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 30, 2021

Lexicon Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-30111**	**76-0474169**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

2445 Technology Forest Blvd., 11th Floor
The Woodlands, Texas 77381
(Address of principal executive offices and Zip Code)

(281) 863-3000
(Registrant's telephone number, including area code)

8800 Technology Forest Place
The Woodlands, Texas 77381
(Former address if changed since last report)

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	LXRX	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 Operation and Financial Condition

On July 30, 2021, we issued a press release to report our financial results for the quarter ended June 30, 2021 and held a conference call to discuss the financial results and to provide a business update. A copy of the press release is attached to this current report on Form 8-K as Exhibit 99.1 and a transcript of the conference call is attached to this current report on Form 8-K as Exhibit 99.2.

The information in this Form 8-K and the Exhibits 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.

Information Regarding Forward-Looking Statements

The press release and transcript attached as Exhibits 99.1 and 99.2, respectively, each contain forward-looking statements within the meaning of the federal securities laws. Such statements are subject to a number of assumptions, risks and uncertainties, many of which are beyond our control. These risks include, but are not limited to, those identified in our annual report on Form 10-K and our other filings with the Securities and Exchange Commission. Investors are cautioned that any such statements are not guarantees of future performance and that actual results or developments may differ materially from those projected in the forward-looking statements. We do not undertake any obligation to update such forward-looking statements as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.		Description
99.1	—	Press Release of Lexicon Pharmaceuticals, Inc. dated July 30, 2021
99.2	—	Transcript of second quarter 2021 earnings conference call of Lexicon Pharmaceuticals, Inc. held on July 30, 2021
EX-104	—	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: August 2, 2021

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

Exhibit 99.1

LEXICON PHARMACEUTICALS REPORTS FIRST QUARTER 2021 FINANCIAL RESULTS AND PROVIDES CLINICAL UPDATE

Conference Call and Webcast at 8:00 am Eastern Time

The Woodlands, Texas, July 30, 2021 - Lexicon Pharmaceuticals, Inc. (Nasdaq: LXRX), today reported financial results for the three months ended June 30, 2021 and provided an update on key milestones.

“We remain on track to submit our New Drug Application (NDA) for sotagliflozin in heart failure late this year, with rising confidence in our opportunity to deliver unique value in an area of high unmet need,” said Lonnel Coats, Lexicon’s president and chief executive officer. “Our confidence is supported by data from our SOLOIST study in patients who had recently been hospitalized for worsening heart failure and results from both our SOLOIST and SCORED studies that were consistent across the spectrum of left ventricular ejection fraction, together with the particularly acute unmet need for effective treatment options among heart failure patients in the hospitalization setting and in the large population of patients with normal, or “preserved,” left ventricular ejection fraction (≥ 50%). We are further encouraged by the feedback from our recently-completed pre-NDA meeting with the FDA and are accelerating our efforts to prepare for a commercial launch in what we believe will be a rapidly growing market served by a concentrated prescriber base.”

“We have seen a meaningful pick-up in enrollment in our two Phase 2 proof-of-concept studies of LX9211 in neuropathic pain while maintaining as a priority the importance of proper patient selection that is built into the study design,” continued Mr. Coats. “Our mitigation efforts have begun to take effect and the COVID-19 environment has improved relative to earlier this year, but not enough to achieve top-line results by year-end. We now expect to have top-line results from these studies in the first half of 2022.”

Second Quarter Highlights

Sotagliflozin

- Two sessions highlighting sotagliflozin were presented at the virtual American College of Cardiology’s 70th Annual Scientific Session (ACC.21).
- A symposium highlighting sotagliflozin was held at the virtual American Diabetes Association’s 81st Scientific Sessions.

LX9211

- Patient enrollment continued in RELIEF-DPN-1, a Phase 2 clinical study of LX9211 for the treatment of diabetic peripheral neuropathic pain. Enrollment is expected to total approximately 300 patients at approximately 40 clinical sites.
- Patient enrollment continued in RELIEF-PHN 1, a Phase 2 clinical study of LX9211 for the treatment of post-herpetic neuralgia. Enrollment is expected to total approximately 74 patients at approximately 20 clinical sites.

Second Quarter 2021 Financial Highlights

Revenues: Revenues for the three months ended June 30, 2021 decreased to $0.2 million from $9.2 million for the corresponding period in 2020, primarily due to the absence of product revenues as a result of the sale of XERMELO during the third quarter of 2020.

