



PIONEERING
MEDICINES
THAT TRANSFORM
PATIENT LIVES



LEXICON

**Our mission
is to pioneer
medicines
that transform
patients' lives.**

We deliver on this mission by using precision science to discover and develop medicines that help patients live better, more empowered lives.



INNOVATION
TRANSPARENCY
RESPECT
INTEGRITY
OWNERSHIP

Our values describe
the core beliefs and
behaviors that we
commit to live by
and demonstrate in
all that we do.



2 APPROVED PRODUCTS



1 PENDING MARKETING APPLICATION



3 CLINICAL-STAGE THERAPEUTIC CANDIDATES

PIPELINE

We are committed to building a robust portfolio of compounds, all of which originated from our own internal drug discovery efforts.

These efforts were driven by a systematic, target biology-driven approach in which we used gene knockout technologies and an integrated platform of advanced medical technologies to systematically study the physiological and behavioral functions of almost 5,000 genes in mice and assessed the utility of the proteins encoded by the corresponding human genes as potential drug targets. We have identified and validated in living animals, or *in vivo*, more than 100 targets with promising profiles for drug discovery.

	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	REGISTRATION	MARKETED	PARTNER
XERMELO® (TELOTRISTAT ETHYL) TARGET: TPH1							
Carcinoid syndrome diarrhea US	→						Wholly owned (US/Japan)
Carcinoid syndrome diarrhea EU	→						Ipsen (ex-US/ex-Japan)
Biliary tract cancer (BTC)	→						Wholly owned (US/Japan)
ZYNGUISTA™ (SOTAGLIFLOZIN) TARGET: SGLT1 / SGLT2							
Type 1 diabetes (T1D) EU	→						Wholly owned
Type 1 diabetes (T1D) US	→						Wholly owned
Type 2 diabetes (T2D), heart failure (HF), diabetic kidney disease (DKD)	→						Wholly owned
LX9211 TARGET: AAK1							
Neuropathic pain	→						Wholly owned



Lonnel Coats

PRESIDENT & CHIEF EXECUTIVE OFFICER

TO OUR SHAREHOLDERS:

OUR PATH to creating value for patients and for shareholders lies in commercial execution and in delivering positive clinical and regulatory outcomes on our portfolio of product candidates. We made significant progress on our XERMELO® (telotristat ethyl) business in carcinoid syndrome diarrhea in 2019, achieving net US sales of \$31 million, up nearly 25% from the prior year. In addition, we initiated a Phase 2 study of telotristat ethyl in biliary tract cancer and were pleased that the safety review of the first dose cohort supported continuation of the study. Numerous investigator-initiated studies of telotristat ethyl should also help inform future development priorities.

We regained full rights to Zynquista™ (sotagliflozin) following the termination of our alliance with Sanofi and settlement of our related disputes. We obtained regulatory approval of Zynquista in Europe for type 1 diabetes with a differentiated label that includes a reduction in the incidence and rates of hypoglycemia. In the U.S., we engaged in formal dispute resolution proceedings with the FDA's Office of New Drugs and Center for Drug Evaluation and Research (CDER), each of which ultimately denied our appeals of the FDA's previously issued complete response letter for sotagliflozin in type 1 diabetes. We obtained preliminary topline results from the first four Phase 3 studies of sotagliflozin in type 2 diabetes and continued to conduct our comprehensive Phase 3 development program for sotagliflozin, which includes two long-term outcomes studies, SCORED and SOLOIST, that are designed to demonstrate benefits in and support labeling for heart failure and chronic kidney disease.

Lastly, we announced positive topline data from our Phase 1 multiple ascending dose study of LX9211, in development for the treatment of neuropathic pain, that support advancement of LX9211 into proof-of-concept studies.

Every drug candidate in our pipeline was discovered using our genomic technology platform. Research and development (R&D) remains an important and integral part of our organization and we are committed to visionary science and to the development of new therapies that can transform patients' lives. Reflecting on our R&D performance in 2019, I am pleased with our progress and believe that advancements we have made to date position us for long-term growth.

Importantly, we continue to maintain a strong financial position by appropriately managing our cash while investing in programs and products that are supported by robust data, and we ended 2019 with approximately \$272 million in cash and equivalents.

We enter 2020 with a well-defined strategy to position the company for future growth, to build long-term sustainable value for shareholders and to continue to deliver on our commitments to patients. This year, we expect efficacy data from our Phase 2 clinical study of telotristat ethyl in biliary tract cancer and initiation of a proof-of-concept Phase 2 study of LX9211 in diabetic peripheral neuropathic pain. In type 1 diabetes, we will be evaluating the feedback CDER provided in its recent response to our appeal. In type 2 diabetes, we expect to receive topline data from the remaining core Phase 3 studies for sotagliflozin and

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to present Phase 3 data at several medical conferences. Event accrual in the fully enrolled SCORED study for sotagliflozin in heart failure and chronic kidney disease remains ongoing, as does patient enrollment in SOLOIST for decompensated acute heart failure. We are engaged in discussions around potential partnerships for sotagliflozin, which will be necessary to complete SCORED and SOLOIST.

I would like to thank everyone who has contributed to the progress we have achieved, none of which would have been possible without our patients and their families and caregivers, our employees, clinical investigators, physicians, board members and shareholders. We remain committed to all our stakeholders and look forward to delivering on our objectives. Thank you for your continued support.

Regards,



Lonnel Coats

President and Chief Executive Officer



ANTICIPATED MILESTONES

XERMELO™ - Carcinoid Syndrome Diarrhea

Manuscript publications

2020

TELOTRISTAT ETHYL - Oncology

Completion of patient enrollment in the first efficacy cohort of the Phase 2 study for biliary tract cancer

H1 2020

Data from the first efficacy cohort of the Phase 2 study in biliary tract cancer

Q4 2020

SOTAGLIFLOZIN - Type 2 Diabetes, Heart Failure and Chronic Kidney Disease

Patient enrollment in SOLOIST (acute decompensated heart failure)

Ongoing

Event accrual in fully enrolled SCORED study (heart failure and chronic kidney disease)

Ongoing

Topline results from core Phase 3 studies (type 2 diabetes)

H1 2020

Presentation of Phase 3 data at ADA, EASD

June, September 2020

LX9211 - Neuropathic Pain

Initiation of Phase 2 study in diabetic peripheral neuropathic pain

H1 2020

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K**

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended **December 31, 2019**

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Transition Period from _____ to _____

Commission File Number: **000-30111**

Lexicon Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

76-0474169

(I.R.S. Employer Identification Number)

8800 Technology Forest Place

(281) 863-3000

The Woodlands Texas 77381

(Address of Principal Executive Offices and Zip Code)

(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Each Class</u>	<u>Trading Symbol(s)</u>	<u>Name of Each Exchange on which Registered</u>
Common Stock, par value \$0.001 per share	LXRX	Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act of 1933. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Securities Exchange Act of 1934. (check one): Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company 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 Securities Exchange Act of 1934.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes No

The aggregate market value of voting stock held by non-affiliates of the registrant as of the last day of the registrant's most recently completed second quarter was approximately \$259.5 million, based on the closing price of the common stock on the Nasdaq Global Select Market on June 30, 2019 of \$6.29 per share. For purposes of the preceding sentence only, our directors, executive officers and controlling stockholders are assumed to be affiliates. As of March 6, 2020, 106,969,973 shares of common stock were outstanding.

Documents Incorporated by Reference

Certain sections of the registrant's definitive proxy statement relating to the registrant's 2020 annual meeting of stockholders, which proxy statement will be filed under the Securities Exchange Act of 1934 within 120 days of the end of the registrant's fiscal year ended December 31, 2019, are incorporated by reference into Part III of this annual report on Form 10-K.

Lexicon Pharmaceuticals, Inc.

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The Lexicon name and logo and XERMELO[®] are registered trademarks of Lexicon Pharmaceuticals, Inc. Zynquista[™] is a trademark of Lexicon Pharmaceuticals, Inc.

In this annual report on Form 10-K, “Lexicon Pharmaceuticals,” “Lexicon,” “we,” “us” and “our” refer to Lexicon Pharmaceuticals, Inc. and its subsidiaries.

This annual report on Form 10-K contains forward-looking statements. These statements relate to future events or our future financial performance. We have attempted to identify forward-looking statements by terminology including “anticipate,” “believe,” “can,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “should” or “will” or the negative of these terms or other comparable terminology. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks outlined under “Item 1A. Risk Factors,” that may cause our or our industry’s actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We are not under any duty to update any of the forward-looking statements after the date of this annual report on Form 10-K to conform these statements to actual results, unless required by law.

PART I

Item 1. *Business*

Overview

Lexicon Pharmaceuticals is a biopharmaceutical company with a mission of pioneering medicines that transform patients' lives. We are devoting most of our resources to the commercialization or development of our three most advanced drugs and drug candidates:

- We are commercializing XERMELO[®] (telotristat ethyl), an orally-delivered small molecule drug, in the United States for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog, or SSA, therapy in adults inadequately controlled by SSA therapy. We have granted Ipsen Pharma SAS, or Ipsen, an exclusive, royalty-bearing right to commercialize XERMELO outside of the United States and Japan. Ipsen is commercializing XERMELO in the United Kingdom, Germany and multiple additional countries. We are also developing telotristat ethyl as a treatment for biliary tract cancer and are conducting a Phase 2a clinical trial of telotristat ethyl in biliary tract cancer patients.
- We are developing Zynquista[™] (sotagliflozin), an orally-delivered small molecule drug candidate, as a treatment for type 1 diabetes. The U.S. Food and Drug Administration, or FDA, has issued a complete response letter regarding our application for regulatory approval to market sotagliflozin for type 1 diabetes in the United States and has confirmed that position in denying two appeals of the complete response letter. Zynquista has been approved in the European Union for use as an adjunct to insulin therapy to improve glycemic control in adults with type 1 diabetes and a body mass index ≥ 27 kg/m², who could not achieve adequate glycemic control despite optimal insulin therapy.

We are also developing sotagliflozin as a treatment for type 2 diabetes, heart failure and chronic kidney disease. We are conducting a comprehensive Phase 3 development program, which includes one long-term outcomes study designed to demonstrate benefits in chronic heart failure and chronic kidney disease in type 2 diabetes patients and another long-term outcomes study designed to demonstrate benefits in acute decompensated heart failure in patients with and without type 2 diabetes. We have reported preliminary top-line results from the first four Phase 3 clinical trials of sotagliflozin in adults living with type 2 diabetes.

- We are developing LX9211, an orally-delivered small molecule drug candidate, as a treatment for neuropathic pain. We have reported top-line results from two Phase 1 clinical trials of LX9211 and are preparing to initiate a Phase 2 clinical trial of LX9211.

Compounds from our most advanced drug programs, as well as compounds from a number of additional drug discovery and development programs that we have advanced into various stages of clinical and preclinical development, originated from our own internal drug discovery efforts. These efforts were driven by a systematic, target biology-driven approach in which we used gene knockout technologies and an integrated platform of advanced medical technologies to systematically study the physiological and behavioral functions of almost 5,000 genes in mice and assessed the utility of the proteins encoded by the corresponding human genes as potential drug targets. We have identified and validated in living animals, or *in vivo*, more than 100 targets with promising profiles for drug discovery.

We are working both independently and through strategic collaborations and alliances with third parties to capitalize on our drug target discoveries and drug discovery and development programs. We seek to retain exclusive or co-exclusive rights to the benefits of certain drug discovery and development programs by developing and commercializing drug candidates from those programs internally, particularly in the United States for indications treated by specialist physicians. We seek to collaborate with other pharmaceutical and biotechnology companies with respect to drug discovery or the development and commercialization of certain of our drug candidates, particularly with respect to commercialization in territories outside the United States or commercialization in the United States for indications treated by primary care physicians, or when the collaboration may otherwise provide us with access to expertise and resources that we do not possess internally or are complementary to our own.

Lexicon Pharmaceuticals was incorporated in Delaware in July 1995, and commenced operations in September 1995. Our corporate headquarters are located at 8800 Technology Forest Place, The Woodlands, Texas 77381, and our telephone number is (281) 863-3000.

Our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are made available

free of charge on our corporate website located at www.lexpharma.com as soon as reasonably practicable after the filing of those reports with the Securities and Exchange Commission. Information found on our website should not be considered part of this annual report on Form 10-K.

Drugs and Drug Candidates

We are devoting most of our resources to the commercialization or development of our three most advanced drugs and drug candidates: XERMELO (telotristat ethyl), which we are commercializing for carcinoid syndrome diarrhea and developing for biliary tract cancer; sotagliflozin, which we are developing for type 1 diabetes and type 2 diabetes, heart failure and chronic kidney disease; and LX9211, which we are developing for neuropathic pain. We have also advanced a number of additional compounds into various stages of clinical and preclinical development.

XERMELO (telotristat ethyl)

We commercially launched XERMELO, an orally-delivered small molecule compound, following regulatory approval in the United States in February 2017 for the treatment of carcinoid syndrome diarrhea in combination with SSA therapy in adults inadequately controlled by SSA therapy. XERMELO was discovered by our scientists and inhibits tryptophan hydroxylase, or TPH, the rate-limiting enzyme for serotonin production which ordinarily is found primarily in enterochromaffin cells of the gastrointestinal tract. Carcinoid syndrome is characterized by frequent and debilitating diarrhea and can result when these cells become cancerous and metastasize to the liver or other organs, where they overproduce serotonin. The recommended dose of XERMELO is 250mg three times daily, and the full prescribing information for XERMELO includes certain warnings and precautions relating to constipation.

We have entered into a license and collaboration agreement under which we granted Ipsen an exclusive, royalty-bearing right and license to commercialize XERMELO outside of the United States and Japan. Ipsen has received approval from the European Commission to market XERMELO for the treatment of carcinoid syndrome diarrhea in all member states of the European Union, Norway and Iceland and from certain other regulatory authorities to market XERMELO in additional countries. Ipsen has commercially launched XERMELO in the United Kingdom, Germany and multiple additional countries.

As part of our life cycle management of the program, we are conducting our TELE-ABC Phase 2a clinical trial evaluating the safety and tolerability of telotristat ethyl and its effects on biliary tract cancer. The trial is expected to enroll approximately 53 patients with unresectable, locally advanced, recurrent or metastatic biliary tract cancer in an open-label, two-stage study of a 250mg three times daily dose of telotristat ethyl over an initial 7-day treatment period, followed by a 500mg three times daily dose of telotristat ethyl over subsequent 21-day treatment cycles until cessation of treatment for disease progression, toxicity or patient withdrawal. Standard of care, first-line chemotherapy doses of cisplatin and gemcitabine are administered on days one and eight of each 21-day treatment cycle. The trial is designed to be conducted in two stages, of which the first stage is expected to enroll approximately 20 patients and the second stage is expected to enroll approximately 33 patients. The primary efficacy endpoint under evaluation is the progression-free survival rate at six months, with secondary endpoints including progression-free survival at 12 months, overall survival rate, survival rates at six and twelve months, disease control rates and weight change. A safety analysis of the first six patients who completed at least the first 21-day treatment cycle supported the continuation of enrollment with no adjustment in the dosing regimen.

Sotagliflozin

Sotagliflozin is an orally-delivered small molecule compound that we are developing for the treatment of type 1 diabetes and type 2 diabetes, heart failure and chronic kidney disease. Sotagliflozin was discovered by our scientists and inhibits both sodium-glucose cotransporter type 2, or SGLT2, a transporter responsible for most of the glucose reabsorption performed by the kidney, and sodium-glucose cotransporter type 1, or SGLT1, a transporter responsible for glucose and galactose absorption in the gastrointestinal tract. Our scientists discovered that mice lacking SGLT1, SGLT2 or both exhibit potent anti-diabetic phenotypes across multiple measures of glucose control and metabolism, and found that compounds inhibiting both targets had a favorable preclinical profile relative to compounds selective for SGLT2.

We had previously granted Sanofi-Aventis Deutschland GmbH, or Sanofi, an exclusive, worldwide (excluding Japan), royalty-bearing right to develop, manufacture and commercialize sotagliflozin. In September 2019, we and Sanofi agreed to terminate our collaboration, pursuant to which we have regained all rights to sotagliflozin and have assumed full responsibility for the worldwide development and commercialization of sotagliflozin in all indications.

Type 1 Diabetes.

The FDA issued a complete response letter in March 2019 regarding our application for regulatory approval to market sotagliflozin for type 1 diabetes in the United States and has confirmed that position in denying two appeals of the complete response letter in November 2019 and March 2020. We are currently evaluating the feedback provided in the FDA's most recent response. In April 2019, Zynquista was approved in the European Union for use as an adjunct to insulin therapy to improve glycemic control in adults with type 1 diabetes and a body mass index ≥ 27 kg/m², who could not achieve adequate glycemic control despite optimal insulin therapy. We have not commercially launched Zynquista for the treatment of type 1 diabetes in the European Union or any other region.

We have completed three Phase 3 clinical trials evaluating the safety and tolerability of sotagliflozin and its effects on glycemic parameters associated with type 1 diabetes.

Our pivotal inTandem1 Phase 3 clinical trial enrolled 793 patients with type 1 diabetes in the United States and Canada in a randomized, double-blind, placebo-controlled study of 200mg and 400mg once daily doses of sotagliflozin over a 24-week treatment period, followed by a 28-week extension. Insulin therapy was optimized in patients over a 6-week period prior to dosing. The primary efficacy endpoint under evaluation in the trial was the reduction of hemoglobin A1c, or A1C, versus placebo on optimized insulin treatment at 24 weeks, with secondary endpoints including percentage of patients achieving A1C levels of less than 7% without experiencing an event of severe hypoglycemia or diabetic ketoacidosis, or DKA, change in meal-time, or bolus, insulin use, body weight, fasting plasma glucose and patient-reported assessments. Data from the study showed that patients treated with sotagliflozin experienced statistically significant reductions in A1C from baseline of 0.43% for the 200mg dose ($p < 0.001$) and 0.48% for the 400mg dose ($p < 0.001$), as compared to a reduction of 0.07% on placebo after 24 weeks of treatment, meeting the study's primary efficacy endpoint at both dose levels. The A1C benefit achieved with sotagliflozin was sustained with statistically significant results over the full 52-week duration of the study for both the 200mg and 400mg doses. Benefits in all secondary efficacy endpoints were observed in both the 200mg and 400mg dose arms compared to placebo, with statistically significant improvements in all secondary efficacy endpoints observed in the 400mg dose arm and in the percentage of patients achieving A1C levels of less than 7% without any severe hypoglycemia or DKA events and weight loss observed in the 200mg dose arm and statistically significant improvements in all secondary efficacy endpoints observed in the 400mg dose arm. Over the full 52-week treatment period, the incidences of treatment-emergent adverse events in the placebo, 200mg and 400mg dose arms were 80.6%, 81.7% and 79.8%, respectively; the incidences of serious adverse events were 7.5%, 10.3% and 11.1%, respectively; and the incidences of discontinuation due to adverse events were 4.1%, 4.9% and 6.5%, respectively. Potential cases of severe hypoglycemia and DKA were reviewed by a blinded adjudication panel, which determined whether such cases met pre-established diagnostic criteria. The number of patients with positively adjudicated severe hypoglycemic events during the full 52-week treatment period was 26 (9.7%), 17 (6.5%) and 17 (6.5%) in the placebo, 200mg and 400mg dose arms, respectively. The number of patients with positively adjudicated DKA events during the full 52-week treatment period was 1 (0.4%), 9 (3.4%) and 11 (4.2%) in the placebo, 200mg and 400mg dose arms, respectively.

Our pivotal inTandem2 Phase 3 clinical trial enrolled 782 patients with type 1 diabetes in Europe and Israel in a randomized, double-blind, placebo-controlled study of 200mg and 400mg once daily doses of sotagliflozin over a 24-week treatment period, followed by a 28-week extension. Insulin therapy was optimized in patients over a 6-week period prior to dosing. As with inTandem1, the primary efficacy endpoint under evaluation in the trial was the reduction of A1C versus placebo on optimized insulin treatment at 24 weeks, with secondary endpoints including percentage of patients achieving A1C levels of less than 7% without experiencing a severe hypoglycemia or DKA event, change in bolus insulin use, body weight, fasting plasma glucose and patient-reported assessments. Data from the study showed that patients treated with sotagliflozin experienced statistically significant reductions in A1C from baseline of 0.39% for the 200mg dose ($p < 0.001$) and 0.37% for the 400mg dose ($p < 0.001$), as compared to a reduction of 0.02% on placebo after 24 weeks of treatment, meeting the study's primary efficacy endpoint at both dose levels. The A1C benefit achieved with sotagliflozin was sustained with statistically significant results over the full 52-week duration of the study for both the 200mg and 400mg doses. Statistically significant improvements in all secondary efficacy endpoints were observed in both the 200mg and 400mg dose arms compared to placebo. Over the full 52-week treatment period, the incidences of treatment-emergent adverse events in the placebo, 200mg and 400mg dose arms were 61.2%, 68.2% and 68.8%, respectively; the incidences of serious adverse events were 6.6%, 10.0% and 8.0%, respectively; and the incidences of discontinuation due to adverse events were 3.5%, 3.8% and 6.8%, respectively. Potential cases of severe hypoglycemia and DKA were reviewed by a blinded adjudication panel, which determined whether such cases met pre-established diagnostic criteria. The number of patients with positively adjudicated severe hypoglycemic events during the full 52-week treatment period was 13 (5.0%), 13 (5.0%) and 6 (2.3%) in the placebo, 200mg and 400mg dose arms, respectively. The number of patients with positively adjudicated DKA events during the full 52-week treatment period was 0 (0.0%), 6 (2.3%) and 9 (3.4%) in the placebo, 200mg and 400mg dose arms, respectively.

We have additionally reported pooled continuous glucose monitoring, or CGM, data from the inTandem1 and inTandem2 clinical trials. The percentage of time during the initial 24-week treatment period spent inside the target range for CGM glucose (70-180 mg/dL) increased from 52.2% to 57.8% in patients treated with 200mg of sotagliflozin and from 50.7% to 64.1% in patients treated with 400mg of sotagliflozin, with no relevant change observed in patients receiving placebo. The differences from placebo were clinically significant for both the 200mg and 400mg dose groups ($p=0.026$ and $p<0.001$, respectively). The increase in time spent in range by both sotagliflozin dose groups was a result of significantly reduced time spent above 180 mg/dL, while the time spent below 70 mg/dL was not increased. These results translate into an additional 1.41 hours and 3.02 hours that a patient would spend within the 70-180 mg/dL target range in a 24-hour period, for the 200mg and 400mg dose groups respectively.

