study; NCT03315143)
 - Efficacy and safety of sotagliflozin versus glimepiride and placebo in subjects with type 2 diabetes mellitus who are taking metformin monotherapy (SOTA-GLIM study; NCT03332771)
 - Efficacy and safety of sotagliflozin versus placebo and empagliflozin in subjects with type 2 diabetes mellitus who have inadequate glycemic control while taking a DPP4 inhibitor alone or with metformin (SOTA-EMPA; NCT03351478)
 - Efficacy and bone safety of sotagliflozin versus placebo in subjects with type 2 diabetes mellitus who have inadequate glycemic control (SOTA-BONE; NCT03386344)

LX2761

Lexicon advanced LX2761, an orally-administered drug candidate targeted to the inhibition of SGLT1 in the gastrointestinal tract, into human clinical studies for the treatment of diabetes, with Phase 1b data expected in 1H 2018.

- Lexicon completed a Phase 1a study of LX2761 in healthy subjects and patients with type 2 diabetes.
- Lexicon initiated a Phase 1b clinical trial of LX2761 in patients with type 2 diabetes.

LX9211

Lexicon advanced LX9211, a novel therapeutic approach to treat neuropathic pain, into human clinical studies, with Phase 1a data expected in 2H 2018.

- Lexicon continued to advance a Phase 1a clinical trial of LX9211, an orally-administered drug candidate selectively targeted to the inhibition of AAK1 (adapter-associated kinase 1) that is being developed for neuropathic pain.

Fourth Quarter and Full-Year 2017 Business Highlights

- Lexicon entered into a definitive term loan agreement with BioPharma Credit PLC and BioPharma Credit Investments IV Sub LP, investment funds managed by Pharmakon Advisors, L.P., that provided Lexicon with up to \$200 million of borrowing capacity available in two tranches, each maturing in December 2022 and bearing interest at 9.0% per annum. The first \$150 million was available immediately and an additional tranche of \$50 million is available for draw by March 2019 at Lexicon's option if net XERMELO sales are greater than \$25 million in the preceding quarter.

Fourth Quarter and Full-Year 2017 Financial Highlights

Unless otherwise stated, all comparisons are for the fourth quarter and full year of 2017 compared to the fourth quarter and full year of 2016.

Revenues: Revenues for the fourth quarter increased 43% from the prior-year period to \$33.0 million, primarily due to milestone payments from the Ipsen alliance for the first commercial sale of XERMELO in the United Kingdom and Germany, and \$5.4 million in net product revenues. Full-year 2017 revenues were \$90.3 million, an increase of 8% year-over-year, primarily due to net product sales and partially offset by lower revenues recognized from the collaboration and license agreement with Sanofi. Net product revenues since March 2017 included \$15.1 million and \$0.8 million, respectively, from the sale of XERMELO in the U.S. and the sale of bulk tablets of telotristat ethyl to Ipsen.

Cost of Sales: Lexicon had cost of sales related to sales of XERMELO of \$0.5 million for the fourth quarter of 2017. Full-year 2017 cost of sales was \$1.9 million, of which \$1.5 million consisted of amortization of intangible assets.

Research and Development (R&D) Expenses: Research and development expenses increased to \$47.2 million for the fourth quarter from \$40.4 million for the same period in 2016, primarily due to professional and consulting fees related to sotagliflozin NDA preparation and higher clinical and preclinical external research and development expenses. Full-year 2017 R&D expenses decreased 12% to \$156.8 million, primarily due to lower clinical and preclinical external research and development costs.

Selling, General and Administrative (SG&A) Expenses: Selling, general and administrative expenses for the fourth quarter were \$16.1 million compared to \$14.0 million for the same period in 2016. The increase was primarily due to higher legal expenses, professional and consulting expenses, salaries and benefits expense, charitable contributions and stock-based compensation. Full-year 2017 SG&A expenses were \$66.2 million for 2017 compared to \$43.0 million for 2016. The full-year 2017 increase in SG&A expenses were primarily due to increased salaries and benefits expense, travel and entertainment, charitable contributions, legal expenses and stock-based compensation.