Research and Development (R&D) Expenses: Research and development expenses for the three months ended June 30, 2021 decreased to $10.3 million from $57.3 million for the corresponding period in 2020, primarily due to decreases in external clinical development costs related to sotagliflozin resulting from the completion of clinical studies.

Selling, General and Administrative (SG&A) Expenses: Selling, general and administrative expenses for the three months ended June 30, 2021 decreased to $7.9 million from $14.1 million for the corresponding period in 2020, primarily due to lower salaries and benefit costs as a result of reductions in personnel in September 2020 and lower marketing expenses.

Net Loss: Net loss for the three months ended June 30, 2021 was $18.1 million, or $0.13 per share, as compared to a net loss of $69.1 million, or $0.65 per share, in the corresponding period in 2020. For the three months ended June 30, 2021 and 2020, net income included non-cash, stock-based compensation expense of $2.8 million and $4.3 million, respectively.

Cash and Investments: As of June 30, 2021, Lexicon had $118.5 million in cash and investments, as compared to $152.3 million as of December 31, 2020.

Conference Call and Webcast Information

Lexicon management will hold a live conference call and webcast today at 8:00 am ET / 7:00 am CT 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 3687855. The live webcast and replay may be accessed by visiting Lexicon's website at www.lexpharma.com/events. An archived version of the webcast will be available on the website for 14 days.

About the SOLOIST and SCORED Studies

SOLOIST was a multi-center, randomized, double-blinded, placebo-controlled Phase 3 study evaluating the cardiovascular efficacy of sotagliflozin versus placebo when added to standard of care in 1,222 patients with type 2 diabetes who had recently been hospitalized for worsening heart failure. The primary endpoint was the total number of events comprised of deaths from cardiovascular causes, hospitalizations for heart failure, and urgent visits for heart failure in patients treated with sotagliflozin compared with placebo.

SCORED was a multi-center, randomized, double-blinded, placebo-controlled Phase 3 study evaluating the cardiovascular efficacy of sotagliflozin versus placebo when added to standard of care in 10,584 patients with type 2 diabetes, chronic kidney disease with eGFR of 25 to 60 ml per minute per 1.73 m^2 of body-surface area, and risks for cardiovascular disease. The primary endpoint was the total number of events comprised of deaths from cardiovascular causes, hospitalizations for heart failure, and urgent visits for heart failure in patients treated with sotagliflozin compared with placebo.

Both SOLOIST and SCORED achieved their respective primary endpoints. Results from both studies were presented at the Late-Breaking Science Session of the American Heart Association (AHA) Scientific Sessions 2020 and simultaneously published in *The New England Journal of Medicine (NEJM)* in two separate articles titled: "Sotagliflozin in Patients with Diabetes and Recent Worsening Heart Failure" and "Sotagliflozin in Patients with Diabetes and Chronic Kidney Disease."

About Lexicon Pharmaceuticals

Lexicon is a 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. Lexicon advanced one of these medicines to market and has a pipeline of promising drug candidates in discovery and clinical and preclinical development in neuropathic pain, heart failure, diabetes and metabolism and other indications. For additional information, please visit www.lexpharma.com.

Safe Harbor Statement

This press release contains "forward-looking statements," including statements relating to Lexicon's financial position and long-term outlook on its business, including the clinical development of, regulatory filings for, and potential therapeutic and commercial potential of LX9211, sotagliflozin and its other potential drug candidates. In addition, this press release also contains forward looking statements relating to Lexicon's growth and future operating results, discovery and development 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 conduct preclinical and clinical development and obtain necessary regulatory approvals of LX9211, sotagliflozin 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, 2020, 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,**	
	2021	**2020**	**2021**	**2020**
	(Unaudited)		**(Unaudited)**	
Revenues:				
Net product revenue	$ -	$ 8,985	$ -	$ 16,862
Collaborative agreements	-	25	-	33
Royalties and other revenue	234	153	261	267
Total revenues	234	9,163	261	17,162
Operating expenses:				
Cost of sales (including finite-lived intangible asset amortization)	-	728	-	1,296
Research and development, including stock-based compensation of $1,223, $1,727, $6,376 and $7,096, respectively	10,257	57,301	22,866	112,482
Selling, general and administrative, including stock-based compensation of $1,457, $1,752, $6,898 and $7,122, respectively	7,936	14,113	16,193	28,801
Impairment loss on buildings	-	1,600	-	1,600
Total operating expenses	18,193	73,742	39,059	144,179
Loss from operations	(17,959)	(64,579)	(38,798)	(127,017)
Interest expense	(169)	(5,125)	(336)	(10,256)
Interest and other income, net	61	633	109	1,591
Net Loss	$ (18,067)	$ (69,071)	$ (39,025)	$ (135,682)
Net loss per common share, basic and diluted	$ (0.13)	$ (0.65)	$ (0.27)	$ (1.27)
Shares used in computing net loss per common share, basic and diluted……	144,451	107,073	143,917	106,804