Our inTandem3 Phase 3 clinical trial enrolled 1,405 patients with type 1 diabetes in the United States and Europe in a randomized, double-blind, placebo-controlled study of a 400mg once daily dose of sotagliflozin over a 24-week treatment period. Insulin therapy was not optimized in patients and eligibility criteria included any background insulin therapy. The primary efficacy endpoint under evaluation in the trial was the proportion of patients achieving A1C levels of less than 7% at 24 weeks without experiencing a severe hypoglycemic or DKA event, with secondary endpoints including the change from baseline in A1C, body weight, systolic blood pressure and bolus insulin use. Data from the study showed statistically significant superiority of sotagliflozin (28.6%) compared to placebo (15.2%) in the proportion of patients achieving A1C levels of less than 7% without experiencing a severe hypoglycemic or DKA event ($p<0.001$), meeting the study's primary endpoint. Patients treated with sotagliflozin also experienced statistically significant improvements in all secondary efficacy endpoints compared to placebo. The incidences of treatment-emergent adverse events in the placebo and 400mg dose arms were 52.5% and 55.1%, respectively; the incidences of serious adverse events were 3.3% and 6.9%, respectively; and the incidences of discontinuation due to adverse events were 2.3% and 6.3%, respectively. Potential cases of severe hypoglycemia and DKA were reviewed by a blinded adjudication panel, which determined whether such cases met pre-established diagnostic criteria. The number of patients with positively adjudicated severe hypoglycemic events during the 24-week treatment period was 17 (2.4%) and 21 (3.0%) in the placebo and 400mg dose arms, respectively. The number of patients with positively adjudicated DKA events during the 24-week treatment period was 4 (0.6%) and 21 (3.0%) in the placebo and 400mg dose arms, respectively. Results from the inTandem3 trial were published in the New England Journal of Medicine in September 2017.

Type 2 Diabetes, Heart Failure and Chronic Kidney Disease.

We are conducting a comprehensive Phase 3 development program for sotagliflozin in type 2 diabetes, heart failure and chronic kidney disease. This Phase 3 program includes two long-term outcomes studies: SCORED, which is designed to demonstrate benefits in chronic heart failure and chronic kidney disease in type 2 diabetes patients, and SOLOIST, which is designed to demonstrate benefits in acute decompensated heart failure in patients with and without type 2 diabetes. We have cooperated with Sanofi in the transition of responsibility for such Phase 3 development program, which was previously conducted by Sanofi, and other activities relating to sotagliflozin.

We have reported preliminary top-line results from the first four Phase 3 clinical trials of sotagliflozin in adults living with type 2 diabetes.

We reported preliminary top-line results in July 2019 from our SOTA-MET Phase 3 clinical trial. SOTA-MET enrolled 518 patients with type 2 diabetes and inadequate blood sugar control on background metformin therapy in a randomized, double-blind, placebo-controlled study of a 400mg once daily dose of sotagliflozin over a 26-week core treatment period, followed by a 53-week extension treatment period. The primary efficacy endpoint under evaluation in the trial was the reduction of A1C versus placebo at 26 weeks. Preliminary results from the study showed that patients treated with sotagliflozin experienced a statistically significant reduction in A1C at 26 weeks versus placebo, meeting the study's primary efficacy endpoint. Sotagliflozin was generally well-tolerated in the trial, with similar overall incidences of serious adverse events in patients treated with sotagliflozin and placebo.

We reported preliminary top-line results in July 2019 from our SOTA-CKD3 Phase 3 clinical trial. SOTA-CKD3 enrolled 787 patients with type 2 diabetes and moderate, or stage 3, chronic kidney disease in a randomized, double-blind, placebo-controlled study of 200mg and 400mg once daily doses of sotagliflozin over a 26-week core treatment period, followed by a 26-week extension period. The primary efficacy endpoint under evaluation in the trial was the reduction of A1C versus placebo at 26 weeks in the overall population of patients with stage 3 chronic kidney disease and in each of the subpopulations of patients with stage 3a and 3b chronic kidney disease. Preliminary results from the study showed that patients in the overall stage 3 population and patients with stage 3a chronic kidney disease who were treated with the 400mg dose of sotagliflozin experienced a statistically significant reduction in A1C at 26 weeks versus placebo. Although sotagliflozin demonstrated numerical improvement on A1C at 26 weeks, a statistically significant reduction in A1C at 26 weeks versus placebo was not

achieved in patients with stage 3b chronic kidney disease. Sotagliflozin was generally well-tolerated in the trial, with similar overall incidences of serious adverse events in patients treated with sotagliflozin and placebo.

We reported preliminary top-line results in July 2019 from our SOTA-CKD4 Phase 3 clinical trial. SOTA-CKD4 enrolled 277 patients with type 2 diabetes and severe, or stage 4, chronic kidney disease in a randomized, double-blind, placebo-controlled study of 200mg and 400mg once daily doses of sotagliflozin over a 26-week core treatment period, followed by a 26-week extension period. The primary efficacy endpoint under evaluation in the trial was the reduction of A1C versus placebo at 26 weeks. Preliminary results from the study showed that patients treated with the 400mg dose of sotagliflozin experienced a clinically meaningful reduction in A1C at 26 weeks that narrowly missed statistical significance versus placebo and achievement of the primary efficacy endpoint. Sotagliflozin was generally well-tolerated in the trial, with similar overall incidences of serious adverse events in patients treated with sotagliflozin and placebo.

We reported top-line results in December 2019 from our SOTA-EMPA Phase 3 clinical trial. SOTA-EMPA enrolled 770 type 2 diabetes patients on dipeptidyl peptidase-4 inhibitors, with or without metformin therapy, in a randomized, double-blind, placebo-controlled study of a 400mg once daily dose of sotagliflozin and a 25mg once daily dose of empagliflozin over a 26-week treatment period. The primary efficacy endpoint under evaluation in the trial was the reduction of A1C versus placebo at 26 weeks. Data from the study showed that patients treated with sotagliflozin experienced a statistically significant reduction in A1C at 26 weeks versus placebo, meeting the study's primary efficacy endpoint. The trial also achieved a key secondary endpoint of noninferiority of sotagliflozin versus empagliflozin on A1C reduction at 26 weeks. Sotagliflozin was generally well-tolerated in the trial, with safety results comparable to previously reported safety results in type 2 diabetes.

In addition to such trials, the Phase 3 development program also includes the following randomized, double-blind, placebo-controlled studies:

- Our SOTA-MONO study of 200mg and 400mg once daily doses of sotagliflozin as monotherapy in approximately 400 patients over a 26-week treatment period;
- Our SOTA-SU study of a 400mg once daily dose of sotagliflozin in approximately 500 patients added to sulfonylurea alone or in combination with metformin therapy over a 26-week core treatment period, followed by a 53-week extension treatment period;
- Our SCORED long-term outcomes study of a 200mg once daily dose of sotagliflozin, titrated to 400mg if the 200mg dose is tolerated, in approximately 10,500 patients with cardiovascular risk factors and moderate or severe renal impairment over a study duration to be determined by cardiovascular outcome events;
- Our SOTA-INS study of 200mg and 400mg once daily doses of sotagliflozin in approximately 560 patients on background basal insulin alone or in addition to other oral antidiabetic drug therapies over a 52-week treatment period;
- Our SOTA-GLIM study of 200mg and 400mg once daily doses of sotagliflozin in approximately 930 patients on background metformin therapy compared to up to a maximum daily dose of 6mg of glimepiride over a 52-week treatment period;
- Our SOTA-BONE study of 200mg and 400mg once daily doses of sotagliflozin in approximately 360 patients aged 55 years or older, with or without any stable anti-diabetes therapy, evaluating efficacy and bone safety over a 26-week core treatment period, followed by a 78-week double-blind extension treatment period; and
- Our SOLOIST long-term outcomes study of a 200mg once daily dose of sotagliflozin, titrated to 400mg if the 200mg is tolerated, in approximately 3,000 patients with acute decompensated heart failure and with or without type 2 diabetes over a study duration to be determined by cardiovascular outcome events.

LX9211

LX9211 is an orally-delivered small molecule compound that we are developing for the treatment of neuropathic pain. LX9211 was discovered by scientists working within our drug discovery alliance with Bristol-Myers Squibb and inhibits adaptor associated kinase 1, or AAK1. Our scientists discovered that mice lacking AAK1 exhibit increased resistance to induced neuropathic pain in preclinical models.

We reported top-line data in December 2018 and December 2019 from two Phase 1 clinical trials evaluating the safety, tolerability and pharmacokinetics of LX9211. The first trial enrolled ten cohorts of healthy volunteers in a randomized, double-blind, placebo-controlled, ascending single dose study of daily doses of LX9211. The second trial enrolled five cohorts of healthy volunteers in a randomized, double-blind, placebo-controlled, ascending multiple dose study of daily doses of LX9211,

followed by a maintenance dose for 14 days. In both trials, LX9211 demonstrated a safety, tolerability and pharmacokinetics profile identifying the maximum tolerated dose and supportive of once-daily dosing, while exhibiting dose proportional pharmacokinetics. The most common adverse events were headache and dizziness, and there were no drug-related serious adverse events.

We are preparing to initiate a Phase 2a clinical trial evaluating the safety and tolerability of LX9211 and its effects on diabetic peripheral neuropathic, or DPN, pain. The trial is expected to enroll approximately 282 patients experiencing DPN pain in a randomized, double-blind, placebo-controlled study of initial 100mg or 200mg loading doses of LX9211, followed by 10mg or 20mg once daily doses of LX9211, respectively. The effects of LX9211 will be assessed over an 11-week evaluation period. The primary efficacy endpoint under evaluation is the reduction in an average daily pain score at 6 weeks, with secondary endpoints including the proportion of patients with 30% or greater and 50% or greater reduction in pain intensity at 6 weeks and the proportion of patients discontinuing treatment due to lack of efficacy. Certain patient-reported outcome measures will also be assessed.

We have obtained exclusive research, development and commercialization rights to LX9211 and additional compounds acting through AAK1 from our alliance with Bristol-Myers Squibb.

Drug Target Discoveries

Our internal drug discovery efforts were driven by a systematic, target biology-driven approach in which we used gene knockout technologies and an integrated platform of advanced medical technologies to systematically study the physiological and behavioral functions of almost 5,000 genes in mice and assessed the utility of the proteins encoded by the corresponding human genes as potential drug targets. We have identified and validated in living animals, or *in vivo*, more than 100 targets with promising profiles for drug discovery.

Collaborations

We are working both independently and through strategic collaborations and alliances with third parties to capitalize on our drug target discoveries and drug discovery and development programs. Consistent with this approach, we seek to retain exclusive rights to the benefits of certain drug discovery and development programs by developing and commercializing drug candidates from those programs internally, particularly in the United States for indications treated by specialist physicians, as we have with XERMELo in the United States. We seek to collaborate with other pharmaceutical and biotechnology companies with respect to drug discovery or the development and commercialization of certain of our drug candidates, particularly with respect to commercialization in territories outside the United States or commercialization in the United States for indications treated by primary care physicians, or when the collaboration may provide us with access to expertise and resources that we do not possess internally or are complementary to our own. We also seek to collaborate with other pharmaceutical and biotechnology companies, research institutes and academic institutions to capitalize on our drug target discoveries.

Strategic Collaborations

Ipsen. We entered into a license and collaboration agreement with Ipsen in October 2014 under which we granted Ipsen an exclusive, royalty-bearing right and license to commercialize XERMELo outside of the United States, Canada and Japan. The collaboration was expanded in March 2015 to include Canada. We have received \$24.5 million in upfront payments and \$22.7 million in regulatory and commercial launch milestones under the agreement. In addition, we are eligible to receive up to an additional \$9.6 million upon the achievement of additional specified regulatory and commercial launch milestones and up to €72 million upon the achievement of specified sales milestones. We are also entitled to tiered, escalating royalties ranging from low twenties to mid-thirties percentages of net sales of XERMELo in the licensed territory, subject to a credit for Ipsen's payments to us for the manufacture and supply of such units of XERMELo and customary royalty reduction provisions.

Bristol-Myers Squibb. We established a drug discovery alliance with Bristol-Myers Squibb Company in December 2003 to discover, develop and commercialize small molecule drugs in the neuroscience field. Bristol-Myers Squibb extended the target discovery term of the alliance in May 2006. We initiated the alliance with a number of neuroscience drug discovery programs at various stages of development and used our gene knockout technologies to identify additional drug targets with promise in the neuroscience field. For those targets that were selected for the alliance, we and Bristol-Myers Squibb worked together, on an exclusive basis, to identify, characterize and carry out the preclinical development of small molecule drugs. Bristol-Myers Squibb has the first option to assume full responsibility for clinical development and commercialization of any drugs resulting from the alliance which enter clinical trials, other than LX9211 and additional compounds acting through AAK1. We received \$86 million in upfront payments and research funding under the agreement during the target discovery

portion of the alliance, which expired in October 2009. In addition, we are entitled to receive clinical and regulatory milestone payments ranging, depending on the timing and extent of our efforts in the alliance, up to \$76 million for each drug developed by Bristol-Myers Squibb under the alliance. We will also earn royalties on sales of drugs commercialized by Bristol-Myers Squibb under the alliance.

We jointly developed LX9211 with Bristol-Myers Squibb as part of the alliance, and obtained from the alliance exclusive research, development and commercialization rights to LX9211 and additional compounds acting through AAK1. We have agreed to pay Bristol-Myers Squibb up to \$34.5 million in clinical and regulatory milestones for the first indication and up to \$16 million in clinical and regulatory milestones for each of the second and third indications, if applicable. We have also agreed to pay single digit royalties on worldwide net sales and up to \$40 million in commercial milestones.

Genentech. We established a drug discovery alliance with Genentech, Inc. in December 2002 to discover novel therapeutic proteins and antibody targets. We and Genentech expanded the alliance in November 2005 for the advanced research, development and commercialization of new biotherapeutic drugs. Under the original alliance agreement, we used our target validation technologies to discover the functions of secreted proteins and potential antibody targets identified through Genentech's internal drug discovery research. In the expanded alliance, we conducted additional, advanced research on a broad subset of those proteins and targets. We have exclusive rights to develop and commercialize biotherapeutic drugs for two of these targets, while Genentech has exclusive rights to develop and commercialize biotherapeutic drugs for the other targets. We retain certain other rights to discoveries made in the alliance, including non-exclusive rights, along with Genentech, for the development and commercialization of small molecule drugs addressing the targets included in the alliance. We received \$58 million in upfront payments, research funding and research milestone payments under the agreement during the research collaboration term, which expired in November 2008. In addition, we are entitled to receive clinical and regulatory milestone payments ranging, depending on the extent of our efforts in the alliance, up to \$25 million for each drug target for which Genentech develops a biotherapeutic drug under the alliance. We will also earn royalties on sales of biotherapeutic drugs commercialized by Genentech under the alliance. Genentech is entitled to receive milestone payments and royalties on sales of biotherapeutic drugs which we develop or commercialize under the alliance.

Other Collaborations

We have established collaborations with a number of pharmaceutical and biotechnology companies, research institutes and academic institutions under which we have received fees in exchange for generating knockout mice for genes requested by the collaborator, providing phenotypic data with respect to such knockout mice or otherwise granting access to some of our technologies and discoveries. In some cases, we remain eligible to receive milestone or royalty payments on the sale of mice and phenotypic data or on products that our collaborators discover or develop using our technology.

Manufacturing and Product Supply

We do not own or operate manufacturing or distribution facilities or resources for clinical or commercial production and distribution of XERMELO or any of our drug candidates. Instead, we have multiple contractual agreements in place with third-party contract manufacturing organizations, or CMOs, who, on our behalf, manufacture commercial supplies of XERMELO and clinical supplies of our drug candidates, and will continue to do so for the foreseeable future. We have selected well-established and reputable global CMOs for our active pharmaceutical ingredient, or API, and drug product manufacturing that have good regulatory standing, large manufacturing capacities, and multiple manufacturing sites within their business footprint. We employ highly skilled personnel with both technical and manufacturing experience to diligently manage the activities at our CMOs. Our quality department audits these suppliers on a periodic basis. Our commercial suppliers are subject to routine inspections by regulatory agencies. We work closely with our third-party manufacturers to ensure compliance with current good manufacturing practices, or cGMP, and other stringent regulatory requirements enforced by the FDA and foreign regulatory agencies in other territories, as applicable.

Raw materials that are used to manufacture our API are sourced from multiple third-party suppliers in Asia and Europe. Third-party API contract manufacturers in Asia and Europe stock sufficient quantities of these materials to ensure they can manufacture adequate API quantities per our requirements, for both clinical and commercial purposes. We store API at third-party facilities, and provide appropriate amounts to third-party drug product contract manufacturers in Asia and North America who then manufacture, package and label our specified quantities of finished goods for XERMELO and our drug candidates. We rely on sole source third-party drug product contract manufacturers in the United States to manufacture, package and label finished drug product for commercial distribution of XERMELO. We also rely on a single third-party logistics provider, with two distribution locations, to provide shipping and warehousing services for our commercial supply of XERMELO in the United States. Our third-party contract manufacturers also need to obtain materials such as excipients, components and reagents to manufacture our API and finished drug products.

Within our supply chain, we have established safety stock amounts for both our API and drug products, and store those quantities for XERMELO in multiple locations. The quantities that we store are based on our business needs and take into account scenarios for demand, production lead times, potential supply interruptions and shelf life for our API and drug products. In parallel, for business continuity reasons, we have established a backup supplier for our API and are in the process of evaluating and expect to establish an additional or backup supplier for our drug product in the near future. We believe that our current manufacturing network has the appropriate capacity to produce sufficient commercial quantities of XERMELO for both our and Ipsen's commercialization efforts in support of the current approved indication of carcinoid syndrome diarrhea, as well as the potential indication of biliary tract cancer, if clinical development in that indication proves to be successful and gains regulatory approval in the future.

Marketing, Sales and Distribution

We have a fully integrated commercial team consisting of sales, marketing, market access, and commercial operations functions. Our specialized sales team promotes XERMELO in the United States, concentrating their efforts on oncologists, oncology nurses and pharmacists. We have also built an internal medical affairs function with responsibility for responding to external inquiries regarding the appropriate use of XERMELO with regularly updated and well-substantiated scientific and medical information. We have a limited distribution network consisting of specialty pharmacies and specialty distributors who distribute XERMELO in fulfillment of prescriptions in the United States. We rely on Ipsen for the commercialization and distribution of XERMELO in territories outside of the United States.

To help ensure that all eligible patients in the United States have appropriate access to XERMELO, we have established a comprehensive reimbursement and support program called LexCares. Through LexCares, we provide co-pay assistance to qualified, commercially insured patients to help minimize out-of-pocket costs and provide free drug to uninsured or under-insured patients who meet certain clinical and financial criteria. In addition, LexCares is designed to provide comprehensive reimbursement support services, such as benefits investigation and, if needed, appeals support.

Competition

The biotechnology and pharmaceutical industries are highly competitive and characterized by rapid technological change. We face significant competition in each of the aspects of our business from other pharmaceutical and biotechnology companies, as well as academic research institutions, clinical reference laboratories and governmental agencies that are pursuing research or development activities similar to ours. Many of our competitors have substantially greater research, development and commercialization capabilities and financial, scientific, marketing and human resources than we do. As a result, our competitors may succeed in developing products earlier than we do, obtaining approvals from the FDA or other regulatory agencies for those products more rapidly than we do, developing products that are more effective than those we develop or commercializing products more effectively and profitably than we do. Similarly, our collaborators face similar competition from other competitors who may succeed in developing products more quickly, developing products that are more effective than those developed by our collaborators or commercialize products more effectively and profitably than our collaborators.

The competition for our products and drug candidates includes both marketed products and drug candidates that are being developed by others, including pharmaceutical products that are currently in a more advanced stage of clinical development or commercialization than are our own drug candidates. These competitive marketed products and drug candidates include compounds that employ different mechanisms of action in addressing diseases and conditions for which we are developing our own drug candidates and, in some cases such as sotagliflozin, that employ the same or similar mechanisms of action.

We believe that our ability to successfully compete with these potentially competitive drug candidates and other competitive products currently on the market will depend on, among other things:

- the efficacy, safety and reliability of our products;
- our ability, and the ability of our collaborators, to complete preclinical and clinical development and obtain regulatory approvals for our drug candidates;
- the timing and scope of regulatory approvals of our products;

- our ability, and the ability of our collaborators, to obtain product acceptance by physicians and other health care providers and secure coverage and adequate reimbursement for product use in approved indications;
- our ability, and the ability of our collaborators, to manufacture and sell commercial quantities of our products;
- the skills of our employees and our ability to recruit and retain skilled employees;
- protection of our intellectual property; and
- the availability of substantial capital resources to fund development and commercialization activities.

Our principal competition for XERMELO includes the use, above their maximum labeled dose, of the established SSA therapies octreotide and lanreotide, injectable products currently marketed by Novartis and Ipsen, respectively, as well as lutetium Lu 177 dotatate, a radiopharmaceutical product currently marketed for the treatment of gastroenteropancreatic neuroendocrine tumors by Advanced Accelerator Applications (a subsidiary of Novartis).

We expect that our principal competition for sotagliflozin in the treatment of type 1 diabetes would include established insulin therapies, as well as selective SGLT2 inhibitors currently being prescribed off-label, but which may gain regulatory approval, for the treatment of type 1 diabetes in the United States. Such selective SGLT2 inhibitors include dapagliflozin, empagliflozin and canagliflozin, currently marketed for the treatment of type 2 diabetes by AstraZeneca, Boehringer Ingelheim and Eli Lilly, and Janssen (a subsidiary of Johnson & Johnson), respectively. In addition, AstraZeneca has received approval in the European Union for the use of dapagliflozin in type 1 diabetes as an adjunct to insulin in patients with a body mass index of 27 kg/m² or greater, when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy.

We expect that our principal competition for sotagliflozin for the treatment of type 2 diabetes would include such selective SGLT2 inhibitors, as well as DPP-4 inhibitors such as sitagliptin, currently marketed for the treatment of type 2 diabetes by Merck. We expect that our principal competition for sotagliflozin for the treatment of heart failure would include such selective SGLT2 inhibitors which may gain regulatory approval for the treatment of heart failure, as well as angiotensin-converting enzyme, or ACE, inhibitors and the combination drug sacubitril/valsartan, currently marketed for the treatment of heart failure by Novartis. We expect that our principal competition for sotagliflozin for the treatment of chronic kidney disease would include canagliflozin and such other selective SGLT2 inhibitors which may gain regulatory approval for the treatment of chronic kidney disease.

Government Regulation

The development, manufacture and sale of pharmaceutical products are subject to extensive regulation by United States and foreign governmental authorities, including federal, state and local authorities. In the United States, new drugs are subject to regulation under the Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder, or the FDC Act. The FDA and comparable governmental authorities regulate, among other things, research and development activities and the testing, manufacture, quality control, safety, efficacy, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, export and import of pharmaceutical products.

The standard process required by the FDA before a drug candidate may be marketed in the United States generally includes the following:

- preclinical laboratory and animal tests performed under current good laboratory practices, or cGLP;
- submission of an IND, which must become effective before human clinical trials may commence;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug candidate for its intended use;
- submission of a New Drug Application, or NDA, for approval of commercial marketing and sale, or of an NDA supplement, or sNDA, for approval of a new indication if the product is already approved for another indication;
- pre-approval inspection of manufacturing facilities and selected clinical investigators for their compliance with cGMP and current good clinical practices, or cGCP;
- if FDA convenes an advisory committee, satisfactory completion of the advisory committee review; and

- FDA approval of the NDA or sNDA.