Income Tax Benefit: During 2017, Lexicon's valuation allowance for its deferred tax assets decreased by \$8.7 million due to the reclassification of intangible assets relating to XERMELO from indefinite-lived to finite-lived assets. This resulted in the related deferred tax liability now being considered a source of taxable income. Lexicon recorded a deferred tax benefit with a corresponding reduction in its deferred tax liability in connection with this reclassification. On December 22, 2017, the Tax Cuts and Jobs Act was enacted and reduced the U.S. federal corporate tax rate from 35 percent to 21 percent. As a result, the fourth quarter 2017 income tax benefit of \$4.0 million represents the re-measurement of the deferred tax benefit and related valuation allowance to the newly enacted U.S. federal corporate tax rate.

Consolidated Net Loss: Net loss for the fourth quarter was \$28.4 million, or \$0.27 per share, compared to a net loss of \$32.4 million, or \$0.31 per share, in the corresponding period in 2016. For the fourth quarter 2017, net loss included non-cash, stock-based compensation expense of \$2.3 million. For the fourth quarter 2016, net loss included non-cash, stock-based compensation expense of \$1.7 million. Net loss for the full-year 2017 was \$129.1 million, or \$1.23, compared to a net loss of \$141.4 million, or \$1.36 per share, in the corresponding period in 2016. For the full-year 2017, net loss included non-cash, stock-based compensation expense of \$9.5 million. For the full-year 2016, net loss included non-cash, stock-based compensation expense of \$7.5 million.

Cash and Investments: As of December 31, 2017, Lexicon had \$310.8 million in cash and investments, as compared to \$346.5 million as of December 31, 2016. The cash position as of December 31, 2017 includes net proceeds of \$145.9 million from the loan agreement discussed above.

Anticipated Upcoming Milestones

- 1Q 2018 – U.S. and EU regulatory filings for sotagliflozin in type 1 diabetes by Sanofi
- 1H 2018 – Initiation of additional Phase 3 sotagliflozin studies in type 2 diabetes by Sanofi
- 1H 2018 – Phase 1b data for LX2761 in patients with type 2 diabetes
- 2H 2018 – Phase 1a data for LX9211 in neuropathic pain
- 2018 – Manuscript publications for XERMELO and sotagliflozin
- 2018 – Launch of XERMELO in additional European countries
- 2018 – Initiation of clinical studies for telotristat ethyl in other therapeutic indications

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 3395518. 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 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 a new 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 commercial business, including 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 conduct preclinical and clinical development and obtain necessary regulatory approvals of sotagliflozin, LX2761 and 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, 2016, 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		Year Ended	
	December 31,		December 31,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Revenues:				
Net product revenue	\$ 5,447	\$ —	\$ 15,890	\$ —
Collaborative agreements	27,486	23,001	74,267	83,182
Royalties and other revenue	114	36	178	155
Total revenues	33,047	23,037	90,335	83,337
Operating expenses:				
Cost of sales (including finite-lived intangible asset amortization)	538	—	1,899	—
Research and development, including stock-based compensation of \$1,207, \$925, \$4,905 and \$3,938, respectively	47,160	40,400	156,813	178,151
Increase (decrease) in fair value of Symphony Icon purchase liability	—	—	2,101	(703)
Selling, general and administrative, including stock-based compensation of \$1,051, \$805, \$4,567 and \$3,514, respectively	16,134	13,967	66,203	43,044
Total operating expenses	63,832	54,367	227,016	220,492
Loss from operations	(30,785)	(31,330)	(136,681)	(137,155)
Interest expense	(2,163)	(1,634)	(6,984)	(6,567)
Interest and other income, net	561	545	1,954	2,293
Net loss before income taxes	(32,387)	(32,419)	(141,711)	(141,429)
Income tax benefit	4,009	—	12,661	—
Consolidated net loss	\$ (28,378)	\$ (32,419)	\$ (129,050)	\$ (141,429)
Consolidated net loss per common share, basic and diluted	\$ (0.27)	\$ (0.31)	\$ (1.23)	\$ (1.36)
Shares used in computing consolidated net loss per common share, basic and diluted	105,588	104,052	105,237	103,863

Consolidated Balance Sheet Data

(In thousands)

	December 31, 2017	December 31, 2016
	(unaudited)	
Cash and investments	\$ 310,788	\$ 346,504
Property and equipment, net	17,687	19,390
Goodwill	44,543	44,543
Other intangible assets	51,885	53,357
Total assets	436,539	475,625
Deferred revenue	62,527	112,306
Current and long-term debt	245,670	101,447
Accumulated deficit	(1,381,404)	(1,250,363)
Total stockholders' equity	52,102	157,401

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