Consolidated Balance Sheet Data *(In thousands)*	**As of June 30, 2021**	**As of December 31, 2020**
	(Unaudited)	
Cash and investments……	$ 118,501	$ 152,275
Property and equipment, net……..	1,201	295
Goodwill…….....	44,543	44,543
Total assets……	171,672	203,788
Current debt……	11,675	11,646
Accumulated deficit……	(1,439,043)	(1,400,018)
Total stockholders' equity……..	137,233	156,371

For Inquiries:

Chas Schultz
Executive Director, Corporate Communications and Investor Relations
Lexicon Pharmaceuticals
(281) 863-3421
cschultz@lexpharma.com

Exhibit 99.2

Event Name: [LXRX] - Lexicon Pharmaceuticals, Inc. Second Quarter 2021 Financial Results Conference Call
Event Date: Friday, July 30, 2021, 8:00 AM Eastern Time

Officers and Speakers
Charles Schultz; Corporate Communications
Lonnel Coats; President and Chief Executive Officer
Jeffrey Wade; EVP of Corporate and Administrative Affairs and Chief Financial Officer

Analysts
Yigal Nochomovitz; Citigroup
Joseph Stringer; Needham & Company

Presentation

Operator: Good morning. My name is Lisa, and I will be your conference operator today. At this time I would like to welcome everyone to the Lexicon Pharmaceuticals, Inc., Second Quarter 2021 Earnings Conference Call.

[Operator Instructions]

Thank you. I would now like to turn the call over to Mr. Chas Schultz. Please go ahead, sir.

Charles Schultz: Thank you, Lisa. Good morning, and welcome to the Lexicon Pharmaceuticals Second Quarter 2021 Financial Results Conference Call. Joining me today are Lonnel Coats, Lexicon's President and Chief Executive Officer; and Jeff Wade, Lexicon's Executive Vice President of Corporate and Administrative Affairs and Chief Financial Officer.

Earlier today Lexicon issued a press release announcing our financial results for the second quarter of 2021, which is available on our website at www.lexpharma.com and through our SEC filings. A webcast of this call, along with a slide presentation, is available on our website. During this call we will review the information provided in the release, provide an update on our clinical programs, and then use the remainder of our time to answer your questions.

Before we begin, let me remind you that we will be making forward-looking statements, including statements relating to the safety, efficacy and the therapeutic and commercial potential of LX9211, sotagliflozin and other drug candidates. These statements may include characterizations of the expected timing and results of clinical trials of LX9211, sotagliflozin and other drug candidates, and the regulatory status and market opportunity for those programs. This call may also contain forward-looking statements relating to our growth and future operating results, discovery and development of our drug candidates, strategic alliances and intellectual property, as well as other matters that are not historical facts or information.

Various risks may cause our actual results to differ materially from those expressed or implied in such forward-looking statements. These risks include uncertainties related to the timing and outcome of planned NDA filing for sotagliflozin in heart failure and our discussions with the

FDA regarding sotagliflozin relating to heart failure and type 1 diabetes; the timing and results of clinical trials and preclinical studies of LX9211, sotagliflozin and other drug candidates; our dependence upon strategic alliances and other third-party relationships; our ability to obtain patent protection for our discoveries; limitations imposed by patents owned or controlled by third parties; and the requirements of substantial funding to conduct our research and development activities. For a list and a description of the risks and uncertainties that we face, please see the reports we have filed with the Securities and Exchange Commission.

I would now like to turn the call over to Lonnel Coats.