This process for the testing and approval of drug candidates requires substantial time, effort and financial resources. Preclinical development of a drug candidate can take from one to several years to complete, with no guarantee that an IND based on those studies will become effective to even permit clinical testing to begin. Before commencing the first clinical trial of a drug candidate in the United States, we must submit an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial. In such a case, we and the FDA must resolve any outstanding concerns before the clinical trial may begin. Submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development, and the FDA must grant permission for each clinical trial to start and continue. Further, an independent institutional review board for each medical center proposing to participate in the clinical trial must review and approve the plan for any clinical trial before it commences at that center. Regulatory authorities or an institutional review board or we may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

For purposes of NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1 clinical trials are conducted in a limited number of healthy human volunteers or, in some cases, patients, to evaluate the safety, dosage tolerance, absorption, metabolism, distribution and excretion of the drug candidate;
- Phase 2 clinical trials are conducted in groups of patients afflicted with a specified disease or condition to obtain preliminary data regarding efficacy as well as to further evaluate safety and optimize dosing of the drug candidate. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials; and
- Phase 3 clinical trials are conducted in larger patient populations at multiple clinical trial sites to obtain statistically significant evidence of the efficacy of the drug candidate for its intended use and to further test for safety in an expanded patient population.

In addition, the FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 studies may be made a condition to be satisfied after a drug receives approval. Failure to satisfy such post-marketing commitments can result in FDA enforcement action, up and to including withdrawal of NDA approval. The results of Phase 4 studies can confirm the effectiveness of a drug candidate and can provide important safety information to augment the FDA's adverse drug reaction reporting system.

After completion of clinical trials, FDA approval of an NDA must be obtained before a new drug may be marketed in the United States. The submission of an NDA requires payment of a substantial user fee to the FDA. An NDA must contain, among other things, information on chemistry, manufacturing controls and potency and purity, non-clinical pharmacology and toxicology, human pharmacokinetics and bioavailability and clinical data. There can be no assurance that the FDA will accept an NDA for filing and, even if accepted for filing, that approval will be granted. The FDA may convene an advisory committee to provide clinical insight on NDA review questions. Although the FDA is not required to follow the recommendations of an advisory committee, the agency typically does so. Among other things, the FDA reviews an NDA to determine whether a product is safe and effective for its intended use and whether the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may deny approval of an NDA by way of a Complete Response letter if the applicable regulatory criteria are not satisfied, or it may require additional clinical data or an additional pivotal Phase 3 clinical trial. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. An NDA may be approved with significant restrictions on its labeling, marketing and distribution under a Risk Evaluation and Mitigation Strategy or otherwise that could restrict the commercial applications of a product or impose costly procedures in connection with the commercialization or use of the product. Once issued, the FDA may withdraw product approval if ongoing regulatory standards are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

In addition to obtaining FDA approval for each product, each drug manufacturing establishment must be inspected and approved by the FDA. All manufacturing establishments are subject to inspections by the FDA and by other federal, state and local agencies and must comply with current Good Manufacturing Practices requirements. Non-compliance with these

requirements can result in, among other things, total or partial suspension of production, failure of the government to grant approval for marketing and withdrawal, suspension or revocation of marketing approvals.

Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes many years, with the actual time required varying substantially based on, among other things, the nature, novelty and complexity of the drug candidate and of the disease or condition. Government regulation may delay or prevent marketing of drug candidates or new diseases for a considerable period of time and impose costly procedures upon our activities. The FDA or any other regulatory agency may not grant approvals for new indications for our product candidates on a timely basis, if at all. Success in earlier-stage clinical trials does not ensure success in later-stage clinical trials. Targets and pathways identified in vitro may be determined to be less relevant in clinical studies and results in animal model studies may not be predictive of human clinical results. Furthermore, data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Even if a drug candidate receives regulatory approval, the approval may be significantly limited to specific disease states, patient populations and dosages. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

Once the FDA approves a product, a manufacturer must provide certain updated safety and efficacy information. Product changes as well as certain changes in a manufacturing process or facility would necessitate additional FDA review and approval. Other post-approval changes may also necessitate further FDA review and approval. Additionally, a manufacturer must meet other requirements including those related to adverse event reporting and record keeping.

Products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers.

The FDA closely regulates the marketing and promotion of drugs, including restricting the promotion of uses for which a drug is not approved by the agency. Not only must a company have appropriate substantiation to support claims made about a drug, under the FDA's current interpretation of relevant laws, a company can make only those claims relating to safety and efficacy that are for indications for which FDA has approved the drug and are otherwise consistent with the FDA-approved label for the drug. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may, in their independent medical judgment, prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturers' communications on the subject of off-label use. Additionally, a significant number of pharmaceutical companies have been the target of inquiries and investigations by various United States federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for off-label uses and other sales practices. These investigations have alleged violations of various United States federal and state laws and regulations, including claims asserting antitrust violations, violations of the FDC Act, false claims laws, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement.

The United States Orphan Drug Act is intended to incentivize the development of products for rare diseases or conditions that affect fewer than 200,000 people in the United States. If a drug is being developed for a rare disease or condition, to be eligible for designation as an orphan drug, the FDA must not have previously approved a drug considered the "same drug" for the same orphan indication. If the FDA has previously approved another same drug for the same indication, the sponsor of the subsequent drug would be required to provide a plausible hypotheses of clinical superiority over the previously approved drug to obtain an orphan designation. Upon FDA receipt of orphan drug designation, the sponsor is eligible for tax credits of up to 25% for qualified clinical trial expenses, the ability to apply for annual grant funding and waiver of PDUFA application fee. In addition, upon marketing approval, an orphan-designated drug could be eligible for seven years of market exclusivity for the approved orphan-designated indication. Such orphan drug exclusivity, if awarded, would only block the approval of any drug considered the same drug for the same orphan indication. Moreover, a subsequent same drug could break a previously approved drug's orphan exclusivity through a demonstration of clinical superiority over the previously approved drug.

The FDA has various programs, including Fast Track, priority review and accelerated approval, which are intended to expedite or simplify the process for developing and reviewing promising drugs, or to provide for the approval of a drug on the

basis of a surrogate endpoint. Generally, drugs that are eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious or life-threatening diseases or conditions and fill unmet medical needs. Priority review is designed to give drugs that treat serious conditions and offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months of NDA filing as compared to a standard review time of 10 months from NDA filing. Certain other types of drug applications are also eligible for priority review. Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track-designated drug and expedite review of the application for a drug designated for priority review. Accelerated approval provides for an earlier approval for a new drug that is intended to treat a serious or life-threatening disease or condition and that fills an unmet medical need based on a surrogate endpoint. As a condition of approval, the FDA may require that a sponsor of a product candidate receiving accelerated approval perform post-marketing clinical trials to confirm the clinically meaningful outcome as predicted by the surrogate marker trial. In addition to the Fast Track, accelerated approval and priority review programs, the FDA also designates Breakthrough Therapy status to drugs that are intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA will seek to ensure the sponsor of a breakthrough therapy product candidate receives intensive guidance on an efficient drug development program, intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review and rolling review.

Additional programs intended to expedite the development of drug products were included in the 21st Century Cures Act, or the Cures Act. The Cures Act includes various provisions to accelerate the development and delivery of new treatments, such as those intended to expand the types of evidence manufacturers may bring to the FDA to support drug approval, to encourage patient-centered drug development, to liberalize the communication of healthcare economic information to payers, and to create greater transparency with regard to manufacturer expanded access programs. Central to the Cures Act are provisions that enhance and accelerate the FDA's processes for reviewing and approving new drugs and supplements to approved NDAs, including provisions that:

- require the FDA to establish a program to evaluate the potential use of real world evidence to help support the approval of a new indication for an approved drug and to help support or satisfy post-approval study requirements;
- provide that the FDA may rely upon qualified data summaries to support the approval of a supplemental application with respect to a qualified indication for an already approved drug;
- require the FDA to issue guidance for purposes of assisting sponsors in incorporating complex adaptive and other novel trial designs into proposed clinical protocols and applications for new drugs; and
- require the FDA to establish a process for the qualification of drug development tools for use in supporting or obtaining FDA approval for or investigational use of a drug.

The Cures Act amends Section 114 of the Food and Drug Administration Modernization Act of 1997 to help clarify and facilitate the dissemination of healthcare economic information, including by broadening the definition of healthcare economic information, expressly extending the dissemination of healthcare economic information to payors, and clarifying that healthcare economic information must only relate to an FDA-approved indication rather than directly relate to the indication.

Regulation Outside of the United States

In addition to regulations in the United States, we are subject to the regulations of other countries governing clinical trials and the manufacturing, commercial sales and distribution of our products outside of the United States. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of countries outside of the United States before we can commence clinical trials in such countries and approval of the regulators of such countries or economic areas, such as the European Union, before we may market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Under European Union regulatory systems, a company may submit marketing authorization applications, or MAAs, either under a centralized or decentralized procedure. Under the centralized procedure, MAAs are submitted to the European Medicines Agency, or EMA, whose Committee for Medicinal Products for Human Use reviews the application and issues an

opinion on it. The opinion is considered by the European Commission which is responsible for deciding applications. If the application is approved, the European Commission grants a single marketing authorization that is valid for all European Union member states as well as Iceland, Liechtenstein and Norway, or the EEA. The national authorization procedures, the decentralized and mutual recognition procedures, as well as national applications, are available for products for which the centralized procedure is not compulsory. The mutual recognition procedure provides for the European Union member states selected by the applicant to mutually recognize a national marketing authorization that has already been granted by the competent authority of another member state, referred to as the Reference Member State, or RMS. The decentralized procedure is used when the product in question has yet to be granted a marketing authorization in any member state. Under this procedure the applicant can select the member state that will act as the RMS. In both the mutual recognition and decentralized procedures, the RMS reviews the application and submits its assessment of the application to the member states where marketing authorizations are being sought, referred to as Concerned Member States or CMS. Within 90 days of receiving the application and assessment report, each CMS must decide whether to recognize the RMS assessment. If a member state does not agree with the assessment, and the disputed points cannot be resolved the matter is eventually referred to the European Commission, whose decision is binding on all member states. If the application is successful national marketing authorizations will be granted by the competent authorities in each of the member states chosen by the applicant.

Conditional marketing authorizations may be granted for a limited number of medicinal products for human use referenced in European Union law applicable to conditional marketing authorizations where the clinical dataset is not comprehensive, if the risk-benefit balance of the product is positive, it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, unmet medical needs will be fulfilled and the benefit to public health of the immediate availability on the market of the medicinal product outweighs the risk inherent in the fact that additional data are still required. Specific obligations, such as the completion of ongoing or new studies and obligations relating to the collection of pharmacovigilance data, may be amongst the conditions stipulated in the marketing authorization.

As in the United States, we may apply for designation of a product as an Orphan drug for the treatment of a specific indication in the European Union before the application for marketing authorization is made. In the European Union, orphan designation is available for products in development which are either intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in the European Union, or intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the community and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the medicinal product. Additionally, the sponsor of an application for orphan drug designation must establish that there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition or even if such treatment exists, the product will be of significant benefit to those affected by that condition.

Orphan drugs in the European Union enjoy economic and marketing benefits, including up to ten years of market exclusivity for the approved indication unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan-designated product. The period of market exclusivity may be reduced to six years if at the end of the fifth year it is established that the criteria for orphan designation are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Healthcare Regulation

Federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, also apply to our business. If we fail to comply with those laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected. The laws that may affect our ability to operate include, but are not limited to: the federal Anti-Kickback Statute, which prohibits, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; and federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent. Additionally, we are subject to state law equivalents of each of the above federal laws, which may be broader in scope and apply regardless of whether the payer is a federal healthcare program, and many of which differ from each other in significant ways and may not have the same effect, further complicate compliance efforts.

Numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use and disclosure of personal information. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information. In addition, most healthcare providers who are expected to prescribe our products and from whom we obtain patient health information, are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of

1996, as amended by the Health Information Technology and Clinical Health Act, or HIPAA. Although we are not directly subject to HIPAA, we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a HIPAA-covered entity, including healthcare providers, in a manner that is not authorized or permitted by HIPAA. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including recently enacted laws in a majority of states requiring security breach notification. These laws could create liability for us or increase our cost of doing business. International laws, such as the EU Data Privacy Directive and Swiss Federal Act on Data Protection, regulate the processing of personal data within the European Union and between countries in the European Union and countries outside of the European Union, including the United States. Failure to provide adequate privacy protections and maintain compliance with safe harbor mechanisms could jeopardize business transactions across borders and result in significant penalties.

In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or the PPACA, created a federal requirement under the federal Open Payments program, that requires certain manufacturers to track and report to the Centers for Medicare and Medicaid Services, or CMS, annually certain payments and other transfers of value provided to physicians and teaching hospitals made in the previous calendar year. In addition, there are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities.

For those marketed products which are covered in the United States by the Medicaid program, we have various obligations, including government price reporting and rebate requirements, which generally require products be offered at substantial rebates/discounts to Medicaid and certain purchasers. We are also required to discount such products to authorized users of the Federal Supply Schedule of the General Services Administration, under which additional laws and requirements apply. These programs require submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations, and the guidance governing such calculations is not always clear. Compliance with such requirements can require significant investment in personnel, systems and resources, but failure to properly calculate our prices, or offer required discounts or rebates could subject us to substantial penalties.

Other Regulations

In addition to the foregoing, our business is subject to regulation under various state and federal environmental laws, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act and the Toxic Substances Control Act. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in and wastes generated by our operations. We believe that we are in material compliance with applicable environmental laws and that our continued compliance with these laws will not have a material adverse effect on our business. We cannot predict, however, whether new regulatory restrictions will be imposed by state or federal regulators and agencies or whether existing laws and regulations will adversely affect us in the future.

Patents and Proprietary Rights

We are able to protect our proprietary rights from unauthorized use by third parties only to the extent that those rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. Accordingly, patents and other proprietary rights are an essential element of our business. We own or exclusively license patents and/or patent applications throughout the world that claim our products and drug candidates, including:

- issued patents and pending patent applications in Europe, the United States, and other countries throughout the world, including Australia, Argentina, Brazil, Canada, China, Europe, India, Israel, Japan, Mexico, New Zealand, South Africa, and South Korea, that claim telotristat ethyl and associated crystalline forms, pharmaceutical compositions comprising telotristat ethyl, and methods of its manufacture and use;
- issued patents and pending patent applications in Europe, the United States, and other countries throughout the world, including Australia, Argentina, Brazil, Canada, China, Europe, India, Israel, Japan, Mexico, New Zealand, South Africa, and South Korea, that claim sotagliflozin and associated crystalline forms, pharmaceutical compositions comprising sotagliflozin, and methods of its manufacture and use; and
- issued patents and pending patent applications in Europe, the United States, and other countries throughout the world, including Australia, Brazil, Canada, China, Europe, India, Israel, Japan, Mexico, New Zealand, South Africa, and

South Korea, that disclose and/or claim LX9211, pharmaceutical compositions comprising LX9211, and methods of its use.

Additionally, we hold rights to a number of patents and patent applications under license agreements with third parties. Many of these licenses are nonexclusive, although some are exclusive in specified fields. Most of the licenses have terms that extend for the life of the licensed patents.

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country. We have filed patent applications and hold issued patents covering our approved drug, XERMELO, and each of our drug candidates. None of our United States patents that claim XERMELO or one of our drug candidates has a normal expiration date earlier than 2026.

All of our employees, consultants and advisors are required to execute a proprietary information agreement upon the commencement of employment or consultation. In general, the agreement provides that all inventions conceived by the employee or consultant, and all confidential information developed or made known to the individual during the term of the agreement, shall be our exclusive property and shall be kept confidential, with disclosure to third parties allowed only in specified circumstances. We cannot assure you, however, that these agreements will provide useful protection of our proprietary information in the event of unauthorized use or disclosure of such information.

Our patent and intellectual property rights are subject to certain rights and uncertainties. See “Risks Related to Our Intellectual Property” under “Item 1A. Risk Factors.”

Executive Officers

Our executive officers and their ages and positions are listed below.

Name	Age	Position with the Company
Lonnell Coats	55	President and Chief Executive Officer and Director
Pablo Lapuerta, M.D.	56	Executive Vice President and Chief Medical Officer
Alan J. Main, Ph.D.	66	Executive Vice President, Commercial Supply Operations
Alexander A. Santini	61	Executive Vice President and Chief Commercial Officer
Praveen Tyle, Ph.D.	59	Executive Vice President, Research and Development
Jeffrey L. Wade	55	Executive Vice President, Corporate and Administrative Affairs and Chief Financial Officer
Brian T. Crum	47	Vice President and General Counsel
James F. Tessmer	60	Vice President, Finance and Accounting

Lonnell Coats has been our president and chief executive officer and a director since July 2014. Mr. Coats previously served in a series of executive leadership positions at Eisai Inc. and Eisai Corporation of North America, where he worked for 18 years before joining our company, most recently as chief executive officer from 2010 to 2014. Prior to joining Eisai, Mr. Coats spent eight years with Janssen Pharmaceuticals, Inc., a division of Johnson & Johnson, where he held a variety of management and sales positions. Mr. Coats serves as a director of Blueprint Medicines Corporation and holds a B.S. from Oakland University.

Pablo Lapuerta, M.D. has been our executive vice president and chief medical officer since February 2015 and previously served in a series of medical and clinical leadership positions since joining our company in 2011. Dr. Lapuerta was formerly vice president at Bristol-Myers Squibb Company with responsibility for global development of an Alzheimer’s disease drug candidate, and prior to that served as senior vice president, clinical strategy and chief medical officer of Cogentus Pharmaceuticals, Inc. and in a variety of clinical development leadership roles at Bristol-Myers Squibb, where he worked for 11 years before joining Cogentus. He holds a B.A. in biology from Harvard College and an M.D. from Harvard Medical School.

Alan J. Main, Ph.D. has been our executive vice president, commercial supply operations since May 2017 and previously served in a series of manufacturing and scientific leadership positions since joining our company in 2001. Dr. Main was president and chief executive officer of Coelacanth Corporation, a leader in using proprietary chemistry technologies to rapidly discover new chemical entities for drug development, until our acquisition of Coelacanth in 2001. Dr. Main was

formerly senior vice president, U.S. Research at Novartis Pharmaceuticals Corporation, where he worked for 20 years before joining Coelacanth. Dr. Main holds a B.S. from the University of Aberdeen, Scotland and a Ph.D. in organic chemistry from the University of Liverpool, England and completed postdoctoral studies at the Woodward Research Institute.

Alexander A. Santini has been our executive vice president and chief commercial officer since November 2016 and previously served in a series of commercial leadership positions since joining our company in April 2015. Mr. Santini was formerly vice president of market access and an executive member at Bayer Healthcare Pharmaceuticals, where he had executive responsibility for market access, pricing, trade and channel management and payer account management, and prior to that served in a variety of commercial leadership roles of increasing responsibility during eight years of service at Bayer and 22 years of service at Berlex Laboratories. Mr. Santini served as a non-commissioned officer in the United States Air Force, where he completed the Radiologic Technology Program at the United States Air Force School of Health Care Science and an AAS in business marketing from Westchester Community College.

Praveen Tyle, Ph.D. has been our executive vice president of research and development since May 2016. Dr. Tyle was previously a member of the executive management team at Osmotica Pharmaceutical Corp., serving as president and chief executive officer from January 2013 through April 2016 and prior to that as executive vice president and chief scientific officer. Prior to his service at Osmotica, Dr. Tyle held a series of scientific leadership positions within the pharmaceutical industry, including executive vice president and chief science officer for the United States Pharmacopeia, senior vice president and global head of research and development and business development and licensing at Novartis OTC, corporate senior vice president of global research and development and chief scientific officer at Bausch & Lomb Incorporated and vice president and global head of pharmaceutical sciences at Pharmacia Corporation. Dr. Tyle serves as director of Eyegate Pharmaceuticals, Inc. and Orient Europharma Ltd. Dr. Tyle received his B.Pharm. from the Indian Institute of Technology, Banaras Hindu University and his Ph.D. in pharmaceutics and pharmaceutical chemistry from the Ohio State University.

Jeffrey L. Wade has been our executive vice president, corporate and administrative affairs and chief financial officer since February 2015 and previously served in a series of finance and legal leadership positions since joining our company in 1999. Mr. Wade was previously a corporate securities and finance attorney for ten years with the law firm of Andrews & Kurth L.L.P., where he represented companies in the biotechnology, information technology and energy industries. Mr. Wade is a member of the board of directors of the Texas Healthcare and Bioscience Institute. He received his B.A. and J.D. from the University of Texas.

Brian T. Crum has been our vice president and general counsel since May 2010 and previously served in a series of legal leadership positions since joining our company in 2001. Mr. Crum was previously a corporate securities attorney with the law firms of Brobeck, Phleger & Harrison LLP and Andrews & Kurth L.L.P., where he represented companies in the energy and information technology industries. Mr. Crum received his B.B.A. and J.D. from the University of Texas.

James F. Tessmer has been our vice president, finance and accounting since November 2007 and previously served in a series of finance and accounting leadership positions since joining our company in 2001. Mr. Tessmer was previously assistant controller for Mariner Health Network, Inc. and prior to that served in a variety of financial and accounting management positions for HWC Distribution Corp. and American General Corporation. Mr. Tessmer is a certified public accountant and received his B.B.A. from the University of Wisconsin – Milwaukee and his M.B.A. from the University of Houston.

Employees

As of February 28, 2020, we employed 184 persons, of whom 29 hold M.D. or Ph.D. degrees and another 53 hold other advanced degrees. All of our employees are located in the United States. None of our employees are represented by a labor union and we believe that our relationship with our employees is good.

Research and Development Expenses

In 2019, 2018 and 2017, respectively, we incurred expenses of \$91.9 million, \$100.2 million and \$152.2 million in company-sponsored as well as collaborative research and development activities, including \$7.1 million, \$6.0 million and \$4.9 million of stock-based compensation expense in 2019, 2018 and 2017, respectively.

Item 1A. Risk Factors

The following risks and uncertainties are important factors that could cause actual results or events to differ materially from those indicated by forward-looking statements. The factors described below are not the only ones we face and additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Business and Industry

We depend heavily on the commercial success of XERMELO. If we do not achieve commercial success with XERMELO, our business will suffer and our stock price will likely decline.

We expect that a significant portion of our total revenues for the next several years will be attributable to sales of XERMELO in the United States, but we cannot be certain that XERMELO will be commercially successful. Our future sales of XERMELO will depend on numerous factors, including:

- the number of patients with carcinoid syndrome diarrhea who are inadequately controlled by SSA therapy, as well as the number of newly diagnosed carcinoid syndrome diarrhea patients;
- competition from SSA therapies, radiopharmaceutical products and any additional products for the treatment of carcinoid syndrome diarrhea that may be approved by the FDA in the future;
- the safety profile of XERMELO, including whether previously unknown side effects or increased incidence or severity of known side effects as compared to those seen during development are identified with the commercial use of XERMELO;
- the effectiveness of our commercial strategy for marketing XERMELO and our execution of that strategy, including our pricing strategy and the effectiveness of our efforts to obtain and maintain adequate third-party reimbursement;
- the acceptance of XERMELO by patients, the medical community and third-party payers; and
- our ability to meet the demand for commercial supplies of XERMELO and to maintain and successfully monitor commercial manufacturing arrangements for XERMELO with third-party manufacturers to ensure they meet our standards and those of the FDA, which extensively regulates and monitors pharmaceutical manufacturing facilities.