Lonnel Coats: Thank you, Chas. Good morning, everyone, and thank you for joining us on the call.

As we noted in our press release this morning, we remain on track to submit our new drug application for sotagliflozin in heart failure late this year, with rising confidence in our opportunity to deliver unique value in an area of high unmet need. Our confidence is supported by the data from our SOLOIST study in patients who have recently been hospitalized for worsening heart failure and results from both our SOLOIST and SCORED studies that demonstrated a reduced risk of cardiovascular death, hospitalization for heart failure and urgent visits for heart failure that was consistent across the full spectrum of left ventricular ejection fraction.

The results of these studies address the areas of greatest unmet need in heart failure: better treatment options for patients hospitalized for worsening heart failure and effective treatment options for the large population of patients with normal or preserved left ventricular ejection fraction, for whom there are essentially no approved therapies. A series of recent developments since our last quarterly call have further reinforced our confidence in the value of sotagliflozin and validated the important areas of differentiation in ways that we believe will translate into benefits for millions of people with heart failure and type 2 diabetes.

Importantly as well, we have completed the work we have described on previous calls to more fully evaluate the intended market for sotagliflozin. It has become clear that this is a market with a concentrated prescriber base, one that we believe can be efficiently addressed with a focused and modestly sized sales force.

Slide 4. Let's get into some of the metrics of the market opportunity. Now, there are nearly a million hospitalizations per year in the United States for heart failure. Heart failure is the leading cause of hospitalizations of Americans 65 and older. The hospitalization setting in patients with worsening heart failure is exactly where our SOLOIST study generated important evidence about the impact of sotagliflozin. A majority of heart failure patients have heart failure with preserved ejection fraction, or HFpEF; that is, left ventricular ejection fraction greater than or equal to 50%. It is these HFpEF patients who are in the greatest need for effective therapies, given that at present, they essentially have no real approved treatment options.

Finally, heart failure is very frequently associated with type 2 diabetes. Some of the most recent evidence suggests that approximately 44% of heart failure patients have type 2 diabetes, and this proportion appears to be growing over time. Patients with diabetes, moreover, tend to be over-represented in the higher-unmet-need area of HFpEF. Next slide.

Our SOLOIST clinical trial was designed to evaluate sotagliflozin in the context of worsening heart failure. Patients who were admitted to the hospital with an episode of acute decompensated heart failure were initially stabilized, then were randomized to either sotagliflozin or placebo on top of standard of care, either before or within three days following discharge from the hospital. About half of patients started therapy before discharge from the hospital, with the balance starting therapy promptly following discharge. This is a unique study design addressing the unique needs and challenges of worsening heart failure, and the results were compelling, with a 33% relative risk reduction in the primary endpoint, or cardiovascular death, hospitalization for heart failure and urgent visits for heart failure. We recognize this was a significant risk to take in going after this population, and we were pleased with the remarkable outcome.

Now, why is that important? Well, one of the developments since our last earnings call that has increased our confidence in the opportunity for sotagliflozin. At the American College of Cardiology scientific sessions in May, data were presented from a recently completed study of the leading brand of heart failure medication, a multibillion-dollar drug, which failed to show a benefit in worsening heart failure. I believe this result came as a surprise to many attendees, given the product's commercial success in heart failure.

The result obviously opens an opportunity relative to the market leader, given that results from SOLOIST showed a clear benefit from treatment with sotagliflozin in people who have recently been hospitalized for worsening heart failure, but it is also a reminder that worsening heart failure represents a distinct set of patients, that success in heart failure generally does not necessarily translate to the unique needs and challenges of this patient population, and that the results of the SOLOIST study offer an opportunity for sustained differentiation given its focus on those unique needs and challenges.

On the next slide, turning to HFpEF specifically, not only does the population of HFpEF patients have the greatest unmet need, it has also been growing as a proportion of overall heart failure patients. This particular figure shows how the proportion of HFpEF patients in a hospitalized setting has been increasing over time. Over the years, a number of new therapies have been introduced for treatment of heart failure with reduced ejection fraction, or HFrEF, but while data has -- may come from others, then we shall see, so far, only sotagliflozin has published data showing clear clinical benefit across the full range of the more difficult-to-treat HFpEF population.