While we believe that XERMELO has a competitive commercial profile, our current estimates of the revenues that XERMELO could generate in future periods may change based upon the above factors, and could prove to be incorrect. If our revenues, market share or other indicators of market acceptance of XERMELO fail to meet the expectations of investors or public market analysts, the market price of our common stock could decline. In addition, if one or more of the factors above negatively affects XERMELO sales, our business and financial condition could be materially harmed and we may be more heavily dependent on the success of our other drug programs.

We depend heavily on our ability to obtain regulatory approval in the United States for sotagliflozin in type 1 diabetes. If we fail to obtain such regulatory approval or fail to successfully commercialize sotagliflozin for type 1 diabetes upon such regulatory approval, our business will suffer and our stock price will likely decline.

The FDA issued a complete response letter in March 2019 regarding our application for regulatory approval to market sotagliflozin for type 1 diabetes in the United States and has confirmed that position in denying two appeals of the complete response letter in November 2019 and March 2020.

We cannot offer any assurances that the FDA will grant marketing approval for sotagliflozin in type 1 diabetes, on acceptable timelines or at all. Furthermore, regulatory approval in the United States for sotagliflozin in type 1 diabetes, even if obtained, may limit the type of patients in which sotagliflozin may be used, such as on the basis of body mass index as in the European Union, or otherwise require specific warning or labeling language or a formal risk evaluation and mitigation strategy, or REMS, any of which may reduce the commercial potential of sotagliflozin in type 1 diabetes. Even if approved, our existing capital resources and commercial infrastructure are insufficient to commercially launch sotagliflozin for type 1 diabetes and we may not be successful in obtaining such resources, building such infrastructure or otherwise effectively commercializing sotagliflozin for type 1 diabetes. Should we fail to obtain regulatory approval in the United States for sotagliflozin in type 1 diabetes, or fail to successfully commercialize sotagliflozin upon such regulatory approval, our business and financial condition could be materially harmed and we may be more heavily dependent on the success of our other drug programs.

We depend heavily on our ability to successfully complete Phase 3 clinical development of sotagliflozin in type 2 diabetes, heart failure and chronic kidney disease, and obtain regulatory approvals for sotagliflozin in those indications. If we fail to successfully complete such Phase 3 clinical development and obtain such regulatory approvals, or fail to successfully commercialize sotagliflozin for type 2 diabetes, heart failure and chronic kidney disease upon such regulatory approvals, our business will suffer and our stock price will likely decline.

We are conducting a comprehensive Phase 3 development program for sotagliflozin in type 2 diabetes, heart failure and chronic kidney disease. Our existing capital resources are insufficient to complete the two long-term outcomes studies included in such Phase 3 development program that are designed to demonstrate benefits in heart failure and chronic kidney disease. Although we seek to collaborate with another pharmaceutical or biotechnology company with respect to the development and commercialization of sotagliflozin in type 2 diabetes, heart failure and chronic kidney disease under terms which would provide additional funding for the completion of the Phase 3 development program, we may be unable to successfully enter into any such collaborative arrangement on reasonable terms, or at all. If we are unable to enter into any such collaborative arrangement, or if we are otherwise unable to raise sufficient additional capital, we will likely elect to, and may be forced to, delay, reduce or wind down the long-term outcomes studies included in such Phase 3 development program.

Even if such additional funding is secured, we cannot offer any assurances or predict with any certainty that such Phase 3 development will be successfully completed, that positive clinical data will be obtained from such Phase 3 development efforts or that regulatory authorities will grant marketing approval for sotagliflozin in type 2 diabetes, heart failure or chronic kidney disease, in any such case on the expected timelines. Furthermore, regulatory approvals for sotagliflozin, even if obtained, may limit the type of patients in which sotagliflozin may be used for type 2 diabetes, heart failure or chronic kidney disease or otherwise require specific warning or labeling language, each of which may reduce the commercial potential of sotagliflozin in those indications. We cannot offer any assurances that the Phase 3 clinical development program will demonstrate a competitive commercial profile for sotagliflozin in type 2 diabetes, heart failure or chronic kidney disease. Even if approved with a competitive commercial profile, our existing resources and commercial infrastructure are insufficient to commercially launch sotagliflozin for type 2 diabetes, heart failure and chronic kidney disease and we or any potential collaborator may be unsuccessful in obtaining such resources, building such infrastructure or otherwise effectively commercializing sotagliflozin for type 2 diabetes, heart failure or chronic kidney disease. Should we or any potential collaborator fail to obtain regulatory approvals for sotagliflozin in those indications or fail to successfully commercialize sotagliflozin upon such regulatory approvals, our business and financial condition could be materially harmed and we may be more heavily dependent on the success of our other drug programs.

Clinical testing of our drug candidates in humans is an inherently risky and time-consuming process that may fail to demonstrate safety and efficacy, which could result in the delay, limitation or prevention of regulatory approval.

In order to obtain regulatory approvals for the commercial sale of any products that we or our collaborators may develop, we or our collaborators are required to complete extensive clinical trials in humans to demonstrate the safety and efficacy of our drug candidates. We or our collaborators may not be able to obtain authority from the FDA, or other equivalent foreign regulatory agencies, to initiate or complete any clinical trials. In addition, we have limited internal resources for making regulatory filings and interacting with regulatory authorities.

Clinical trials are inherently risky and the results from nonclinical testing of a drug candidate that is under development may not be predictive of results that will be obtained in human clinical trials. In addition, the results of early human clinical trials may not be predictive of results that will be obtained in larger-scale, advanced stage clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after achieving positive results in earlier trials. Although Phase 2 proof-of-concept clinical trials of sotagliflozin in type 2 diabetes patients were positive, we cannot assure you that the Phase 3 development program for sotagliflozin being conducted in type 2 diabetes, heart failure and chronic kidney disease will yield positive results. Negative or inconclusive results from a nonclinical study or a clinical trial could cause us, our collaborators or the FDA or other equivalent foreign regulatory agencies to terminate a nonclinical study or clinical trial or require that we or our collaborators repeat or modify it. Furthermore, we, one of our collaborators or a regulatory agency with jurisdiction over the trials may suspend clinical trials at any time if the subjects or patients participating in such trials are being exposed to unacceptable health risks or for other reasons.

Any nonclinical or clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities. Nonclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. The FDA or institutional review boards at the medical institutions and healthcare facilities where we or our collaborators sponsor clinical trials may suspend any trial indefinitely if they find deficiencies in the conduct of these trials. Clinical trials must be conducted in accordance with the FDA's current Good Clinical Practices. The FDA and these institutional review boards have authority to oversee our and our collaborators' clinical trials, and the FDA may require large

numbers of subjects or patients. In addition, we or our collaborators must manufacture, or contract for the manufacture of, the drug candidates that we use in our clinical trials under the FDA's current Good Manufacturing Practices.

The rate of completion of clinical trials is dependent, in part, upon the rate of enrollment of patients. Patient accrual is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the nature of the study, the existence of competitive clinical trials and the availability of alternative treatments. Delays in planned patient enrollment may result in increased costs and prolonged clinical development, which in turn could allow our competitors to bring products to market before we do and impair our ability to commercialize our products or potential products.

We or our collaborators may not be able to successfully complete any clinical trial of a drug candidate within any specified time period. In some cases, we or our collaborators may not be able to complete the trial at all. Moreover, clinical trials may not show our drug candidates to be both safe and effective. Thus, the FDA and other regulatory authorities may not approve any additional drug candidates that we develop for any indication or may limit the approved indications or impose other conditions.

Our drug candidates are subject to a lengthy and uncertain regulatory process that may not result in the necessary regulatory approvals, which could adversely affect our and our collaborators' ability to commercialize products.

Our drug candidates, as well as the activities associated with their research, development and commercialization, are subject to extensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for any drug candidate would prevent us from commercializing that drug candidate. The process of obtaining regulatory approvals is expensive, and often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the drug candidates involved. Before a new drug application can be filed with the FDA, the drug candidate must undergo extensive clinical trials, which can take many years and may require substantial expenditures. Any clinical trial may fail to produce results satisfactory to the FDA. For example, the FDA could determine that the design of a clinical trial is inadequate to produce reliable results. Furthermore, prior to approving a new drug, the FDA typically requires that the efficacy of the drug be demonstrated in two double-blind, controlled studies. The regulatory process also requires nonclinical testing, and data obtained from nonclinical and clinical activities are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. In addition, delays or rejections may be encountered based upon changes in regulatory policy for product approval during the period of product development and regulatory agency review. Changes in regulatory approval policy, regulations or statutes or the process for regulatory review during the development or approval periods of our drug candidates may cause delays in the approval or rejection of an application. Even if the FDA or a comparable authority in another country approves a drug candidate, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product and may impose ongoing requirements for post-approval studies, including additional research and development and clinical trials. These agencies also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

The commercial success of any products that we or our collaborators may develop will depend upon the degree of market acceptance among physicians, patients, health care payers and the medical community.

Our or our collaborators' ability to commercialize any products that we or they may develop will be highly dependent upon the extent to which such products gain market acceptance among physicians, patients, health care payers, such as commercial health insurers, Medicare and Medicaid, and the medical community. If such products do not achieve an adequate level of acceptance, we may not generate adequate product revenues and we may not become profitable. The degree of market acceptance of such products will depend upon a number of factors, including:

- the effectiveness, or perceived effectiveness, of our products in comparison to competing products;
- the existence of any significant side effects, as well as their severity in comparison to any competing products;
- potential advantages or disadvantages in relation to alternative treatments;
- current and future indications for which our products may be approved;
- the ability to offer our products for sale at competitive prices;
- relative convenience and ease of administration;

- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

If we are unable to maintain an effective sales force, marketing infrastructure and distribution capabilities, we will not be able to successfully commercialize any products that we or our collaborators may develop.

In order to successfully commercialize any product that we or our collaborators may develop, we or they must build or maintain an effective commercialization infrastructure supporting such product, including sales force, marketing organization and distribution capabilities. Factors that may hinder efforts to effectively establish, manage and maintain such infrastructure for products that we or our collaborators may develop include:

- inability to recruit, retain and effectively manage adequate numbers of effective sales and marketing personnel;
- inability to maintain relationships with third-party logistics providers, pharmacies, third-party manufacturers and other third parties instrumental in the commercial manufacture and distribution of such products;
- inability to establish or implement internal controls and procedures required in connection with sales of such products;
- inability of sales personnel to obtain access to or convince adequate numbers of physicians to prescribe such products; and
- potential lack of complementary products to be offered by sales personnel, which may put us or our collaborators at a competitive disadvantage relative to companies with more extensive product lines.

If we or our collaborators are unable to sustain our or their sales force, marketing infrastructure and distribution capability for such products, we may not be able to generate any product revenue, may generate increased expenses and may never become profitable.

We or our collaborators will need to expend significant time and resources to train our sales forces to be credible, persuasive and compliant in discussing such products with the physicians treating the patients indicated under the label. We or our collaborators will also need to continue to train our sales forces to ensure that a consistent and appropriate message about such products is being delivered to potential customers. If we or our collaborators are unable to effectively train our sales forces and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits and risks of such products and their proper administration, our and their ability to successfully commercialize such products could be diminished, which could have a material adverse effect on our financial condition, stock price and operations.

If we are unable to maintain adequate coverage and reimbursement from third-party payers for any products that we or our collaborators may develop, our revenues and prospects for profitability will suffer.

Our ability to successfully commercialize any products that we or our collaborators may develop is highly dependent on the extent to which coverage and reimbursement for such products are available from third-party payers, including governmental payers, such as Medicare and Medicaid, and private health insurers, including managed care organizations and group purchasing organizations. Many patients are not capable of paying themselves for the products that we or our collaborators may develop, and rely on third-party payers to pay for, or subsidize, their medical needs. If third-party payers do not provide coverage or reimbursement for such products, our revenues and prospects for profitability will suffer. In addition, even if third-party payers provide some coverage or reimbursement for such products, the availability of such coverage or reimbursement for prescription drugs under private health insurance and managed care plans often varies based on the type of contract or plan purchased.

In addition, in some foreign countries, particularly the countries in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, price negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement and/or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost effectiveness of our drug candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in the commercialization of our drug candidates. Third-party payers are challenging the prices charged for medical products and services, and many third-party payers limit reimbursement for newly approved health care

products. In particular, third-party payers may limit the indications for which they will reimburse patients who use any products that we or our collaborators may develop. Cost-control initiatives could decrease prices we or our collaborators might establish for products that may be developed, which would result in lower product revenues to us.

We may not be able to manufacture products that we or our collaborators may develop in commercial quantities, which would impair our ability to commercialize such products.

Other than XERMELO, our drug candidates have been manufactured in relatively small quantities for nonclinical and clinical trials. If any of these drug candidates are approved by the FDA or other regulatory agencies for commercial sale, we or our collaborators will need to manufacture them in larger quantities. We may not be able to successfully increase the manufacturing capacity, whether in collaboration with third-party manufacturers or on our own, for any approved product in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we or our collaborators are unable to successfully increase the manufacturing capacity for any such product, the regulatory approval or commercial launch of that product may be delayed or there may be a shortage in supply. Pharmaceutical products typically require precise, high-quality manufacturing. The failure to achieve and maintain these high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously hurt our business.

We and our collaborators are subject to extensive and rigorous ongoing regulation relating to any products that we or our collaborators may develop.

We and our collaborators are subject to extensive and rigorous ongoing domestic and foreign government regulation of, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing of any products which receive regulatory approvals from the FDA or foreign regulatory authorities. The failure to comply with these requirements or the identification of safety problems during commercial marketing could lead to the need for product marketing restrictions, product withdrawal or recall or other voluntary or regulatory action, which could delay further marketing until the product is brought into compliance. The failure to comply with these requirements may also subject us or our collaborators to stringent penalties.

We are subject to certain healthcare laws, regulation and enforcement; our failure to comply with those laws could have a material adverse effect on our results of operations and financial condition.

We are subject to certain healthcare laws and regulations and enforcement by the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, without limitation:

- the federal Anti-Kickback Law, which constrains our marketing practices, educational programs, pricing policies, relationships with healthcare providers or other entities, and other business activities, by prohibiting, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;
- the Foreign Corrupt Practices Act, a United States law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals);

- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- state and federal government price reporting laws that require us to calculate and report complex pricing metrics to government programs, where such reported price may be used in the calculation of reimbursement and/or discounts on our marketed drugs (participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs, and potentially limit our ability to offer certain marketplace discounts); and
- state and federal marketing expenditure tracking and reporting laws, which generally require certain types of expenditures in the United States to be tracked and reported. Compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of our activities.

In addition, certain marketing practices, including off-label promotion, may also violate certain federal and state health regulatory fraud and abuse laws as well as false claims laws, including the civil False Claims Act. Suits filed under the civil False Claims Act, known as “qui tam” actions, can be brought by any individual on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in any amounts paid by the entity to the government in fines or settlement. The filing of qui tam actions has caused a number of pharmaceutical, medical device and other healthcare companies to defend a civil False Claims Act action. When an entity is determined to have violated the civil False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we, or our officers or employees, may be subject to penalties, including administrative civil and criminal penalties, damages, fines, withdrawal of regulatory approval, the curtailment or restructuring of our operations, the exclusion from participation in Medicare, Medicaid and other federal and state healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to sell our products or operate our business and also adversely affect our financial results. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use and disclosure of personal information. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information. In addition, most healthcare providers who may be expected to prescribe our products and from whom we may obtain patient health information are subject to privacy and security requirements under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA. Although we are not directly subject to HIPAA, we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including recently enacted laws in a majority of states requiring security breach notification. These laws could create liability for us or increase our cost of doing business. International laws, such as the EU Data Privacy Directive and Swiss Federal Act on Data Protection, regulate the processing of personal data within Europe and between European countries and the United States. Failure to provide adequate privacy protections and maintain compliance with safe harbor mechanisms could jeopardize business transactions across borders and result in significant penalties.

Current healthcare laws and regulations and future legislative or regulatory reforms to the healthcare system may negatively affect our revenues and prospects for profitability.

A primary trend in the United States and some foreign countries is toward reform and cost containment in the health care industry. The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals that may have the effect of reducing the prices that we are able to charge for products we or our collaborators may develop. Healthcare reform measures which may be adopted in the future in the United States and foreign jurisdictions may result in more rigorous coverage criteria and significant downward pressure on the prices drug manufacturers may charge. As a result, our revenues and prospects for profitability could be significantly harmed.

As a result of the overall trend towards cost-effectiveness criteria and managed healthcare in the United States, third-party payers are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs. They may use tiered reimbursement and may adversely affect demand for products we or our collaborators may develop by placing them in an expensive tier. They may also refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payers will reimburse for newly approved drugs, which in turn will put pressure on the pricing of drugs. Further, we do not have experience in ensuring approval by applicable third-party payers outside of the United States for coverage and reimbursement of pharmaceutical products. We also anticipate pricing pressures in connection with the sale of products we or our collaborators may develop due to the increasing influence of health maintenance organizations and additional legislative proposals.

Pricing for pharmaceutical products has come under increasing scrutiny by governments, legislative bodies and enforcement agencies. These activities may result in actions that have the effect of reducing our revenue or harming our business or reputation.

Many companies in our industry have received a governmental request for documents and information relating to drug pricing and patient support programs. We may become subject to similar requests, which would require us to incur significant expense and result in distraction for our management team. Additionally, to the extent there are findings, or even allegations, of improper conduct on the part of our company, such findings could further harm our business, reputation and/or prospects. It is possible that such inquiries could result in negative publicity or other negative actions that could harm our reputation, changes in our product pricing and distribution strategies, reduced demand for our approved products and/or reduced reimbursement of approved products, including by federal health care programs such as Medicare and Medicaid and state health care programs.

Our competitors may develop products that impair the value of any products that we or our collaborators may develop.

The pharmaceutical and biotechnology industries are highly diversified and are characterized by rapid technological change. We and our collaborators face, and will continue to face, intense competition from biotechnology and pharmaceutical companies, as well as academic research institutions, clinical reference laboratories and government agencies that are pursuing research and development activities similar to ours. In addition, significant delays in the development of our drug candidates could allow our competitors to bring products to market before us, which would impair our or our collaborators' ability to commercialize our drug candidates. Any products that we or our collaborators develop will compete in highly competitive markets. Further, our competitors may be more effective at using their technologies to develop commercial products. Many of the organizations competing with us have greater capital resources, larger research and development staff and facilities, more experience in obtaining regulatory approvals and more extensive product manufacturing and marketing capabilities. As a result, our competitors may be able to more easily develop products that would render any products that we or our collaborators develop obsolete and noncompetitive. For example, dapagliflozin, empagliflozin and canagliflozin are currently being marketed by AstraZeneca, Boehringer Ingelheim and Eli Lilly, and Janssen (a subsidiary of Johnson & Johnson), respectively, for the treatment of type 2 diabetes and certain other indications, such as heart failure, cardiovascular death, major adverse cardiovascular events and end-stage kidney disease. Each of those products act through SGLT2, one of the targets of sotagliflozin. In addition, there may be drug candidates of which we are not aware at an earlier stage of development that may compete with our drug candidates.

We face business disruption and related risks resulting from the recent outbreak of the novel coronavirus 2019 (COVID-19), which could have a material adverse effect on our business.

Our commercialization efforts and development programs could be disrupted and materially adversely affected by the recent outbreak of COVID-19. As a result of measures imposed by the governments in affected regions, many commercial activities, businesses and schools have been suspended as part of quarantines and other measures intended to contain this outbreak. The spread of COVID-19 from China to other countries has resulted in the International Health Regulations Emergency Committee of the World Health Organization declaring the outbreak of COVID-19 as a "public health emergency of international concern," and the World Health Organization characterizing COVID-19 as a pandemic. While the COVID-19 outbreak may still be in early stages, international stock markets have begun to reflect the uncertainty associated with the potential economic impact of the outbreak and the significant declines in the Dow Industrial Average at the end of February and in March 2020 has been largely attributed to the effects of COVID-19. We are still assessing the potential impact COVID-19 may have on our ability to effectively conduct our commercialization efforts and development programs and otherwise conduct our business operations as planned, but there can be no assurance that we will be able to avoid part or all of any impact from the spread of COVID-19 or its consequences, including downturns in business sentiment generally or in our industry and business in particular.

Risks Related to Our Capital Requirements and Financial Results

We will need additional capital in the future and, if it is unavailable, we will be forced to delay, reduce or eliminate our commercialization efforts or product development programs. If additional capital is not available on reasonable terms, we will be forced to obtain funds, if at all, by entering into financing agreements on unattractive terms.

As of December 31, 2019, we had \$271.7 million in cash, cash equivalents and investments. We anticipate that our existing capital resources and the cash and revenues we expect to derive from product revenues, collaborations and other sources will enable us to fund our currently planned operations for at least the next 12 months. However, we caution you that we may generate less cash and revenues or incur expenses more rapidly than we currently anticipate. Our currently planned operations for the next twelve months include the continued commercialization of XERMELO in the United States and the continued nonclinical and clinical development of telotristat ethyl, sotagliflozin, LX9211 and our other drug candidates.

Although difficult to accurately predict, the amount of our future capital requirements will be substantial and will depend on many factors, including:

- the success of our sales, marketing, distribution and other commercialization activities for XERMELO in the United States and the revenues we generate from such activities;
- the success of Ipsen's sales, marketing, distribution and other commercialization activities for XERMELO outside of the United States and Japan and our receipt of any milestone payments and royalties;
- our ability to obtain regulatory approval for the marketing and sale of sotagliflozin for type 1 diabetes in the United States;
- the timing, progress and results of our clinical trials of telotristat ethyl, sotagliflozin, LX9211 and our other drug candidates and our ability to obtain necessary regulatory approvals based on such clinical trials;
- our success in establishing new collaborations and licenses, including for the development and commercialization of sotagliflozin;
- the amount and timing of our research, development and commercialization expenditures;
- the effect of competing programs and products, and of technological and market developments; and
- the filing, maintenance, prosecution, defense and enforcement of patent claims and other intellectual property rights.

If our capital resources are insufficient to meet future capital requirements, we will need to raise additional funds to continue our currently planned operations. Our ability to raise additional capital is dependent on a number of factors, including the market demand for our securities, which itself is subject to a number of pharmaceutical development and business risks and uncertainties, as well as uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to us. If we raise additional capital by issuing equity securities, our then-existing stockholders will experience dilution and the terms of any new equity securities may have preferences over our common stock. The affirmative and restrictive covenants and the pledge of substantially all of our assets as collateral under our existing term loan with BioPharma Credit PLC and BioPharma Credit Investments IV Sub LP, or the BioPharma Term Loan, restrict our ability to raise additional capital by issuing debt securities. We cannot be certain that additional financing, whether debt or equity, will be available in amounts or on terms acceptable to us, if at all. We may be unable to raise sufficient additional capital on reasonable terms, and if so, we will be forced to delay, reduce or eliminate our clinical development programs or commercialization efforts or obtain funds, if at all, by entering into financing agreements on unattractive terms.

We have a history of net losses, and we expect to continue to incur net losses and may not achieve or maintain profitability.

We have incurred net losses since our inception, including an aggregate net loss of \$113.4 million for the three years ended December 31, 2019. As of December 31, 2019, we had an accumulated deficit of \$1.3 billion. Because of the numerous risks and uncertainties associated with successfully developing and commercializing drug products, we are unable to predict the extent of any future losses or whether or when we will become profitable, if at all. The size of our net losses will depend, in part, on the rate of decline or growth in our revenues and on the amount of our expenses. We expect to continue to incur significant expenses over the next several years as we expect to make significant investments in the commercialization of XERMELO in the United States and the continued nonclinical and clinical development of telotristat ethyl, sotagliflozin, LX9211 and our other drug candidates.

Prior to the commercial launch of XERMELO, we derived substantially all of our revenues from strategic collaborations and other research and development collaborations and technology licenses. Future revenues from our commercialization of XERMELO are uncertain because they depend on a number of factors, including market acceptance of XERMELO, the success of our sales, marketing, distribution and other commercialization activities and the cost and availability of reimbursement for XERMELO. Future revenues from our existing collaborations are uncertain because they depend, to a large degree, on the achievement of milestones and payment of royalties we earn from any products developed or commercialized under the collaborations. Our ability to secure future revenue-generating agreements will depend upon our ability to address the needs of our potential future collaborators and licensees, and to negotiate agreements that we believe are in our long-term best interests. We may determine that our interests are better served by retaining rights to our discoveries and advancing our therapeutic programs to a later stage, which could limit our near-term revenues and increase expenses. Because of these and other factors, our operating results have fluctuated in the past and are likely to do so in the future, and we do not believe that period-to-period comparisons of our operating results are a good indication of our future performance.

We expect to spend significant amounts to fund our commercialization activities with respect to XERMELO in the United States and our planned nonclinical and clinical development of telotristat ethyl, sotagliflozin, LX9211 and our other drug candidates. As a result, we will need to generate substantial additional revenues to achieve profitability in future periods. Even if we do achieve profitability in future periods, we may not be able to sustain or increase such profitability on a quarterly or annual basis.

Our operating results have been and likely will continue to fluctuate, and we believe that period-to-period comparisons of our operating results are not a good indication of our future performance.

Our operating results have fluctuated in the past and are likely to fluctuate in the future. A number of factors, many of which we cannot control, could subject our operating results to volatility, including:

- our ability to successfully commercialize XERMELO in the United States and the amount of revenues generated from such commercialization efforts;
- our ability to obtain regulatory approval of sotagliflozin for type 1 diabetes in the United States;
- the success of our ongoing nonclinical and clinical development efforts;
- the timing and amount of expenses incurred with respect to our nonclinical and clinical development and commercialization efforts;
- our success in establishing new collaborations and technology licenses, including for the development and commercialization of sotagliflozin, and the timing and financial terms of such arrangements;
- the success rate of our development efforts leading to opportunities for new collaborations and licenses, as well as milestone payments and royalties;
- the timing and willingness of our collaborators to commercialize pharmaceutical products that would result in milestone payments and royalties;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products and technologies;
- general and industry-specific economic conditions, which may affect our and our collaborators' research and development expenditures.

Because of these and other factors, including the risks and uncertainties described in this section, our operating results have fluctuated in the past and are likely to do so in the future. Due to the likelihood of fluctuations in our revenues and expenses, we believe that period-to-period comparisons of our operating results are not a good indication of our future performance.

We have substantial indebtedness that may limit cash flow available to invest in the ongoing needs of our business.

We have incurred \$245.2 million of indebtedness. Although the affirmative and restrictive covenants and the pledge of substantially all of our assets as collateral under the BioPharma Term Loan restrict our ability to obtain additional debt

financing, we could in the future incur additional indebtedness beyond such amount. Our substantial debt combined with our other financial obligations and contractual commitments could have significant adverse consequences, including:

- requiring us to dedicate a substantial portion of cash flow from operations to the payment of interest on, and principal of, our debt, which will reduce the amounts available to fund working capital, capital expenditures, product commercialization and development efforts and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

We intend to satisfy our current and future debt service obligations with our existing cash and cash equivalents and marketable securities and funds from external sources. However, we may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt. Funds from external sources may not be available on acceptable terms, if at all. In addition, a failure to comply with the covenants under our existing debt instruments could result in an event of default under those instruments. In the event of an acceleration of amounts due under our debt instruments as a result of an event of default, including upon the occurrence of an event that would reasonably be expected to have a material adverse effect on our business, operations, properties, assets or condition or a failure to pay any amount due, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and the lenders could seek to enforce their security interests in the collateral securing such indebtedness.

If we do not effectively manage our affirmative and restrictive covenants under the BioPharma Term Loan, our financial condition and results of operations could be adversely affected.

Our obligations under the BioPharma Term Loan are secured by a first lien security interest in substantially all of our assets. In addition, the BioPharma Term Loan requires that we comply with certain affirmative and restrictive covenants, including among other things, covenants restricting dispositions, fundamental changes in our business, mergers or acquisitions, indebtedness, encumbrances, distributions, investments, transactions with affiliates and subordinated debt, any of which could restrict our business and operations, particularly our ability to respond to changes in our business or to take specified actions to take advantage of certain business opportunities that may be presented to us. Our failure to comply with any of these covenants could result in a default under the BioPharma Term Loan, which could permit the lenders to declare all or part of any outstanding borrowings to be immediately due and payable. If we are unable to repay those amounts, the lenders could enforce the security interest granted to them to secure that debt, which would seriously harm our business.

Risks Related to Our Relationships with Third Parties

We are significantly dependent upon our collaborations with Ipsen and other pharmaceutical and biotechnology companies. If pharmaceutical products are not successfully and timely developed and commercialized under our collaborations, our opportunities to generate revenues from milestones and royalties will be greatly reduced.

We have entered into a collaboration agreement with Ipsen for the commercialization of XERMELO outside of the United States and Japan. We have also established collaborative arrangements with other pharmaceutical and biotechnology companies with respect to the research, development and commercialization of drug candidates from other programs. We have derived a substantial majority of our revenues to date from these strategic collaborations and other research and development collaborations and technology licenses. Future revenues from our existing collaborations depend upon the achievement of milestones and payment of royalties we earn from any future products developed under the collaborations. If our relationship terminates with any of our collaborators, as occurred with our terminated collaboration agreement with Sanofi, our reputation in the business and scientific community may suffer and revenues will be negatively impacted to the extent such losses are not offset by additional collaboration agreements. If milestones are not achieved under our collaborations or our collaborators are unable to successfully develop and commercialize products from which milestones and royalties are payable, we will not earn the revenues contemplated by those collaborations.

We have limited or no control over the resources that any collaborator may devote to the development and commercialization of products under our alliances. Any of our present or future collaborators may not perform their obligations as expected. These collaborators may breach or terminate their agreements with us or otherwise fail to conduct research,

development or commercialization activities successfully or in a timely manner. Further, our collaborators may elect not to develop pharmaceutical products arising out of our collaborative arrangements or may not devote sufficient resources to the development, regulatory approval, manufacture, marketing or sale of these products. If any of these events occurs, we may not receive collaboration revenue or otherwise realize anticipated benefits from such collaborations, our product development efforts may be delayed and our business, operating results and financial condition could be adversely affected.

Conflicts with our collaborators could jeopardize the success of our collaborative agreements and harm our product development efforts.

We may pursue opportunities in specific disease and therapeutic modality fields that could result in conflicts with our collaborators, if any of our collaborators takes the position that our internal activities overlap with those activities that are exclusive to our collaboration. Moreover, disagreements could arise with our collaborators over rights to our intellectual property or our rights to share in any of the future revenues of compounds or therapeutic approaches developed by our collaborators. Any conflict with or among our collaborators could result in the termination of our collaborative agreements, delay collaborative research or development activities, impair our ability to renew or obtain future collaborative agreements or lead to costly and time consuming litigation. Conflicts with our collaborators could also have a negative impact on our relationship with existing collaborators, materially impairing our business and revenues. Some of our collaborators are also potential competitors or may become competitors in the future. Our collaborators could develop competing products, preclude us from entering into collaborations with their competitors or terminate their agreements with us prematurely. Any of these events could harm our product development efforts.

We depend on third-party manufacturers, including sole source suppliers, to manufacture commercial quantities of XERMELO. We may not be able to maintain these relationships and could experience supply disruptions outside of our control.

We rely on a network of third-party manufacturers to manufacture and supply XERMELO for commercial sale. As a result of our reliance on these third-party manufacturers and suppliers, including sole source suppliers for certain steps in the manufacture of XERMELO, we could be subject to significant supply disruptions. Our supply chain for sourcing raw materials and manufacturing drug product ready for distribution is a multi-step endeavor. Third-party contract manufacturers procure raw materials, convert these raw materials into API, and then convert the API into final dosage form. Establishing and managing this supply chain requires a significant financial commitment and the creation and maintenance of numerous third party contractual relationships. Although we attempt to effectively manage the business relationships with companies in our supply chain, we do not have control over their operations.

We require our own commercial supply of XERMELO for sale in the United States, and are required under our collaboration agreement to supply Ipsen's commercial requirements of XERMELO in the European Union and other territories outside of the United States and Japan. We currently rely, and expect to continue to rely, on sole source third-party manufacturers to produce final drug product and package and label XERMELO. While we have identified and expect to qualify and engage back-up third-party manufacturers as additional or alternative suppliers for the production of final drug product and packaging and labeling of XERMELO, we currently do not have such arrangements in place. Moreover, some of these alternative manufacturers will need to be approved by the FDA before we can use them for manufacturing XERMELO. It is also possible that supplies of materials that cannot be second-sourced can be managed with inventory planning. There can be no assurance, however, that failure of any of our sole source third-party manufacturers to meet our and Ipsen's commercial demands for XERMELO in a timely manner, or our failure to engage qualified additional or back-up suppliers for the production of final drug product and packaging and labeling of XERMELO, would not have a material adverse effect on commercialization of XERMELO and our business.

Supply disruptions may result from a number of factors, including shortages in product raw materials, labor or technical difficulties, regulatory inspections or restrictions, shipping or customs delays or any other performance failure by any third-party manufacturer on which we rely. Any supply disruptions could disrupt sales of XERMELO, which could have a material adverse impact on our business.

We rely on a single third-party logistics provider and a limited distribution network of specialty pharmacies and specialty distributors for distribution of XERMELO in fulfillment of prescriptions in the United States, and their failure to distribute XERMELO effectively would adversely affect sales of XERMELO.

We rely on a single third-party logistics provider for shipping and warehousing of our commercial supply of XERMELO and a limited distribution network of specialty pharmacies and specialty distributors for dispensation of XERMELO to patients in fulfillment of prescriptions in the United States. Although our third-party logistics provider stores our commercial supply of XERMELO at two separate warehouses, the use of a single third-party logistics provider increases

the risk that a fire or damage from another type of disaster at either of the warehouses may result in a disruption of our commercialization efforts. Our use of a limited distribution network of specialty pharmacies and specialty distributors for dispensation of XERMELO involves certain additional risks, including, but not limited to, risks that these specialty pharmacies and specialty distributors will:

- not provide us accurate or timely information regarding their inventories, the number of patients who are using XERMELO or complaints about XERMELO;
- reduce or discontinue their efforts to sell or support or otherwise not effectively sell or support XERMELO;
- not devote the resources necessary to sell XERMELO in the volumes and within the time frames that we expect;
- be unable to satisfy their financial obligations to us; or
- cease operations.

If our third-party logistics provider or any of our specialty pharmacies or specialty distributors do not fulfill their contractual obligations to us, or refuse or fail to adequately distribute XERMELO and serve patients, or the agreements are terminated without adequate notice, shipments of XERMELO, and associated revenues, would be adversely affected. In addition, we expect that it may take a significant amount of time if we were required to change our third-party logistics provider or any of our specialty pharmacies or specialty distributors.

We rely on third parties to carry out drug development activities.

We rely on clinical research organizations and other third-party contractors to carry out many of our drug development activities, including the performance of nonclinical laboratory and animal tests under the FDA's current Good Laboratory Practices regulations and the conduct of clinical trials of our drug candidates in accordance with protocols we establish. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, our drug development activities may be delayed, suspended or terminated. Such a failure by these third parties could significantly impair our ability to develop and commercialize the affected drug candidates.

We lack the capability to manufacture materials for nonclinical studies, clinical trials or commercial sales and rely on third parties to manufacture our drug candidates, which may harm or delay our product development and commercialization efforts.

We currently do not have the manufacturing capabilities or experience necessary to produce materials for nonclinical studies, clinical trials or commercial sales and intend in the future to continue to rely on collaborators and third-party contractors to produce such materials. We will rely on selected manufacturers to deliver materials on a timely basis and to comply with applicable regulatory requirements, including the current Good Manufacturing Practices of the FDA, which relate to manufacturing and quality control activities. These manufacturers may not be able to produce material on a timely basis or manufacture material at the quality level or in the quantity required to meet our development timelines and applicable regulatory requirements. In addition, there are a limited number of manufacturers that operate under the FDA's current Good Manufacturing Practices and that are capable of producing such materials, and we may experience difficulty finding manufacturers with adequate capacity for our needs. If we are unable to contract for the production of sufficient quantity and quality of materials on acceptable terms, our product development and commercialization efforts may be delayed. Moreover, noncompliance with the FDA's current Good Manufacturing Practices can result in, among other things, fines, injunctions, civil and criminal penalties, product recalls or seizures, suspension of production, failure to obtain marketing approval and withdrawal, suspension or revocation of marketing approvals.

Risks Related to Our Intellectual Property

If we are unable to adequately protect our intellectual property, third parties may be able to use our products and technologies, which could adversely affect our ability to compete in the market.

Our success will depend in part upon our ability to obtain patents and maintain adequate protection of the intellectual property related to our products and technologies. The patent positions of biotechnology and pharmaceutical companies, including our patent position, are generally uncertain and involve complex legal and factual questions. We will be able to protect our intellectual property rights from unauthorized use by third parties only to the extent that our products and technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We will continue to apply for patents covering our products and technologies as, where and when we deem appropriate. However, pending patent

applications do not provide protection against competitors because they are not enforceable until they issue as patents. Further, the disclosures contained in our current and future patent applications may not be sufficient to meet statutory requirements for patentability and our applications may fail to result in issued patents. Once issued, patents still may not provide commercially meaningful protection. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from developing competing products and technologies. Furthermore, others may independently develop similar or alternative products or technologies or design around our patents. If anyone infringes upon our or our collaborators' patent rights, enforcing these rights may be difficult, costly and time-consuming and, as a result, it may not be cost-effective or otherwise expedient to pursue litigation to enforce those patent rights.

Our patents may be challenged by third parties as invalid or unenforceable under U.S. or foreign laws, or they may be infringed by third parties. As a result, we may be involved in the defense and enforcement of our patent or other intellectual property rights in a court of law, U.S. Patent and Trademark Office inter partes review or reexamination proceeding, foreign opposition proceeding or related legal and administrative proceeding in the United States and elsewhere. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation may be substantial and the outcome can be uncertain. An adverse outcome may allow third parties to use our intellectual property without a license and negatively impact our business.

In addition, because patent applications can take many years to issue, third parties may have pending applications, unknown to us, which may later result in issued patents that cover the production, manufacture, commercialization or use of our products and drug candidates. If any such patents are issued to other entities, we will be unable to obtain patent protection for the same or similar discoveries that we make relating to our products and drug candidates. Moreover, we may be blocked from using our drug targets or drug candidates or developing or commercializing our products and other drug candidates, or may be required to obtain a license that may not be available on reasonable terms, if at all. Further, others may discover uses for our drug targets and drug candidates other than those covered in our issued or pending patents, and these other uses may be separately patentable. Even if we have a patent claim on a particular technology or product, the holder of a patent covering the use of that technology or product could exclude us from selling a product that is based on the same use of that product.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, if the patent owner has failed to "work" the invention in that country or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Compulsory licensing of life-saving drugs is also becoming increasingly popular in developing countries either through direct legislation or international initiatives. Such compulsory licenses could be extended to include some of our products and drug candidates, which could limit our potential revenue opportunities. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patent and other intellectual property protection, which makes it difficult to stop infringement.

We rely on trade secret protection for some of our confidential and proprietary information. We have taken security measures to protect our proprietary information and trade secrets, but these measures may not provide adequate protection. While we seek to protect our proprietary information by entering into confidentiality agreements with employees, collaborators and consultants, we cannot assure you that our proprietary information will not be disclosed, or that we can meaningfully protect our trade secrets. In addition, our competitors may independently develop substantially equivalent proprietary information or may otherwise gain access to our trade secrets.

We may be involved in patent litigation and other disputes regarding intellectual property rights and may require licenses from third parties for our planned nonclinical and clinical development and commercialization activities. We may not prevail in any such litigation or other dispute or be able to obtain required licenses.

Our products and those of our collaborators, as well as our nonclinical and clinical development efforts, may give rise to claims that they infringe the patents of others. We are aware that other companies and institutions are developing products acting through the same drug targets through which some of our drug candidates currently in clinical development act, have conducted research on many of the same targets that we have identified and have filed patent applications potentially covering drug targets that we have identified and certain therapeutic products addressing such targets. In some cases, patents have issued from these applications. In addition, many companies and institutions have well-established patent portfolios directed to common techniques, methods and means of developing, producing and manufacturing pharmaceutical products. These or other companies or institutions could bring legal actions against us or our collaborators for damages or to stop us or our collaborators from engaging in certain nonclinical or clinical development activities or from manufacturing and marketing therapeutic products that allegedly infringe their patent rights. If any of these actions are successful, in addition to our potential liability for

damages, these entities would likely require us or our collaborators to obtain a license in order to continue engaging in the infringing activities or to manufacture or market the infringing therapeutic products or may force us to terminate such activities or manufacturing and marketing efforts.

We may deem it advisable to pursue litigation against others to enforce our patents and intellectual property rights and may be the subject of litigation brought by third parties to enforce their patent and intellectual property rights. In addition, we may become involved in litigation based on intellectual property indemnification undertakings that we have given to certain of our collaborators. Patent litigation is expensive and requires substantial amounts of management attention. The eventual outcome of any such litigation is uncertain and involves substantial risks.

We believe that there will continue to be significant litigation in our industry regarding patent and other intellectual property rights. We have expended and many of our competitors have expended and are continuing to expend significant amounts of time, money and management resources on intellectual property litigation. If we become involved in future intellectual property litigation, it could consume a substantial portion of our resources and could negatively affect our results of operations.

Data breaches and cyber-attacks could compromise our intellectual property or other sensitive information and cause significant damage to our business and reputation.

In the ordinary course of our business, we collect, maintain and transmit sensitive data on our networks and systems, including our intellectual property and proprietary or confidential business information (such as research data and personal information) and confidential information with respect to our customers, clinical trial patients and our business partners. We have also outsourced significant elements of our information technology infrastructure and, as a result, third parties may or could have access to our confidential information. The secure maintenance of this information is critical to our business and reputation. We believe that companies have been increasingly subject to a wide variety of security incidents, cyber-attacks and other attempts to gain unauthorized access. These threats can come from a variety of sources, ranging in sophistication from an individual hacker to a state-sponsored attack and motive (including corporate espionage). Cyber threats may be generic, or they may be custom-crafted against our information systems. Our network and storage applications and those of our vendors may be subject to unauthorized access by hackers or breached due to operator error, malfeasance or other system disruptions. It is often difficult to anticipate or immediately detect such incidents and the damage caused by such incidents. These data breaches and any unauthorized access or disclosure of our information or intellectual property could compromise our intellectual property and expose sensitive business information. A data security breach could also lead to public exposure of personal information of our clinical trial patients, customers and others. Cyber-attacks could cause us to incur significant remediation costs, result in product development delays, disrupt key business operations and divert attention of management and key information technology resources. Our network security and data recovery measures and those of our vendors may not be adequate to protect against such security breaches and disruptions. These incidents could also subject us to liability, expose us to significant expense and cause significant harm to our reputation and business.

We may be subject to damages resulting from claims that we, our employees or independent contractors have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees and independent contractors were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, independent contractors or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and divert management's attention. If we fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key research personnel and/or their work product could hamper or prevent our ability to commercialize certain drug candidates, which could severely harm our business.

Risks Related to Employees and Facilities Operations

If we are unable to manage our growth, our business, financial condition, results of operations and prospects may be adversely affected.

We have experienced and may continue to experience growth in the number of our employees and in the scope of our operations. This growth places significant demands on our management, operational and financial resources, and our current and planned personnel, systems, procedures and controls may not be adequate to support our growth. To effectively manage our potential growth, we must continue to improve existing, and implement new, operational and financial systems, procedures

and controls and must expand, train and manage our growing employee base, and there can be no assurance that we will effectively manage our growth without experiencing operating inefficiencies or control deficiencies. We may need to increase our medical, clinical, commercial and other personnel, and recruiting and retaining qualified individuals is difficult. If we are unable to manage our growth effectively, or are unsuccessful in recruiting qualified personnel when advisable, our business, financial condition, results of operations and prospects may be adversely affected.

The loss of key personnel or the inability to attract and retain additional personnel could impair our ability to operate and expand our operations.

We are highly dependent upon the principal members of our management, as well as medical, clinical and commercial staff, the loss of whose services might adversely impact the achievement of our objectives. Retaining and, where advisable, recruiting qualified medical, clinical and commercial personnel are critical to support activities related to successfully executing on our commercial plan for XERMELO and advancing our nonclinical and clinical development programs for telotristat ethyl, sotagliflozin, LX9211 and our other drug candidates. Competition is intense for experienced medical, clinical and commercial personnel, and we may be unable to retain or recruit such personnel with the expertise or experience necessary to allow us to successfully develop and commercialize our products. Further, all of our employees are employed “at will” and, therefore, may leave our employment at any time.

Facility security breaches may disrupt our operations, subject us to liability and harm our operating results.

Any break-in or trespass of our facilities that results in the misappropriation, theft, sabotage or any other type of security breach with respect to our proprietary and confidential information, including research or clinical data, or that results in damage to our equipment and assets could subject us to liability and have a material adverse impact on our business, operating results and financial condition.

Our facilities are located near coastal zones, and the occurrence of a hurricane or other disaster could damage our facilities and equipment, which could harm our operations.

Our facilities are located in The Woodlands, Texas and Basking Ridge, New Jersey, and therefore our facilities are vulnerable to damage from hurricanes. We are also vulnerable to damage from other types of disasters, including fire, floods, power loss, communications failures, terrorism and similar events and any insurance we may maintain may not be adequate to cover our losses. If any disaster were to occur, our ability to operate our business at our facilities could be seriously, or potentially completely, impaired.