In this regard, at the same American College of Cardiology scientific sessions in May that I mentioned above, Dr. Deepak Bhatt presented pooled data from SOLOIST and SCORED, shown here, demonstrating sotagliflozin's benefit across the full spectrum of left ventricular ejection fraction, including patients with reduced ejection fraction below 40%, patients with mid-range ejection fraction between 40% and 50%, and patients with preserved ejection fraction at greater than or equal to 50%. We believe that the data presented were very well received, as the current leading brand of heart failure medication is indicated with a label outlining that benefits are seen primarily in patients with below-normal left ventricular ejection fraction, and there are no approved therapies for people with ejection fraction equal or greater than 50%.

You can clearly see in these data the impact of sotagliflozin on all patient populations across the entire spectrum of left ventricular ejection fraction. In the traditional HFrEF population with

ejection fraction of less than 40%, there was a 22% relative risk reduction in the primary endpoint of the studies of total cardiovascular death, hospitalizations due to heart failure and urgent heart failure visits. In the mid-range ejection fraction, there was a 39% relative risk reduction, and on the right, you see that a highly significant relative risk reduction of 37% was achieved in a HFpEF population, a robust result that has not been seen from any other therapy to date.

So to recap, we have rising confidence in the opportunity for us to bring sotagliflozin to market, importantly, in the United States, which we think is the most substantial market opportunity, with or without a partner. We have compelling data from SOLOIST and SCORED that address the areas of greatest unmet need in heart failure, better treatment options for patients hospitalized for worsening heart failure, and effective treatment options for a large population of patients with HFpEF, for whom there are essentially no approved therapies.

We believe that this will be a rapidly growing market. It may actually grow more rapidly if there are more treatment options for HFpEF, which represents a majority of heart failure patients for whom to date there have been no truly effective options. Importantly, this is a market that our work indicates can be addressed with a focused, modestly sized sales force. These factors combine to give us the opportunity to generate significant value by bringing sotagliflozin to market on our own and/or to set a bar by which to judge the value of any potential partnership.

Finally, we are encouraged by the feedback from our recently completed pre-NDA meeting with the FDA, which has added to our sense of urgency and factored into our decision to accelerate our efforts to prepare for potential U.S. commercial launch in 2022.

One of the important elements of this acceleration of these preparations was just announced this morning: This coming Monday, Dr. Craig Granowitz will be joining us as our Chief Medical Officer. Many of you probably know of Dr. Granowitz, who has extensive industry experience in scientifically differentiating cardiovascular medicines, as demonstrated by his track record at Amarin and Merck, among others. Craig has a lot of work ahead, and we welcome him to our leadership team.

Now, on to type 1 diabetes. We continue to believe that sotagliflozin demonstrated a positive benefit-risk profile in the largest Phase 3 development program ever conducted in type 1 diabetes and that it has the potential to become an important new treatment option as an adjunct to insulin for type 1 diabetes patients. We requested an opportunity for an administrative hearing with the FDA on whether there are grounds for its previous denial of our NDA for type 1 diabetes. I am pleased to say, this week, the FDA indicated that it is willing to have a good faith discussion with Lexicon on a potential path forward for the sotagliflozin NDA, and we are working with CDER on a joint request to hold the administrative hearing process in abeyance while those discussions are pursued. While it is early, we are looking forward to those discussions, and we're hopeful that together with the FDA we can quickly find a potential path forward.

Let me move to the next slide on LX9211. We have seen a meaningful pickup in enrollment in our two Phase 2 proof-of-concept studies for LX9211 in neuropathic pain while maintaining as a priority the importance of proper patient selection that is built into this study design. Our mitigation efforts have begun to take effect and the COVID-19 environment has improved

relative to earlier this year, but not enough to achieve top line results by the year-end. We now expect to have top line results from these studies in the first half of 2022.

I'd like to take a quick moment to wrap up with our pipeline. We continue to make great strides in the advancement of our pipeline that has been built on our rich scientific platform and years of research and development. In addition to the programs that we are developing directly, we do have interest in the form of milestones and royalties in other programs that have been developed or facilitated using our technology. We have a milestone and royalty interest relating to TerSera's development and potential future commercialization of telotristat ethyl in biliary tract cancer in accordance with the terms of the agreement under which we sold telotristat ethyl and related assets to TerSera last year. We also have a milestone and royalty interest in UTTR1147A, a Genentech IL22-Fc that is in Phase 2 clinical development, under the terms of our longstanding target discovery and biotherapeutics alliance with Genentech.