Risks Related to Environmental and Product Liability

We have used hazardous chemicals and radioactive and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development processes have historically involved the controlled use of hazardous materials, including chemicals and radioactive and biological materials. Our operations have produced hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may face liability for any injury or contamination that results from our use or the use by third parties of these materials, and such liability may exceed our insurance coverage and our total assets. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development and production efforts.

In addition, our collaborators may use hazardous materials in connection with our collaborative efforts. In the event of a lawsuit or investigation, we could be held responsible for any injury caused to persons or property by exposure to, or release of, these hazardous materials used by these parties. Further, we may be required to indemnify our collaborators against all damages and other liabilities arising out of our development activities or products produced in connection with these collaborations.

Our business has a substantial risk of product liability and we face potential product liability exposure far in excess of our limited insurance coverage.

We may be held liable if any product that we or our collaborators develop or commercialize, or any product that is made with the use or incorporation of any of our technologies, causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing or sale. Regardless of merit or eventual outcome, product liability claims could result in

decreased demand for our products and product candidates, injury to our reputation, withdrawal of patients from our clinical trials, product recall, substantial monetary awards to third parties and the inability to commercialize any products that we may develop. These claims might be made directly by consumers, health care providers, pharmaceutical companies or others selling or testing our products. We have obtained limited product liability insurance coverage for our clinical trials and commercial activities. However, our insurance may not reimburse us or may not be sufficient to reimburse us for expenses or losses we may suffer. Moreover, if insurance coverage becomes more expensive, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, juries have awarded large judgments in class action lawsuits for claims based on drugs that had unanticipated side effects. In addition, the pharmaceutical and biotechnology industries, in general, have been subject to significant medical malpractice litigation. A successful product liability claim or series of claims brought against us could harm our reputation and business.

Risks Related to Our Common Stock

Invus, L.P., Invus C.V. and their affiliates own a controlling interest in our outstanding common stock and may have interests which conflict with those of our other stockholders.

Invus, L.P. and Invus C.V., which we collectively refer to as Invus, and their affiliates currently own approximately 60.8% of the outstanding shares of our common stock and are thereby able to control the election and removal of our directors and determine our corporate and management policies, including potential mergers or acquisitions, asset sales, the amendment of our articles of incorporation or bylaws and other significant corporate transactions. This concentration of ownership may delay or deter possible changes in control of our company, which may reduce the value of an investment in our common stock. The interests of Invus and its affiliates may not be aligned with the interests of other holders of our common stock.

Invus has additional rights under our stockholders' agreement with Invus, L.P. relating to the membership of our board of directors, which provides Invus with substantial influence over significant corporate matters.

Under our stockholders' agreement with Invus, L.P., Invus has the right to designate a number of directors equal to the percentage of all the outstanding shares of our common stock owned by Invus and its affiliates, rounded up to the nearest whole number of directors. Invus has designated three of the nine current members of our board of directors. While Invus has not presently exercised its director designation rights in full, it may exercise them at any time in the future in its sole discretion. To facilitate the exercise of such rights, we have agreed, upon written request from Invus, to take all necessary steps in accordance with our obligations under the stockholders' agreement to (1) increase the number of directors to the number specified by Invus (which number shall be no greater than reasonably necessary for the exercise of Invus' director designation rights under the stockholders' agreement) and (2) cause the appointment to the newly created directorships of directors so designated by Invus pursuant to its rights under the stockholders' agreement.

Invus also has the right to require proportionate representation of Invus-appointed directors on the audit, compensation and corporate governance committees of our board of directors, subject to certain restrictions. Invus-designated directors currently serve as one of the three members of each of the compensation committee and the corporate governance committee of our board of directors. No Invus-designated directors currently serve on the audit committee of our board of directors.

The provisions of the stockholders' agreement relating to Invus' rights to designate members of our board of directors and its audit, compensation and corporate governance committees will terminate if the percentage of all the outstanding shares of our common stock owned by Invus and its affiliates falls below 10%. Invus also has the right to terminate these provisions at any time in its discretion.

Our stock price may be extremely volatile.

The trading price of our common stock has been highly volatile, and we believe the trading price of our common stock will remain highly volatile and may fluctuate substantially due to factors such as the following, many of which we cannot control:

- the commercial success of XERMELo and the revenues we generate from sales of XERMELo;
- results or delays in our or our collaborators' clinical trials;
- the announcement of FDA approval or non-approval, or delays in the FDA review process, of our or our collaborators' drug candidates or those of our competitors or actions taken by regulatory agencies with respect to our, our collaborators' or our competitors' clinical trials;

- actions taken by regulatory agencies with respect to XERMELO, sotagliflozin, LX9211 and our other drug candidates;
- the announcement of new products by our competitors;
- quarterly variations in our or our competitors' results of operations;
- developments in our relationships with our collaborators, including conflicts, litigation or the termination or modification of our agreements;
- the announcement of an in-licensed drug candidate or strategic acquisition;
- litigation, including intellectual property infringement and product liability lawsuits, involving us;
- failure to achieve operating results projected by securities analysts;
- changes in earnings estimates or recommendations by securities analysts;
- the satisfaction of outstanding debt obligations or entry into new financing arrangements;
- developments in the biotechnology or pharmaceutical industry;
- sales of large blocks of our common stock or sales of our common stock by our executive officers, directors and significant stockholders;
- departures of key personnel or board members;
- FDA or international regulatory actions;
- third-party coverage and reimbursement policies;
- disposition of any of our drug programs or other technologies; and
- other factors, including general market, economic and political conditions and other factors unrelated to our operating performance or the operating performance of our competitors.

These factors may materially adversely affect the market price of our common stock. In addition, the stock markets in general, and the markets for biotechnology and pharmaceutical stocks in particular, have historically experienced significant volatility that has often been unrelated or disproportionate to the operating performance of particular companies. For example, negative publicity regarding drug pricing and price increases by pharmaceutical companies has negatively impacted, and may continue to negatively impact, the markets for biotechnology and pharmaceutical stocks. Likewise, the broader financial markets could experience significant volatility that could also negatively impact the markets for biotechnology and pharmaceutical stocks. These broad market fluctuations have adversely affected and may in the future adversely affect the trading price of our common stock. Excessive volatility may continue for an extended period of time.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. A securities class action suit against us, such as the securities litigation which is currently pending, could result in substantial costs and divert management's attention and resources, which could have a material and adverse effect on our business.

We are subject to securities litigation, which is expensive and could divert management attention.

Companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation and we are currently a target of this type of litigation. On January 28, 2019, a purported securities class action complaint captioned Daniel Manopla v. Lexicon Pharmaceuticals, Inc., Lonnel Coats, Jeffrey L. Wade and Pablo Lapuerta, M.D. was filed against us, and certain of our officers in the U.S. District Court for the Southern District of Texas, Houston Division. A first amended complaint was filed on July 30, 2019 and we filed a motion to dismiss such first amended complaint on September 30, 2019. The plaintiff filed an opposition to our motion to dismiss on November 14, 2019 and we filed a reply in support of our motion to dismiss on December 13, 2019. The lawsuit purports to be a class action brought on behalf of purchasers of our securities during the period from March 11, 2016 through January 17, 2019. The complaint alleges that the defendants violated federal securities laws by making materially false and misleading statements and/or omissions concerning

data from our Phase 3 clinical trials of sotagliflozin in type 1 diabetes patients and the prospects of FDA approval of sotagliflozin for the treatment of type 1 diabetes. The complaint purports to assert claims for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. The complaint seeks, on behalf of the purported class, an unspecified amount of monetary damages, interest, fees and expenses of attorneys and experts, and other relief. This case, and other litigation of this type, could result in substantial costs and diversion of management's attention and resources, which could adversely impact our business. Any adverse determination in litigation could also subject us to significant liabilities.

Future sales of our common stock, or the perception that such sales may occur, may depress our stock price.

A substantial number of shares of our common stock is reserved for issuance upon conversion of notes evidencing our current indebtedness, upon the exercise of stock options and upon vesting of restricted stock units. If our stockholders sell substantial amounts of our common stock (including shares issued upon the conversion of notes, exercise of stock options or vesting of restricted stock units) in the public market, or if the market perceives that such sales may occur, the market price of our common stock could fall and it may become more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate. For example, following an acquisition, a significant number of shares of our common stock held by new stockholders may become freely tradable or holders of registration rights could cause us to register their shares for resale. Sales of these shares of common stock held by existing stockholders could cause the market price of our common stock to decline.

Conversion of our 5.25% Convertible Senior Notes due 2021 may dilute the ownership interest of our existing stockholders, including holders who had previously converted their notes, or may otherwise depress the price of our common stock.

The conversion of some or all of our 5.25% Convertible Senior Notes due 2021 will dilute the ownership interests of existing stockholders to the extent we deliver shares upon conversion of any of the notes. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the notes may encourage short selling by market participants because the conversion of the notes could be used to satisfy short positions, or anticipated conversion of the notes into shares of our common stock could depress the price of our common stock.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline.

We may engage in future acquisitions, which may be expensive and time consuming and from which we may not realize anticipated benefits.

We may acquire additional businesses, technologies and products if we determine that these businesses, technologies and products complement our existing technology or otherwise serve our strategic goals. If we do undertake any transactions of this sort, the process of integrating an acquired business, technology or product may result in operating difficulties and expenditures and may not be achieved in a timely and non-disruptive manner, if at all, and may absorb significant management attention that would otherwise be available for ongoing development of our business. If we fail to integrate acquired businesses, technologies or products effectively or if key employees of an acquired business leave, the anticipated benefits of the acquisition would be jeopardized. Moreover, we may never realize the anticipated benefits of any acquisition, such as increased revenues and earnings or enhanced business synergies. Future acquisitions could result in potentially dilutive issuances of our equity securities, the incurrence of debt and contingent liabilities and amortization expenses related to intangible assets, which could materially impair our results of operations and financial condition.

Item 1B. Unresolved Staff Comments

None.

Item 2. *Properties*

We currently own approximately 260,000 square feet of space for our corporate offices and laboratories in buildings located in The Woodlands, Texas, a suburb of Houston, Texas, and lease approximately 25,000 square feet of office space in Basking Ridge, New Jersey.

In August 2018, our subsidiary Lex-Gen Woodlands, L.P. entered into a term loan and security agreement refinancing the previously existing mortgage on our facilities in The Woodlands, Texas. The loan agreement provides for a \$12.9 million mortgage on the property and has a two-year term with a 10-year amortization. The mortgage loan bears interest at a rate per annum equal to the greater of (a) the 30-day LIBOR rate plus 5.5% and (b) 7.5% and provides for a balloon payment of \$10.3 million due in August 2020. The mortgage debt, net of issuance costs, was \$11.0 million as of December 31, 2019.

In January 2020, Lex-Gen Woodlands, L.P. entered into a real estate purchase and sale agreement under which we agreed to sell our facilities in The Woodlands, Texas for a purchase price of \$15.0 million. Such sale is subject to normal and customary closing conditions, including a study period, which extends until April 9, 2020, during which the purchaser may conduct inspections, analyses and other studies of the property and may terminate the agreement in its discretion. Such sale is also subject to the negotiation and execution by the parties of a leaseback agreement for a period of up to six months with respect to a portion of the property concurrently with closing.

In March 2015, our subsidiary Lexicon Pharmaceuticals (New Jersey), Inc. leased a 25,000 square-foot office space in Basking Ridge, New Jersey. The term of the lease extends from June 1, 2015 through December 31, 2022, and provides for escalating yearly base rent payments starting at \$482,000 and increasing to \$646,000 in the final year of the lease.

We believe that our facilities are well-maintained, in good operating condition and acceptable for our current operations.

Item 3. *Legal Proceedings*

On January 28, 2019, a purported securities class action complaint captioned Daniel Manopla v. Lexicon Pharmaceuticals, Inc., Lonnel Coats, Jeffrey L. Wade and Pablo Lapuerta, M.D. was filed against us and certain of our officers in the U.S. District Court for the Southern District of Texas, Houston Division. A first amended complaint was filed on July 30, 2019 and we filed a motion to dismiss such first amended complaint on September 30, 2019. The plaintiff filed an opposition to our motion to dismiss on November 14, 2019 and we filed a reply in support of our motion to dismiss on December 13, 2019. The lawsuit purports to be a class action brought on behalf of purchasers of our securities during the period from March 11, 2016 through July 29, 2019. The complaint alleges that the defendants violated federal securities laws by making materially false and misleading statements and/or omissions concerning data from our Phase 3 clinical trials of sotagliflozin in type 1 diabetes patients and the prospects of FDA approval of sotagliflozin for the treatment of type 1 diabetes. The complaint purports to assert claims for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. The complaint seeks, on behalf of the purported class, an unspecified amount of monetary damages, interest, fees and expenses of attorneys and experts, and other relief.

In addition, we are from time to time party to claims and legal proceedings that arise in the normal course of our business and that we believe will not have, individually or in the aggregate, a material adverse effect on our results of operations, financial condition or liquidity.

Item 4. *Mine Safety Disclosures*

Not applicable.

PART II

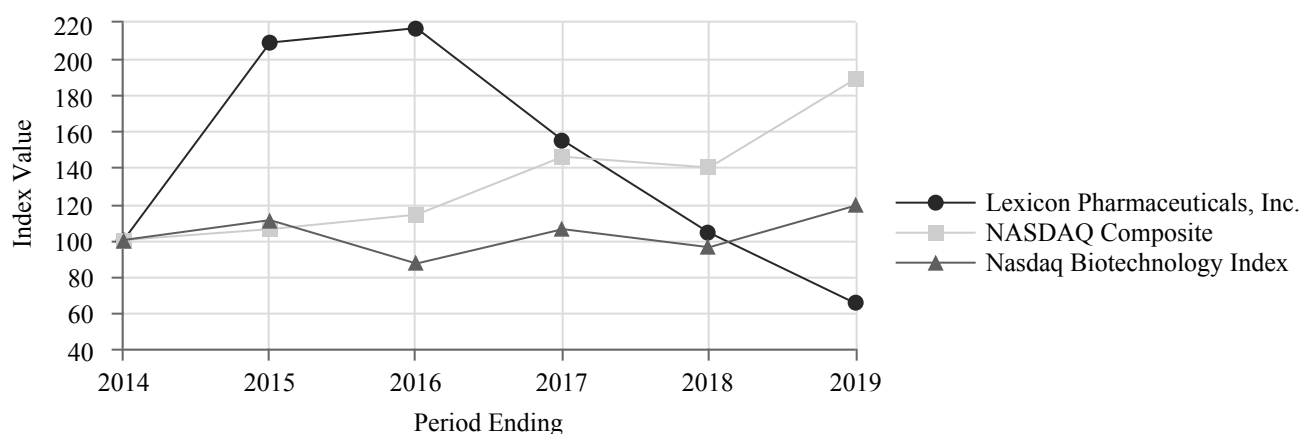
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is quoted on The Nasdaq Global Select Market under the symbol “LXRX.” As of March 6, 2020, there were approximately 359 holders of record of our common stock.

We have never paid cash dividends on our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the expansion and operation of our business and do not anticipate paying cash dividends in the foreseeable future.

Performance Graph

The following performance graph compares the performance of our common stock to the Nasdaq Composite Index and the Nasdaq Biotechnology Index for the period beginning December 31, 2014 and ending December 31, 2019. The graph assumes that the value of the investment in our common stock and each index was \$100 at December 31, 2014, and that all dividends were reinvested.



	December 31,					
	2014	2015	2016	2017	2018	2019
Lexicon Pharmaceuticals, Inc.	100	209	217	155	104	65
Nasdaq Composite Index	100	106	114	146	140	189
Nasdaq Biotechnology Index	100	111	87	106	96	119

The foregoing stock price performance comparisons shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference by any general statement incorporating by reference this annual report on Form 10-K into any filing under the Securities Act of 1933 or under the Securities Exchange Act of 1934, except to the extent that we specifically incorporate such comparisons by reference.

Item 6. Selected Financial Data

The statements of comprehensive income (loss) data for the years ended December 31, 2019, 2018 and 2017 and the balance sheet data as of December 31, 2019 and 2018 have been derived from our audited financial statements included elsewhere in this annual report on Form 10-K. The statements of comprehensive income (loss) data for the years ended December 31, 2016 and 2015, and the balance sheet data as of December 31, 2017, 2016 and 2015 have been derived from our audited financial statements not included in this annual report on Form 10-K. Our historical results are not necessarily indicative of results to be expected for any future period. The data presented below has been derived from financial statements that have been prepared in accordance with accounting principles generally accepted in the United States and should be read with our financial statements, including the notes, and with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this annual report on Form 10-K.

	Year Ended December 31,				
	2019	2018	2017	2016	2015
Statements of Comprehensive Income (Loss) Data:	(in thousands, except per share data)				
Revenues	\$ 322,073	\$ 63,209	\$ 91,689	\$ 79,256	\$ 130,014
Operating expenses:					
Cost of sales (including finite-lived intangible asset amortization)	3,231	2,491	1,899	—	—
Research and development, including stock-based compensation of \$7,096 in 2019, \$6,010 in 2018, \$4,905 in 2017, \$3,938 in 2016 and \$3,693 in 2015	91,924	100,243	152,223	163,973	95,065
Increase (decrease) in fair value of Symphony Icon, Inc. purchase liability	—	—	2,101	(703)	5,927
Selling, general and administrative, including stock-based compensation of \$7,122 in 2019, \$5,686 in 2018, \$4,567 in 2017, \$3,514 in 2016 and \$3,150 in 2015	56,835	63,754	66,090	43,157	23,835
Impairment loss	28,638	—	—	—	3,597
Total operating expenses	180,628	166,488	222,313	206,427	128,424
Income (loss) from operations	141,445	(103,279)	(130,624)	(127,171)	1,590
Interest and other income (expense), net	(17,326)	(17,269)	(5,030)	(4,274)	(6,150)
Net income (loss) before taxes	124,119	(120,548)	(135,654)	(131,445)	(4,560)
Income tax benefit	6,014	—	12,661	—	—
Net income (loss)	\$ 130,133	\$ (120,548)	\$ (122,993)	\$ (131,445)	\$ (4,560)
Net income (loss) per common share, basic	\$ 1.23	\$ (1.14)	\$ (1.17)	\$ (1.27)	\$ (0.04)
Net income (loss) per common share, diluted	\$ 1.16	\$ (1.14)	\$ (1.17)	\$ (1.27)	\$ (0.04)
Shares used in computing net income (loss) per common share, basic	106,218	105,830	105,237	103,863	103,591
Shares used in computing net income (loss) per common share, diluted	116,747	105,830	105,237	103,863	103,591
	As of December 31,				
	2019	2018	2017	2016	2015
Balance Sheet Data:	(in thousands)				
Cash, cash equivalents and short-term investments	\$ 271,659	\$ 160,052	\$ 310,788	\$ 346,504	\$ 521,352
Working capital	272,413	136,573	216,506	205,618	409,565
Total assets	417,715	284,136	436,539	475,625	651,960
Long-term debt, net of current portion	234,171	243,887	231,576	85,167	100,960
Accumulated deficit	(1,341,444)	(1,471,577)	(1,365,241)	(1,240,257)	(1,108,812)
Lexicon Pharmaceuticals, Inc. stockholders’ equity (deficit)	117,101	(26,405)	68,265	167,507	285,972

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read with "Selected Financial Data" and our financial statements and notes included elsewhere in this annual report on Form 10-K.

Overview

We are a biopharmaceutical company with a mission of pioneering medicines that transform patients' lives. We are devoting most of our resources to the commercialization or development of our three most advanced drugs and drug candidates:

- We are commercializing XERMELO (telotristat ethyl), an orally-delivered small molecule drug, in the United States for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog, or SSA, therapy in adults inadequately controlled by SSA therapy. We have granted Ipsen Pharma SAS, or Ipsen, an exclusive, royalty-bearing right to commercialize XERMELO outside of the United States and Japan. Ipsen is commercializing XERMELO in the United Kingdom, Germany and multiple additional countries. We are also developing telotristat ethyl as a treatment for biliary tract cancer and are conducting a Phase 2a clinical trial of telotristat ethyl in biliary tract cancer patients.
- We are developing Zynquista (sotagliflozin), an orally-delivered small molecule drug candidate, as a treatment for type 1 diabetes. The FDA has issued a complete response letter regarding our application for regulatory approval to market sotagliflozin for type 1 diabetes in the United States and has confirmed that position in denying two appeals of the complete response letter. Zynquista has been approved in the European Union for use as an adjunct to insulin therapy to improve glycemic control in adults with type 1 diabetes and a body mass index ≥ 27 kg/m², who could not achieve adequate glycemic control despite optimal insulin therapy.

We are also developing sotagliflozin as a treatment for type 2 diabetes, heart failure and chronic kidney disease. We are conducting a comprehensive Phase 3 development program, which includes one long-term outcomes study designed to demonstrate benefits in chronic heart failure and chronic kidney disease in type 2 diabetes patients and another long-term outcomes study designed to demonstrate benefits in acute decompensated heart failure in patients with and without type 2 diabetes. We have reported preliminary top-line results from the first four Phase 3 clinical trials of sotagliflozin in adults living with type 2 diabetes.

- We are developing LX9211, an orally-delivered small molecule drug candidate, as a treatment for neuropathic pain. We have reported top-line results from two Phase 1 clinical trials of LX9211 and are preparing to initiate a Phase 2 clinical trial of LX9211.

Compounds from our most advanced drug programs, as well as compounds from a number of additional drug discovery and development programs that we have advanced into various stages of clinical and preclinical development, originated from our own internal drug discovery efforts. These efforts were driven by a systematic, target biology-driven approach in which we used gene knockout technologies and an integrated platform of advanced medical technologies to systematically study the physiological and behavioral functions of almost 5,000 genes in mice and assessed the utility of the proteins encoded by the corresponding human genes as potential drug targets. We have identified and validated in living animals, or *in vivo*, more than 100 targets with promising profiles for drug discovery.

We are working both independently and through strategic collaborations and alliances with third parties to capitalize on our drug target discoveries and drug discovery and development programs. We seek to retain exclusive or co-exclusive rights to the benefits of certain drug discovery and development programs by developing and commercializing drug candidates from those programs internally, particularly in the United States for indications treated by specialist physicians. We seek to collaborate with other pharmaceutical and biotechnology companies with respect to drug discovery or the development and commercialization of certain of our drug candidates, particularly with respect to commercialization in territories outside the United States or commercialization in the United States for indications treated by primary care physicians, or when the collaboration may otherwise provide us with access to expertise and resources that we do not possess internally or are complementary to our own.

We commercially launched XERMELO following regulatory approval in the United States in February 2017 for the treatment of carcinoid syndrome diarrhea in combination with SSA therapy in adults inadequately controlled by SSA therapy. Prior to the launch of XERMELO, we derived substantially all of our revenues from strategic collaborations and other research and development collaborations and technology licenses. To date, we have generated a substantial portion of our revenues from a limited number of sources.