Our scientific platform continues to provide continued opportunities for value both internally with collaborators and other third parties.

I'd like to stop at this moment and pass the call over to Jeff to walk you through our financial results for the second quarter and provide financial guidance for 2021. Jeff?

Jeffrey Wade: Thank you, Lonnel. To begin, I will discuss key aspects of our second quarter financials. More financial details can be found in the press release that we issued earlier today and in our upcoming 10-Q SEC filing.

As indicated in our press release, we had revenues of $0.2 million in the second quarter. The reduction from $9.2 million for the corresponding period in 2020 was primarily due to the absence of product revenues in the 2021 second quarter as a result of our sale of telotristat ethyl during the third quarter of 2020.

Research and development expenses for the second quarter decreased to $10.3 million from $57.3 million for the corresponding period in 2020. This was primarily due to decreases in external clinical development costs related to sotagliflozin, resulting from the completion of clinical studies.

Selling, general and administrative expenses for the second quarter decreased to $7.9 million from $14.1 million for the same period in 2020, primarily due to lower salaries and benefit costs as a result of reductions in personnel in September 2020 and lower marketing expenses.

In total, we had a net loss for the second quarter of $18.1 million, or $0.13 per share, as compared to a net loss of $69.1 million, or $0.65 per share, in the corresponding period of 2020. Our net loss for the second quarter of 2021 and 2020 included noncash stock-based compensation expense of $2.8 million and $4.3 million respectively.

We ended the second quarter of 2021 with $118.5 million in cash and short-term investments, as compared to $152.3 million as of December 31, 2020.

Financial guidance for 2021 has not changed from the guidance given on our first quarter 2021 financial results conference call. We continue to expect our 2021 operating expenses to be in the

range of $85 million to $100 million, which is a sizeable decrease from the $204.4 million in operating expenses we had in 2020. We expect noncash expenses to be approximately $11 million of our total operating expenses. Research and development expenses are expected to continue to be in the range of $60 million to $70 million. This estimate includes the expected spend for our ongoing two Phase 2 clinical studies of LX9211, the remaining closeout of our sotagliflozin studies and the expected cost to submit a new drug application for sotagliflozin in heart failure. It also includes investment in medical affairs activities and in preclinical and discovery-stage programs. We also continue to expect G&A expenses, including precommercial launch activities for sotagliflozin in heart failure, to be in the range of $25 million to $30 million.

I will now turn the call back to Lonnel.

Lonnel Coats: Thank you, Jeff. I want to thank everyone for joining us this morning. We will open the line up now for any questions.

Questions & Answers

Operator: [Operator Instructions]

Your first question comes from the line of Yigal Nochomovitz with Citigroup.

Yigal Nochomovitz: Now that EMPEROR-Preserved has read out [indiscernible], it obviously becomes harder for you to make the argument that sota is the only SGLT2 that has demonstrated positive data on the composite of CV death, HHF and urgent heart failure visit, in HFpEF, based on the pooled analysis of SOLOIST and SCORED. So with that being said, can you help us understand where you see sota's differentiation in the heart failure space in light of this recent EMPEROR-Preserved data? Thank you.

Jeffrey Wade: So at this point, we don't actually know what the EMPEROR-Preserved data are, other than that they met the endpoint. So we're looking forward to seeing those data on August 27 at the ESC. We will also be presenting some data at ESC and look forward to giving you the opportunity to review some additional data from Lexicon.

We do continue to believe that sotagliflozin will be differentiated, and I think that the opportunity is both in worsening heart failure, and we discussed, and in heart failure with preserved ejection fraction, but as we also mentioned, I think it's important to realize that the portion of the patient population with heart failure with preserved ejection fraction has been very underserved, and one of the opportunities here is that if there are competitors, this is likely to be a more rapidly growing market than if not. And we think that we're going to have some unique advantages based on our differentiated mechanism, and that that's going to be something that provides us with long-term value across both worsening heart failure, where we have really unique data, and in the HFpEF space, where there is such tremendous unmet need.

Lonnel Coats: Yigal, I would just add that I think everyone should wait before they make judgment about where everybody is going to land in this area. So what we know today for sure, to Jeff's point, there would have been an assumption that the current market leader would have won in worsening heart failure, and they didn't. And we are very clearly positioned in worsening heart failure today, regardless of what's going to happen with others, because others did not

conduct the same type of trial design. So as we seek the indication, I think that will have a uniqueness.