Our operating results and, in particular, our ability to generate additional revenues are dependent on many factors, including our ability to successfully commercialize XERMELO in the United States and the amount of revenues generated from such commercialization efforts; Ipsen's ability to successfully commercialize XERMELO outside of the United States and Japan and our receipt of any milestone payments and royalties; the success of our ongoing nonclinical and clinical development efforts and ability to obtain necessary regulatory approvals of the drug candidates which are the subject of such efforts; our success in establishing new collaborations and licenses, including for the development and commercialization of sotagliflozin; and general and industry-specific economic conditions which may affect research and development expenditures.

Future revenues from our commercialization of XERMELO are uncertain because they depend on a number of factors, including market acceptance of XERMELO, the success of our sales, marketing, distribution and other commercialization activities and the cost and availability of reimbursement for XERMELO.

Future revenues from our collaboration with Ipsen are uncertain because they depend, to a large degree, on the achievement of milestones and payment of royalties we earn from Ipsen's commercialization of XERMELO. Our ability to secure future revenue-generating agreements will depend upon our ability to address the needs of our potential future collaborators and licensees, and to negotiate agreements that we believe are in our long-term best interests. We may determine, as we have with certain of our drug candidates, including XERMELO in the United States and Japan, that our interests are better served by retaining rights to our discoveries and advancing our therapeutic programs to a later stage, which could limit our near-term revenues and increase expenses. Because of these and other factors, our operating results have fluctuated in the past and are likely to do so in the future, and we do not believe that period-to-period comparisons of our operating results are a good indication of our future performance.

Since our inception, we have incurred significant losses and, as of December 31, 2019, we had an accumulated deficit of \$1.3 billion. Our losses have resulted principally from costs incurred in research and development, selling, general and administrative costs associated with our operations, and non-cash stock-based compensation expenses associated with stock options and restricted stock granted to employees and consultants. Research and development expenses consist primarily of salaries and related personnel costs, external research costs related to our nonclinical and clinical efforts, material costs, facility costs, depreciation on property and equipment, and other expenses related to our drug discovery and development programs. Selling, general and administrative expenses consist primarily of salaries and related expenses for executive, sales and marketing, and administrative personnel, professional fees and other corporate expenses, including information technology, facilities costs and general legal activities. We expect to continue to incur significant research and development costs in connection with the continuing development of our drug candidates. As a result, we will need to generate significantly higher revenues to achieve profitability.

Critical Accounting Policies

Revenue Recognition

Product Revenues

Product revenues consist of commercial sales of XERMELO in the United States and sales of bulk tablets of XERMELO to Ipsen. Product revenues are recognized when the customer obtains control of our product, which occurs upon delivery to the customer. We recognize product revenue net of applicable reserves for variable consideration, including allowances for customer credits, estimated rebates, chargebacks, discounts, returns, distribution service fees, and government rebates, such as Medicare Part D coverage gap reimbursements in the United States, as discussed below. Our net product revenues reflect our best estimates of the amounts of consideration to which we are entitled based on the terms of the respective underlying contracts. Product shipping and handling costs are considered a fulfillment activity when control transfers to our customers and such costs are included in cost of sales.

Customer Credits: Our customers are offered various forms of consideration, including allowances, service fees and prompt payment discounts. We expect that our customers will earn prompt payment discounts. As a result, we deduct the full amount of those discounts from total product sales when revenues are recognized. Service fees are also deducted from product sales as they are earned.

Rebates: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program. Rebate amounts are based upon contractual agreements or legal requirements with public sector (e.g., Medicaid) benefit providers. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or legal requirements with public sector benefit providers. The allowance for rebates is based on statutory discount

rates and expected utilization. Our estimates for expected utilization of rebates are based on third party market research data and data received from the specialty pharmacies. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known unpaid rebates from the prior quarter. If actual future rebates vary from estimates, we may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Chargebacks: Chargebacks are discounts that occur when contracted customers purchase directly from a specialty pharmacy or distributor, who acts as a retailer. Contracted customers, which currently consist primarily of Public Health Service Institutions, non-profit clinics, and federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The specialty pharmacy or distributor, in turn, charges back to us the difference between the price paid by the specialty pharmacy or distributor and the discounted price paid to the specialty pharmacy or distributor by the customer. The allowance for chargeback is based on known sales to contracted customers.

Medicare Part D Coverage Gap: The Medicare Part D prescription drug benefit mandates manufacturers to fund a portion of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. Our estimates for the expected Medicare Part D coverage gap are based on data received from the specialty pharmacies and projections based on historical data. Funding of the coverage gap is generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters. If actual future funding varies from estimates, we may need to adjust prior period accruals, which would affect revenues in the period of adjustment.

Co-payment assistance: Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. We accrue a liability for co-payment assistance based on actual program participation and estimates of program redemption using data provided by third-party administrators.

Collaborative Agreements

Revenues under collaborative agreements include both license revenue and contract research revenue. We perform the following five steps in determining the amount of revenue to recognize as it fulfills its performance obligations under each of its agreements: (i) identify the contract(s) with a customer; (ii) identify the performance obligation in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation in the contract, and (v) recognize revenue when (or as) we satisfy the performance obligation. We apply this five-step model to contracts when it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services we transfer to the customer. At contract inception, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. We develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract.

At contract inception, we evaluate whether development milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal will not occur, the associated development milestone value is included in the transaction price. Development milestones that are not within our control or the control of our licensee, including those requiring regulatory approval, are not considered probable of being achieved until those approvals are received. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue when (or as) the performance obligation is satisfied. At the end of each reporting period, we re-evaluate the probability of achievement of the development milestones and any related constraint, and if necessary, adjust our estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues in the period of adjustment.

In agreements in which a license to our intellectual property is determined distinct from other performance obligations identified in the agreement, we recognize revenue when the license is transferred to the licensee and the licensee is able to use and benefit from the license.

For agreements that include sales-based royalties, including milestones based on a level of sales, the license is deemed to be the predominant item to which the royalties relate and we recognize revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

We may receive payments from our licensees based on billing schedules established in each contract. Upfront payments and fees are recorded as deferred revenue upon receipt or when due, and may require deferral of revenue recognition to a future period until we perform our obligations under these agreements. Amounts are recorded as accounts receivable when our right to consideration is unconditional.

Research and Development Expenses

Research and development expenses consist of costs incurred for research and development activities solely sponsored by us as well as collaborative research and development activities. These costs include direct and research-related overhead expenses and are expensed as incurred. Technology license fees for technologies that are utilized in research and development and have no alternative future use are expensed when incurred.

We are presently devoting most of our resources to the commercialization or development of our three most advanced drugs and drug candidates:

- XERMELO (telotristat ethyl), an orally-delivered small molecule drug that we are commercializing for carcinoid syndrome diarrhea and developing for biliary tract cancer;
- Zynquista (sotagliflozin), an orally-delivered small molecule drug candidate that we are developing as a treatment for type 1 diabetes and type 2 diabetes, heart failure and chronic kidney disease; and
- LX9211, an orally-delivered small molecule drug candidate, that we are developing as a treatment for neuropathic pain.

Compounds from our most advanced drug programs, as well as compounds from a number of additional drug discovery and development programs that we have advanced into various stages of clinical and preclinical development, originated from our own internal drug discovery efforts. These efforts were driven by a systematic, target biology-driven approach in which we used gene knockout technologies and an integrated platform of advanced medical technologies to systematically study the physiological and behavioral functions of almost 5,000 genes in mice and assessed the utility of the proteins encoded by the corresponding human genes as potential drug targets. We have identified and validated in living animals, or *in vivo*, more than 100 targets with promising profiles for drug discovery.

The drug development process takes many years to complete. The cost and length of time varies due to many factors including the type, complexity and intended use of the drug candidate. We estimate that drug development activities are typically completed over the following periods:

Phase	Estimated Completion Period
Preclinical development	1-2 years
Phase 1 clinical trials	1-2 years
Phase 2 clinical trials	1-2 years
Phase 3 clinical trials	2-4 years

We expect research and development costs to remain substantial in the future as we continue to fund our nonclinical and clinical development efforts and advance new drug candidates into clinical development. Due to the variability in the length of time necessary for drug development, the uncertainties related to the cost of these activities and ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the ultimate costs to bring our potential drug candidates to market are not available.

We record significant accrued liabilities related to unbilled expenses for products or services that we have received from service providers, specifically related to ongoing nonclinical studies and clinical trials. These costs primarily relate to clinical study management, monitoring, laboratory and analysis costs, drug supplies, toxicology studies and investigator grants. We have multiple drugs in concurrent nonclinical studies and clinical trials at clinical sites throughout the world. In order to ensure that we have adequately provided for ongoing nonclinical and clinical development costs during the period in which we incur such costs, we maintain accruals to cover these expenses. Substantial portions of our nonclinical studies and clinical trials are performed by third-party laboratories, medical centers, contract research organizations and other vendors. For nonclinical studies, we accrue expenses based upon estimated percentage of work completed and the contract milestones remaining. For clinical studies, expenses are accrued based upon the number of patients enrolled and the duration of the study. We monitor patient enrollment, the progress of clinical studies and related activities to the extent possible through internal reviews of data reported to us by the vendors and clinical site visits. Our estimates depend on the timeliness and accuracy of

the data provided by our vendors regarding the status of each program and total program spending. We periodically evaluate the estimates to determine if adjustments are necessary or appropriate based on information we receive. Although we use consistent milestones or subject or patient enrollment to drive expense recognition, the assessment of these costs is a subjective process that requires judgment. Upon settlement, these costs may differ materially from the amounts accrued in our consolidated financial statements.

Our estimates of the clinical study costs and costs to transition activities from Sanofi for development of sotagliflozin for type 2 diabetes, heart failure and chronic kidney disease were based on estimates of the services to be received and efforts to be expended pursuant to contracts with multiple vendors and the CRO that will conduct and manage the clinical studies on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract. In accruing the relevant costs, we estimated the time period over which services will be performed and the level of effort required to complete each study. Upon completion and settlement, these costs may differ materially from the amounts accrued in our consolidated financial statements.

We record our research and development costs by type or category, rather than by project. Significant categories of costs include personnel, facilities and equipment costs and third-party and other services. In addition, a significant portion of our research and development expenses is not tracked by project as it benefits multiple projects. Consequently, fully-loaded research and development cost summaries by project are not available.

Stock-based Compensation Expense

We recognize compensation expense in our statements of comprehensive income (loss) for share-based payments, including stock options and restricted stock units issued to employees, based on their fair values on the date of the grant, with the compensation expense recognized over the period in which an employee is required to provide service in exchange for the stock award. Stock-based compensation expense for awards without performance conditions is recognized on a straight-line basis. Stock-based compensation expense for awards with performance conditions is recognized over the period from the date the performance condition is determined to be probable of occurring through the time the applicable condition is met. We had stock-based compensation expense of \$14.2 million for the year ended December 31, 2019. As of December 31, 2019, stock-based compensation cost for all outstanding unvested options and restricted stock units was \$24.0 million, which is expected to be recognized over a weighted-average vesting period of 1.1 years.

The fair value of stock options is estimated at the date of grant using the Black-Scholes option-pricing model. For purposes of determining the fair value of stock options, we segregate our options into two homogeneous groups, based on exercise and post-vesting employment termination behaviors, resulting in different assumptions used for expected option lives. Historical data is used to estimate the expected option life for each group. Expected volatility is based on the historical volatility in our stock price. The following weighted-average assumptions were used for options granted in the years ended December 31, 2019, 2018 and 2017, respectively:

	Expected Volatility	Risk-free Interest Rate	Expected Term	Dividend Rate
December 31, 2019:				
Employees	88 %	2.2 %	4	0 %
Officers and non-employee directors	77 %	2.6 %	8	0 %
December 31, 2018:				
Employees	58 %	2.6 %	4	0 %
Officers and non-employee directors	63 %	2.8 %	8	0 %
December 31, 2017:				
Employees	61 %	1.7 %	4	0 %
Officers and non-employee directors	70 %	2.2 %	8	0 %

Impairment of Long-Lived Assets

Our long-lived assets include property, plant and equipment, right-of-use assets for leases, finite-lived intangible assets and goodwill. We regularly review long-lived assets for impairment. The recoverability of long-lived assets, other than goodwill, is measured by comparing the assets carrying amount to the expected undiscounted future cash flows that the asset is expected to generate. Determining whether an impairment has occurred typically requires various estimates and assumptions, including determining which cash flows are directly related to the potentially impaired asset, the useful life over which cash flows will occur, their amount, and the asset's residual value, if any. We use internal cash flow estimates, quoted market prices

when available and independent appraisals as appropriate to determine fair value. We derive the required cash flow estimates from our historical experience and our internal business plans and apply an appropriate discount rate. There were no significant impairments of long-lived assets in 2019, 2018 or 2017.

Indefinite-lived intangible assets, composed primarily of in-process research and development, or IPR&D, projects acquired in business combinations which have not reached technological feasibility, are reviewed annually for impairment and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. Estimating future cash flows of an IPR&D product candidate for purposes of an impairment analysis requires us to make significant estimates and assumptions regarding the amount and timing of costs to complete the project and the amount, timing and probability of achieving revenues from the completed product similar to how the acquisition date fair value of the project was determined. In 2019, we terminated certain research and development activities related to a program for treatment of irritable bowel syndrome and as a result, recognized \$28.6 million of impairment to indefinite-lived intangible assets. There were no impairments to indefinite-lived intangible assets in 2018 or 2017.

Goodwill is not amortized, but is tested at least annually for impairment at the reporting unit level. We have determined that the reporting unit is the single operating segment disclosed in our current financial statements. Impairment is the condition that exists when the carrying amount of goodwill exceeds its implied fair value. The first step in the impairment process is to determine the fair value of the reporting unit and then compare it to the carrying value, including goodwill. We determined that the market capitalization approach is the most appropriate method of measuring fair value of the reporting unit. Under this approach, fair value is calculated as the average closing price of our common stock for the 30 days preceding the date that the annual impairment test is performed, multiplied by the number of outstanding shares on that date. A control premium, which is representative of premiums paid in the marketplace to acquire a controlling interest in a company, is then added to the market capitalization to determine the fair value of the reporting unit. If the fair value exceeds the carrying value, no further action is required and no impairment loss is recognized. Additional impairment assessments may be performed on an interim basis if we encounter events or changes in circumstances that would indicate that, more likely than not, the carrying value of goodwill has been impaired. There was no impairment of goodwill in 2019, 2018 and 2017.

Business Combinations

We allocate the purchase price of acquired businesses to the tangible and intangible assets acquired and liabilities assumed based upon their estimated fair values on the acquisition date. The purchase price allocation process requires management to make significant estimates and assumptions, especially at acquisition date with respect to intangible assets and in-process research and development.

These assumptions are based in part on historical experience and are inherently uncertain. Examples of critical estimates in valuing certain of the intangible assets we have acquired or may acquire in the future include but are not limited to: the feasibility and timing of achievement of development, regulatory and commercial milestones; expected costs to develop the in-process research and development into commercially viable products; and future expected cash flows from product sales.

In connection with the purchase price allocations for acquisitions, we estimate the fair value of the contingent payments. The estimated fair value of any contingent payments is determined utilizing a probability-based income approach inclusive of an estimated discount rate.

Unanticipated events and circumstances may occur which may affect the accuracy or validity of such assumptions, estimates or actual results.

Recent Accounting Pronouncements

See Note 3, Recent Accounting Pronouncements, of the Notes to Consolidated Financial Statements, for a discussion of the impact of new accounting standards on our consolidated financial statements.

Results of Operations – Comparison of Years Ended December 31, 2019, 2018 and 2017

The following discussion and analysis should be read with “Results of Operations” and our financial statements and notes included in our annual report on Form 10-K for the year ended December 31, 2018.

Revenues

Total revenues and dollar and percentage changes as compared to the prior year are as follows (dollar amounts are presented in millions):

	Year Ended December 31,		
	2019	2018	2017
Total revenues	\$ 322.1	\$ 63.2	\$ 91.7
Dollar increase (decrease)	\$ 258.9	\$ (28.5)	
Percentage increase (decrease)	410 %	(31)%	

Years Ended December 31, 2019 and 2018

- *Net product revenues* – Net product revenue increased 22% in 2019 to \$32.3 million, primarily from revenues recognized from the sale of XERMELO in the United States. Sales of bulk tablets of XERMELO to Ipsen were comparable in both years. Product revenues are recorded net of estimated product returns, pricing discounts including rebates offered pursuant to mandatory federal and state government programs and chargebacks, prompt pay discounts and distribution fees and co-pay assistance. Revenue recognition policies require estimates of the aforementioned sales allowances each period.
- *Collaborative agreements* – Revenue from collaborative agreements increased in 2019 to \$289.2 million, due to \$260 million in revenues recognized from amounts payable by Sanofi pursuant to the termination of our collaboration agreement and recognition of amounts allocated to the performance obligation for development activities of sotagliflozin in the Sanofi collaboration agreement.
- *Royalties and other revenue* – Revenues from royalties and other revenue increased 44% in 2019 to \$0.5 million.

In 2019, no customers for XERMELO sales represented more than 10% of revenues. In 2018, two specialty pharmacies, Biologics, Inc. and Diplomat Pharmacy, represented 25% and 14% of revenues, respectively.

In 2019 and 2018, Sanofi represented 89% and 53% of revenues, respectively.

Cost of Sales

Total cost of sales and dollar and percentage changes as compared to the prior year are as follows (dollar amounts are presented in millions):

	Year Ended December 31,		
	2019	2018	2017
Total cost of sales	\$ 3.2	\$ 2.5	\$ 1.9
Dollar increase	\$ 0.7	\$ 0.6	
Percentage increase	30 %	31 %	

Years Ended December 31, 2019 and 2018

Cost of sales increased 30% in 2019 to \$3.2 million. We began capitalizing inventory in 2017 following FDA approval of XERMELO, as the related costs were expected to be recoverable through the commercialization of the product. Costs incurred prior to FDA approval were recorded as research and development expenses in the consolidated statements of comprehensive income (loss). Cost of sales consists of third-party manufacturing costs, freight and indirect overhead costs associated with sales of XERMELO. The pre-commercialized inventory is expected to be sold over approximately the next twelve months. As a result, cost of sales will reflect a lower average per unit cost of materials. Cost of sales in each of 2019 and 2018 included \$1.8 million of amortization of intangible assets related to XERMELO.

Research and Development Expenses

Research and development expenses and dollar and percentage changes as compared to the prior year are as follows (dollar amounts are presented in millions):

	Year Ended December 31,		
	2019	2018	2017
Total research and development expense	\$ 91.9	\$ 100.2	\$ 152.2
Dollar decrease	\$ (8.3)	\$ (52.0)	
Percentage decrease	(8)%	(34)%	

Research and development expenses consist primarily of third-party and other services principally related to nonclinical and clinical development activities, salaries and other personnel-related expenses, facility and equipment costs and stock-based compensation.

Years Ended December 31, 2019 and 2018

- *Third-party and other services* – Third-party and other services decreased 12% in 2019 to \$55.9 million, primarily due to decreases in professional and consulting fees and lower external clinical development costs relating to sotagliflozin. Third-party and other services relate principally to our clinical trial and related development activities, such as nonclinical and clinical studies and contract manufacturing.
- *Personnel* – Personnel costs decreased 3% in 2019 to \$20.7 million, primarily due to lower headcount. Salaries, bonuses, employee benefits, payroll taxes, recruiting and relocation costs are included in personnel costs.
- *Stock-based compensation* – Stock-based compensation expense increased 18% in 2019 to \$7.1 million, primarily due to a shorter vesting period of the annual restricted stock unit awards granted in 2019 and 2018.
- *Facilities and equipment* – Facilities and equipment costs decreased 3% in 2019 to \$2.7 million.
- *Other* – Other costs decreased 13% in 2019 to \$5.5 million.

Selling, General and Administrative Expenses

Selling, general and administrative expenses and dollar and percentage changes as compared to the prior year are as follows (dollar amounts are presented in millions):

	Year Ended December 31,		
	2019	2018	2017
Total selling, general and administrative expense	\$ 56.8	\$ 63.8	\$ 66.1
Dollar decrease	\$ (6.9)	\$ (2.3)	
Percentage decrease	(11)%	(4)%	

Selling, general and administrative expenses consist primarily of personnel costs to support the commercialization of XERMELO and our research and development activities, professional and consulting fees, stock-based compensation expense, and facility and equipment costs.

Years Ended December 31, 2019 and 2018

- *Personnel* – Personnel costs increased 1% in 2019 to \$28.4 million, primarily due to higher incentive compensation costs. Salaries, bonuses, employee benefits, payroll taxes, recruiting and relocation costs are included in personnel costs.
- *Professional and consulting fees* – Professional and consulting fees decreased 39% in 2019 to \$12.2 million, primarily due to lower marketing costs.

- *Stock-based compensation* – Stock-based compensation expense increased 25% in 2019 to \$7.1 million, primarily due to a shorter vesting period of the annual restricted unit awards granted in 2019 and 2018.
- *Facilities and equipment* – Facilities and equipment decreased 8% in 2019 to \$1.8 million.
- *Other* – Other costs decreased 8% in 2019 to \$7.3 million, primarily due to decreases in sponsorships and contributions to charitable foundations.

Impairment Loss

Impairment loss of \$28.6 million in the year ended December 31, 2019 was recognized to an indefinite-lived intangible asset associated with the 2010 acquisition of Symphony Icon, due to the decision to terminate research and development activities related to a program for irritable bowel syndrome that was among the assets acquired.

Interest Expense and Interest and Other Income, Net

Interest Expense. Interest expense was \$20.7 million and \$20.8 million in the years ended December 31, 2019 and 2018, respectively.

Interest and Other Income (Expense), Net. Interest and other income, net was \$3.4 million and \$3.5 million in the years ended December 31, 2019 and 2018, respectively.

Income Tax Benefit

The income tax benefit for the year ended December 31, 2019 was \$6.0 million, due to the release of the deferred tax liability related to the impairment of the indefinite-lived intangible asset (see Note 7, Income Taxes of the Notes to Consolidated Financial Statements, for more information). There was no income tax expense or benefit in 2018.

Net Income (Loss) and Net Income (Loss) per Common Share

Net income was \$130.1 million, or \$1.16 per diluted share, in 2019 as compared to a net loss of \$120.5 million, or loss of \$1.14 per share in 2018.

Liquidity and Capital Resources

We have financed our operations from inception primarily through sales of common and preferred stock, contract and milestone payments we received under our strategic and other collaborations, target validation, database subscription and technology license agreements, product sales, government grants and contracts, and financing under debt and lease arrangements. We have also financed certain of our research and development activities under our agreements with Symphony Icon, Inc. In December 2017, we entered into a loan agreement with BioPharma Credit PLC and BioPharma Credit Investments IV Sub LP (the “BioPharma Term Loan”) under which \$150 million was funded.