The second one is, to Jeff's point, the preserved population is growing at a fairly nice rate. There are no therapies, and if there are going to be competition, then I think it'll be good because it'll help grow the market much faster and increase our opportunity to participate relative to our uniqueness.

I also would just lastly say, is that we look forward to seeing what the data is going to look like from others, but today, there is no one else who has presented the same data that we have presented to date. And so we'll have to wait and see what others say later.

Yigal Nochomovitz: Okay, makes sense. And so it sounds, based on your comments, that you've done more work on the heart failure space and now you think you could potentially launch independently. Could you just give us a sense as to what size of the sales force you might envision for launching in the United States?

Lonnel Coats: Yes, that's a great question. I said this before when we got started in the beginning of the year -- or initially, we were going to wait and see how partnerships went before we decided to advance the NDA, and we did some preliminary work and realized that that probably wasn't smart. We needed to advance the NDA ourselves. So we started advancing the NDA fairly quickly, which we're glad we did, particularly since we've had the pre-NDA feedback.

The second thing is, we started to do more work coming into the second quarter in analyzing the market ourselves, particularly as we saw some of the weakness that was coming out in data from others, where we thought we had a strength. And so we took that to market and we challenged ourselves to get a better understanding from KOLs, from payers, from folks in the pricing marketplace, and I have to tell you, when we got the results back on where we would place ourselves and we could place sotagliflozin in the market, regardless of what others are going to call out in the future, it was quite remarkable.

And I also believe the reason it was remarkable is because you have a significantly unmet need in the marketplace that is not addressed by current therapies and is growing at a pretty nice clip. And so as a result of that, we feel as though we can go after a concentrated base of cardiologists. This is a cardiology drug, and we will go after cardiologists. I won't get into the numbers today, but I will tell you, you should be thinking in a size more of the hundred-or-so range at best.

Yigal Nochomovitz: Got it. Thanks, Lonnel. And Jeff, just on the cash situation, so you have about $120 million; how far does that get you in terms of the runway? And when do you believe you're going to need to take steps to finance the company again in order to prepare to independently launch sota in heart failure?

Jeffrey Wade: So the activities that we have planned for this year fit within our previously announced guidance for this year. Obviously, if we launch, it will require some more resources, and we'll address that when we need to, but for the near term, I think we're in good shape and will be marshalling our resources to do what we need to do between now and the NDA filing time period.

Lonnel Coats: And Yigal, I think one of the first things that we have -- we've done one of the first things that were important, so we didn't just wake up and decide to do this. The hiring of Dr. Craig Granowitz was carefully planned because we believe in order to differentiate and highlight the differentiation of our product, because we do expect to have competition in this market, you need folks who understand that and how best to do that scientifically. And so the first step for us in the investment is to bring him in, and I think he will start to assemble his medical team to begin to do the work scientifically to start the engagement with KOLs and creating a value proposition that we'll take to payers.

Yigal Nochomovitz: Got it, thanks. And if I could just squeeze one last question in: Just remind us, what is the reason why RELIEF-DPN is about four times larger than RELIEF-PHN on enrollment target. Is that just because of the size of the indication, or is there some other strategic reason why the trials are so differently sized?

Jeffrey Wade: Yes, two reasons. One is that this is a more heterogeneous population. The people with PHN have a little bit more consistency in their condition than with -- people with DPN have. It's more heterogeneous in terms of their background and the experience that they have with diabetic neuropathic pain. The other is that diabetic neuropathic pain tends to have a larger placebo effect and more variability, and as a result of that, we felt that it was important to have a larger sample size, because we want to give ourselves the best opportunity to be successful in this study. So those are the -- those are really the two reasons. I guess there's one other, is that the DPN study is a three-arm study, so one placebo arm and two dose arms, whereas the PHN study is a two-arm study.

Lonnel Coats: Yes, what I would add to that, which is -- which adds to some degree of the time it takes to do this work, is that the #1 reason drugs fail in this category, in CNS, particularly in pain, is small sample size, and so we've tried to avoid that. The second one is that you have to put some inclusion and exclusionary criteria in to make sure you get the right patients. When you do that, you're generally going to run into a higher screen failure rate, and so we're pleased with what we're seeing because we're starting to feel as though we are getting the right patients, and so it's important for us to take the time to engineer a successful trial versus a speedy trial. So the way this is designed is to give ourselves an increased chance of success in reducing the placebo effect, as well as having the proper sample size to overcome it.

Operator: [Operator Instructions]

Your next question comes from the line of Joseph Stringer with Needham & Company.

Joseph Stringer: So you've taken some initial steps here in terms of sota for heart failure, in terms of commercializing it on your own. Just -- guess I'm just curious, would there be any scenario in which you would still consider a partnership for this? And would you still be open to that, is the first question.

The second question is around the [indiscernible] trials. Just curious if the -- I know that you've previously opened some more sites for some of these to help speed along the enrollment, so just curious how those -- how that's played out, given COVID-related headwinds there? Would you ever consider opening additional sites? Or maybe give us some additional color there. Thanks.

Lonnel Coats: Joey, great questions. Let me first start with the partnership piece. We haven't ended discussions, and there are interested parties. What I will say is that as we did the work, our confidence just greater and greater that we can do this ourselves. What we understand better today is, what is the value of this asset? We clearly have a better understanding of that today than we ever did at any point in time, particularly since others have turned over their cards and we see what's happening with the market leader, and the opportunity to differentiate against the market leader, as well as feedback we've received from KOLs on our profile, as well as what we've seen from payers. So today, we have a better sense of what we could on our own, and that then says, any partner who wants to discuss with us going forward has to discuss what they can do for us greater than us doing it on our own. We now have that work, and I think that's only beneficial to all our stakeholders that we have done that.

Now, one of the things I would say about partnership discussions, they tend to like to do a slow dance; here, we breakdance. And so I believe the market and the regulatory discussions we're having are moving at an accelerated pace where we cannot be slow-dancing this. And if we're going to create value, then the best way to do it is to control the rate, the speed and the strategy that creates that value. So we're not foreclosed to a partner, but the rate and the timing in which we do that will be distinctly based on what value they bring above and beyond what we do on our own.

The second one, in terms of increasing the sites for 9211, yes, we saw early on, and we've said this in previous calls, we started to see the effect of the COVID-19 patient -- on our patient enrollment, and we tried to start to mitigate that coming out of the first quarter by adding additional sites. It takes a long time to add additional sites. But what we are seeing is a much better environment. Since vaccinations have occurred, the environment is improving. The mitigation plans that we've put in place of adding new sites is adding value. It's just not enough, essentially, to be able to have the top line results by the end of this year. So we felt it better to make sure we have good sites that are giving us the right patients and keep working those and nurturing those and extending the timeline to ensure ourselves that we get a good sample size and a good sense of how the drug's working with good sites. And so we moved the timeline as a result.

Operator: At this time there are no further questions. Are there any closing remarks?

Lonnel Coats: Yes. Let me just thank everyone for joining us this morning. I'm extremely excited. We've done the work. We truly believe sotagliflozin is going to be a remarkably important product introduced in the market next year for heart failure, particularly those patients living with type 2 diabetes. We think we will be unique; we'll have to wait and see what others are going to say and do, but at the end of the day, it is a growing market that is facilitated by good science, and we can see what the SGLT2s are doing in HFrEF, and I think it's early days in terms of what you're seeing, the impact of SGLT2s in heart failure, particularly HFrEF, and it's remarkably early days in the area of HFpEF, and I think you're going to see just an expanding market and expanding opportunity, more specifically, for sotagliflozin, and we're really looking forward to getting that work started as we build out our team.

The second thing is, I am just thrilled with our engagements that we've had with the FDA recently, not just in the area of heart failure, which is encouraging us to accelerate this program

forward in this indication, and the recent developments that we've had in our conversations with them to sit down and have more conversations about a path forward for type 1 diabetes. So I couldn't be more excited relative to those engagements.

Last but not least, very encouraged by LX9211. Our goal is to engineer a successful trial -- not to speed through it, but to engineer it so we have every chance of success. I think we're on path to do that. So I remain remarkably bullish on our near-term catalyst that we are creating here at Lexicon.

With that, I will say thank you for joining us, and we look forward to the next conference call.

Operator: This concludes today's conference. You may now disconnect.