As of December 31, 2019, we had \$271.7 million in cash, cash equivalents and short-term investments. As of December 31, 2018, we had \$160.1 million in cash, cash equivalents and short-term investments. We generated cash of \$113.8 million from operations in 2019. This consisted primarily of the net income for the year of \$130.1 million and non-cash charges of \$28.6 million related to impairment of intangible assets, \$14.2 million related to stock-based compensation expense and \$5.1 million related to depreciation and amortization expense, including amortization of debt issuance costs. Partially offsetting this was a net increase in operating assets, net of liabilities of \$58.3 million. Investing activities used cash of \$155.9 million in 2019, primarily due to net purchases of investments of \$155.8 million. Financing activities used cash of \$2.2 million, primarily to repay \$1.3 million of debt borrowings and to repurchase \$0.9 million of common stock.

Facilities. In August 2018, our subsidiary Lex-Gen Woodlands, L.P. entered into a term loan and security agreement refinancing the previously existing mortgage on our facilities in The Woodlands, Texas. The loan agreement provides for a \$12.9 million mortgage on the property and has a two-year term with a 10-year amortization. The mortgage loan bears interest at a rate per annum equal to the greater of (a) the 30-day LIBOR rate plus 5.5% and (b) 7.5% and provides for a balloon payment of \$10.3 million due in August 2020.

In January 2020, Lex-Gen Woodlands, L.P. entered into a real estate purchase and sale agreement under which we agreed to sell our facilities in The Woodlands, Texas for a purchase price of \$15.0 million. Such sale is subject to normal and customary closing conditions, including a study period, which extends until April 9, 2020, during which the purchaser may

conduct inspections, analyses and other studies of the property and may terminate the agreement in its discretion. Such sale is also subject to the negotiation and execution by the parties of a leaseback agreement for a period of up to six months with respect to a portion of the property concurrently with closing.

In March 2015, our subsidiary Lexicon Pharmaceuticals (New Jersey), Inc. leased a 25,000 square-foot office space in Basking Ridge, New Jersey. The term of the lease extends from June 1, 2015 through December 31, 2022, and provides for escalating yearly base rent payments starting at \$482,000 and increasing to \$646,000 in the final year of the lease.

Including the lease and debt obligations described above, we had incurred the following contractual obligations as of December 31, 2019:

Contractual Obligations	Payments due by period (in millions)				
	Total	Less than 1 year	2-3 years	4-5 years	More than 5 years
Debt	\$ 248.6	\$ 11.1	\$ 237.5	\$ —	\$ —
Interest payment obligations	50.0	18.9	31.1	—	—
Total	\$ 298.6	\$ 30.0	\$ 268.6	\$ —	\$ —

Our future capital requirements will be substantial and will depend on many factors, including our ability to successfully commercialize XERMELO in the United States and the amount of revenues generated from such commercialization efforts; Ipsen's ability to successfully commercialize XERMELO outside of the United States and Japan and our receipt of any milestone payments and royalties; the success of our ongoing nonclinical and clinical development efforts and ability to obtain necessary regulatory approvals of the drug candidates which are the subject of such efforts; our success in establishing new collaborations and licenses, including for the development and commercialization of sotagliflozin; the amount and timing of our research, development and commercialization expenditures; the resources we devote to developing and supporting our products and other factors. Our capital requirements will also be affected by any expenditures we make in connection with license agreements and acquisitions of and investments in complementary technologies and businesses. We expect to continue to devote substantial capital resources to continue commercializing XERMELO in the United States; to successfully complete our nonclinical and clinical development efforts with respect to telotristat ethyl, sotagliflozin, LX9211 and our other drug candidates; and for other general corporate activities. We believe that our current unrestricted cash and investment balances and cash and revenues we expect to derive from strategic and other collaborations and other sources will be sufficient to fund our operations for at least the next 12 months. During or after this period, if cash generated by operations is insufficient to satisfy our liquidity requirements, we will need to sell additional equity or debt securities or obtain additional credit arrangements. Additional financing may not be available on terms acceptable to us or at all. The sale of additional equity or convertible debt securities may result in additional dilution to our stockholders.

Disclosure about Market Risk

We are exposed to limited market and credit risk on our cash equivalents which have maturities of three months or less at the time of purchase. We maintain a short-term investment portfolio which consists of U.S. Treasury bills and corporate debt securities that mature three to 12 months from the time of purchase, which we believe are subject to limited market and credit risk. We currently do not hedge interest rate exposure or hold any derivative financial instruments in our investment portfolio.

We had approximately \$271.7 million in cash and cash equivalents and short-term investments as of December 31, 2019. We believe that the working capital available to us will be sufficient to meet our cash requirements for at least the next 12 months. We are not subject to interest rate sensitivity on our outstanding Convertible Notes and our BioPharma Term Loan as each generally have a fixed rate of 5.25% and 9% per annum, respectively. The Convertible Notes interest is payable in cash semi-annually in arrears and matures in December 2021, unless earlier converted or repurchased in accordance with their terms. The BioPharma Term Loan bears interest payable quarterly in arrears, and provides for interest-only payments followed by payment of principal at maturity in December 2022.

We have operated primarily in the United States and substantially all sales to date have been made in U.S. dollars. Accordingly, we have not had any material exposure to foreign currency rate fluctuations.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

See "Disclosure about Market Risk" under "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" for quantitative and qualitative disclosures about market risk.

Item 8. Financial Statements and Supplementary Data

The financial statements required by this Item are incorporated under Item 15 in Part IV of this report.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures**Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) as of the end of the period covered by this report. Based on that evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective as of December 31, 2019 to ensure that the information required to be disclosed by us in the reports we file under the Securities Exchange Act is gathered, analyzed and disclosed with adequate timeliness, accuracy and completeness.

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act).

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2019. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control-Integrated Framework* (2013 Framework).

Based on such assessment using those criteria, management concluded that, as of December 31, 2019, our internal control over financial reporting was effective.

Changes in Internal Control Over Financial Reporting

Subsequent to our evaluation described above, there were no significant changes in internal controls or other factors during the fiscal quarter ended December 31, 2019 that could significantly affect internal controls, including any corrective actions with regard to significant deficiencies and material weaknesses.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Lexicon Pharmaceuticals, Inc.

Opinion on Internal Control over Financial Reporting

We have audited Lexicon Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission 2013 framework (the COSO criteria). In our opinion, Lexicon Pharmaceuticals, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2019 and 2018, the related consolidated statements of comprehensive income (loss), stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2019, and the related notes and our report dated March 12, 2020 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Houston, Texas
March 12, 2020

Item 9B. *Other Information*

None.

PART III

Item 10. *Directors, Executive Officers and Corporate Governance*

The information required by this Item is hereby incorporated by reference from (a) the information appearing under the captions “Election of Directors,” “Stock Ownership of Certain Beneficial Owners and Management,” “Corporate Governance” and “Executive and Director Compensation” in our definitive proxy statement which involves the election of directors and is to be filed with the Securities and Exchange Commission pursuant to the Securities Exchange Act of 1934 within 120 days of the end of our fiscal year on December 31, 2019 and (b) the information appearing under Item 1 in Part I of this report.

Item 11. *Executive Compensation*

The information required by this Item is hereby incorporated by reference from the information appearing under the captions “Corporate Governance” and “Executive and Director Compensation” in our definitive proxy statement which involves the election of directors and is to be filed with the Commission pursuant to the Securities Exchange Act of 1934 within 120 days of the end of our fiscal year on December 31, 2019. Notwithstanding the foregoing, in accordance with the instructions to Item 407(e)(5) of Regulation S-K, the information contained in our proxy statement under the sub-heading “Compensation Committee Report” shall not be deemed to be filed as part of or incorporated by reference into this annual report on Form 10-K.

Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*

The information required by this Item is hereby incorporated by reference from the information appearing under the captions “Stock Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in our definitive proxy statement which involves the election of directors and is to be filed with the Commission pursuant to the Securities Exchange Act of 1934 within 120 days of the end of our fiscal year on December 31, 2019.

Item 13. *Certain Relationships and Related Transactions, and Director Independence*

The information required by this Item is hereby incorporated by reference from the information appearing under the captions “Corporate Governance” and “Transactions with Related Persons” in our definitive proxy statement which involves the election of directors and is to be filed with the Commission pursuant to the Securities Exchange Act of 1934 within 120 days of the end of our fiscal year on December 31, 2019.

Item 14. *Principal Accounting Fees and Services*

The information required by this Item as to the fees we pay our principal accountant is hereby incorporated by reference from the information appearing under the caption “Ratification and Approval of Independent Auditors” in our definitive proxy statement which involves the election of directors and is to be filed with the Commission pursuant to the Securities Exchange Act of 1934 within 120 days of the end of our fiscal year on December 31, 2019.

PART IV

Item 15. *Exhibits and Financial Statement Schedules*

- (a) Documents filed as a part of this report:
1. Consolidated Financial Statements

	Page
Report of Independent Registered Public Accounting Firm	F-1
Consolidated Balance Sheets	F-2
Consolidated Statements of Comprehensive Income (Loss)	F-3
Consolidated Statements of Stockholders' Equity (Deficit)	F-4
Consolidated Statements of Cash Flows	F-5
Notes to Consolidated Financial Statements	F-6

2. Financial Statement Schedules

All other financial statement schedules are omitted because they are not applicable or not required, or because the required information is included in the financial statements or notes thereto.

3. Exhibits

Exhibit No.	Description
3.1	— Amended and Restated Certificate of Incorporation (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K dated April 26, 2012 and incorporated by reference herein).
3.2	— Certificate of Amendment to Amended and Restated Certificate of Incorporation (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K dated May 20, 2015 and incorporated by reference herein).
3.3	— Second Amended and Restated Bylaws (filed as Exhibit 3.2 to the Company's Current Report on Form 8-K dated April 26, 2012 and incorporated by reference herein).
4.1	— Securities Purchase Agreement, dated June 17, 2007, with Invus, L.P. (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated June 17, 2007 and incorporated by reference herein).
4.2	— Amendment, dated October 7, 2009, to Securities Purchase Agreement, dated June 17, 2007, with Invus, L.P. (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated October 7, 2009 and incorporated by reference herein).
4.3	— Registration Rights Agreement, dated June 17, 2007, with Invus, L.P. (filed as Exhibit 10.3 to the Company's Current Report on Form 8-K dated June 17, 2007 and incorporated by reference herein).
4.4	— Stockholders' Agreement, dated June 17, 2007, with Invus, L.P. (filed as Exhibit 10.4 to the Company's Current Report on Form 8-K dated June 17, 2007 and incorporated by reference herein).
4.5	— Supplement to Transaction Agreements, dated March 15, 2010, with Invus, L.P. and Invus C.V. (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated March 15, 2010 and incorporated by reference herein).
4.6	— Supplement No. 2 to Transaction Agreements, dated February 23, 2012, with Invus, L.P. and Invus C.V. (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated February 23, 2012 and incorporated by reference herein).
4.7	— Indenture related to the 5.25% Convertible Senior Notes due 2021, dated as of November 26, 2014, with Wells Fargo Bank, N.A. (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K dated November 26, 2014 and incorporated by reference herein).
4.8	— Form of 5.25% Convertible Senior Notes due 2021 (filed as Exhibit A to Exhibit 4.1 to the Company's Current Report on Form 8-K dated November 26, 2014 and incorporated by reference herein).
10.1	— Offer Letter, dated July 1, 2014, with Lonnel Coats, as amended (filed as Exhibit 10.1 to the Company's Annual Report on Form 10-K for the period ended December 31, 2018 and incorporated by reference herein).
10.2	— Offer Letter, dated March 10, 2011, with Pablo Lapuerta, M.D. (filed as Exhibit 10.5 to the Company's Annual Report on Form 10-K for the period ended December 31, 2011 and incorporated by reference herein).
10.3	— Offer Letter, dated March 23, 2016, with Praveen Tyle, Ph.D. (filed as Exhibit 10.4 to the Company's Annual Report on Form 10-K for the period ended December 31, 2016 and incorporated by reference herein).

Exhibit No.	Description
10.4	— Offer Letter, dated March 16, 2015, with Alexander A. Santini, as amended (filed as Exhibit 10.4 to the Company's Annual Report on Form 10-K for the period ended December 31, 2018 and incorporated by reference herein).
10.5	— Employment Agreement with Jeffrey L. Wade, J.D. (filed as Exhibit 10.3 to the Company's Registration Statement on Form S-1 (Registration No. 333-96469) and incorporated by reference herein).
10.6	— Form of Indemnification Agreement with Officers and Directors (filed as Exhibit 10.7 to the Company's Registration Statement on Form S-1 (Registration No. 333-96469) and incorporated by reference herein).
10.7	— Summary of Non-Employee Director Compensation (filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2019 and incorporated by reference herein).
*10.8	— 2017 Equity Incentive Plan, as amended.
10.9	— 2017 Non-Employee Directors' Equity Incentive Plan, as amended (filed as Exhibit 10.9 to the Company's Annual Report on Form 10-K for the period ended December 31, 2018 and incorporated by reference
10.10	— Form of Stock Option Agreement with Officers under the 2017 Equity Incentive Plan (filed as Exhibit 10.11 to the Company's Annual Report on Form 10-K for the period ended December 31, 2017 and
*10.11	— Form of Restricted Stock Unit Agreement with Officers.
10.12	— Form of Notice of Stock Option Grant to Directors under the 2017 Non-Employee Directors' Equity Incentive Plan (filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2019 and incorporated by reference herein).
10.13	— Form of Notice of Restricted Stock Unit Grant to Directors under the 2017 Non-Employee Directors' Equity Incentive Plan (filed as Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2019 and incorporated by reference herein).
†10.14	— Collaboration and License Agreement, dated November 5, 2015, with Sanofi (filed as Exhibit 10.14 to the Company's Annual Report on Form 10-K/A for the period ended December 31, 2015 and incorporated by reference herein).
†10.15	— Amendment No. 1, dated July 1, 2017, to Collaboration and License Agreement, dated November 5, 2015, with Sanofi (filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2017 and incorporated by reference herein).
§10.16	— Confidential Termination and Settlement Agreement and Mutual Releases, dated September 9, 2019, with Sanofi-Aventis Deutschland GmbH (filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2019 and incorporated by reference herein).
†10.17	— License and Collaboration Agreement, dated October 21, 2014, with Ipsen Pharma SAS (filed as Exhibit 10.1 to the amendment to the Company's Quarterly Report on Form 10-Q/A for the period ended September 30, 2014, as filed on December 23, 2014, and incorporated by reference herein).
†10.18	— First Amendment, dated March 17, 2015, to License and Collaboration Agreement, dated October 21, 2014, with Ipsen Pharma SAS (filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2015 and incorporated by reference herein).
*10.19	— Second Amendment, dated January 28, 2020, to License and Collaboration Agreement, dated October 21, 2014, with Ipsen Pharma SAS.
10.20	— Collaboration and License Agreement, dated December 17, 2003, with Bristol-Myers Squibb Company (filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2015 and incorporated by reference herein).
10.21	— First Amendment, dated May 30, 2006, to Collaboration and License Agreement, dated December 17, 2003, with Bristol-Myers Squibb Company (filed as Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2015 and incorporated by reference herein).
†10.22	— Second Amendment, dated November 2, 2016, to Collaboration and License Agreement, dated December 17, 2003, with Bristol-Myers Squibb Company (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated November 2, 2016 and incorporated by reference herein).
†10.23	— Second Amended and Restated Collaboration and License Agreement, dated November 30, 2005, with Genentech, Inc. (filed as Exhibit 10.22 to the Company's Annual Report on Form 10-K for the period ended December 31, 2005 and incorporated by reference herein).
10.24	— Amendment, dated June 8, 2009, to Second Amended and Restated Collaboration and License Agreement, dated November 30, 2005, with Genentech, Inc. (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K/A dated June 8, 2009 and incorporated by reference herein).
†10.25	— Commercial Supply Agreement, dated June 6, 2016, with Catalent CTS, LLC (filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q/A for the period ended March 31, 2017 and incorporated by reference herein).

Exhibit No.	Description
†10.26	— Amendment One to Commercial Supply Agreement, dated April 4, 2018, with Catalent CTS, LLC (filed as Exhibit 10.23 to the Company's Annual Report on Form 10-K for the period ended December 31, 2018 and incorporated by reference herein).
†10.27	— Amendment Two to Commercial Supply Agreement, dated April 27, 2018, with Catalent CTS, LLC (filed as Exhibit 10.24 to the Company's Annual Report on Form 10-K for the period ended December 31, 2018 and incorporated by reference herein).
10.28	— Term Loan and Security Agreement, dated August 30, 2018, between Lex-Gen Woodlands, L.P. and Revere Credit Opportunities Fund III, LP (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated August 30, 2018 and incorporated by reference herein).
†10.29	— Loan Agreement, dated December 4, 2017, with BioPharma Credit PLC and BioPharma Credit Investments IV Sub LP (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated December 4, 2017 and incorporated by reference herein).
10.30	— Real Estate Purchase and Sale Agreement, dated January 20, 2020, between Lex-Gen Woodlands, L.P. and FFC Equity Holdings, L.P. (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated January 10, 2020 and incorporated by reference herein).
21.1	— Subsidiaries (filed as Exhibit 21.1 to the Company's Annual Report on Form 10-K for the period ended December 31, 2010 and incorporated by reference herein).
*23.1	— Consent of Independent Registered Public Accounting Firm.
*24.1	— Power of Attorney (contained in signature page).
*31.1	— Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
*31.2	— Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
*32.1	— Certification of Principal Executive and Principal Financial Officers Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
*101.INS	— XBRL Instance Document.
*101.SCH	— XBRL Taxonomy Extension Schema Document.
*101.CAL	— XBRL Taxonomy Extension Calculation Linkbase Document.
*101.DEF	— XBRL Taxonomy Extension Definition Linkbase Document.
*101.LAB	— XBRL Taxonomy Extension Label Linkbase Document.
*101.PRE	— XBRL Taxonomy Extension Presentation Linkbase Document.

* Filed herewith.

† Confidential treatment has been requested for a portion of this exhibit. The confidential portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission.

§ Portions of the exhibit have been omitted.

Item 16. *Form 10-K Summary*

Not applicable.

Signatures

Pursuant to the requirements of Section 13 or 15(d) 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.

Date: March 12, 2020

Lexicon Pharmaceuticals, Inc.
By: /s/ LONNEL COATS
Lonnell Coats
President and Chief Executive Officer

Date: March 12, 2020

By: /s/ JEFFREY L. WADE
Jeffrey L. Wade
Executive Vice President, Corporate and Administrative Affairs and Chief Financial Officer

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Lonnell Coats and Jeffrey L. Wade, or either of them, each with the power of substitution, his or her attorney-in-fact, to sign any amendments to this Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, here ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
<u>/s/ LONNEL COATS</u> Lonnell Coats	President, Chief Executive Officer and Director (Principal Executive Officer)	March 12, 2020
<u>/s/ JEFFREY L. WADE</u> Jeffrey L. Wade	Executive Vice President, Corporate and Administrative Affairs and Chief Financial Officer (Principal Financial Officer)	March 12, 2020
<u>/s/ JAMES F. TESSMER</u> James F. Tessmer	Vice President, Finance and Accounting (Principal Accounting Officer)	March 12, 2020
<u>/s/ RAYMOND DEBBANE</u> Raymond Debbane	Chairman of the Board of Directors	March 12, 2020
<u>/s/ PHILIPPE J. AMOUYAL</u> Philippe J. Amouyal	Director	March 12, 2020
<u>/s/ SAMUEL L. BARKER</u> Samuel L. Barker, Ph.D.	Director	March 12, 2020
<u>/s/ ROBERT J. LEFKOWITZ</u> Robert J. Lefkowitz, M.D.	Director	March 12, 2020
<u>/s/ ALAN S. NIES</u> Alan S. Nies, M.D.	Director	March 12, 2020
<u>/s/ FRANK P. PALANTONI</u> Frank P. Palantoni	Director	March 12, 2020
<u>/s/ CHRISTOPHER J. SOBECKI</u> Christopher J. Sobecki	Director	March 12, 2020
<u>/s/ JUDITH L. SWAIN</u> Judith L. Swain, M.D.	Director	March 12, 2020

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Lexicon Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Lexicon Pharmaceuticals, Inc. (the “Company”) as of December 31, 2019 and 2018, the related consolidated statements of comprehensive income (loss), stockholders’ equity (deficit), and cash flows for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with US generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company’s internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) and our report dated March 12, 2020 expressed an unqualified opinion thereon.

Adoption of ASU No. 2014-09

As discussed in Note 2 to the consolidated financial statements, the Company changed its method for accounting for revenues in 2018 due to the adoption of ASU No. 2014-09, *Revenue from Contracts with Customers*.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the US federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2002.

Houston, Texas
March 12, 2020

Lexicon Pharmaceuticals, Inc.
Consolidated Balance Sheets
(In thousands, except par value)

	As of December 31,	
	2019	2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 36,112	\$ 80,386
Short-term investments	235,547	79,666
Accounts receivable, net of allowances of \$4	56,532	5,924
Inventory	4,243	4,680
Prepaid expenses and other current assets	5,320	2,668
Total current assets	337,754	173,324
Property and equipment, net of accumulated depreciation and amortization of \$61,741 and \$60,006, respectively	14,047	15,865
Goodwill	44,543	44,543
Intangible assets	19,716	50,119
Other assets	1,655	285
Total assets	\$ 417,715	\$ 284,136
Liabilities and Equity		
Current liabilities:		
Accounts payable	\$ 12,178	\$ 12,052
Accrued liabilities	42,151	21,245
Current portion of deferred revenue	—	2,339
Current portion of long-term debt, net of deferred financing costs	11,012	1,115
Total current liabilities	65,341	36,751
Deferred revenue, net of current portion	—	23,651
Long-term debt, net of deferred financing costs	234,171	243,887
Deferred tax liabilities	—	6,014
Other long-term liabilities	1,102	238
Total liabilities	300,614	310,541
Commitments and contingencies		
Stockholders' Equity (Deficit):		
Preferred stock, \$.01 par value; 5,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$.001 par value; 225,000 shares authorized; 106,679 and 106,162 shares issued, respectively	106	106
Additional paid-in capital	1,462,172	1,447,954
Accumulated deficit	(1,341,444)	(1,471,577)
Accumulated other comprehensive gain (loss)	84	(12)
Treasury stock, at cost, 407 and 236 shares, respectively	(3,817)	(2,876)
Total stockholders' equity (deficit)	117,101	(26,405)
Total liabilities and equity (deficit)	\$ 417,715	\$ 284,136

The accompanying notes are an integral part of these consolidated financial statements.

Lexicon Pharmaceuticals, Inc.

Consolidated Statements of Comprehensive Income (Loss)
(In thousands, except per share amounts)

	Year Ended December 31,		
	2019	2018	2017
Revenues:			
Net product revenue	\$ 32,331	\$ 26,583	\$ 15,890
Collaborative agreements	289,231	36,271	75,621
Royalties and other revenue	511	355	178
Total revenues	<u>322,073</u>	<u>63,209</u>	<u>91,689</u>
Operating expenses:			
Cost of sales (including finite-lived intangible asset amortization)	3,231	2,491	1,899
Research and development, including stock-based compensation of \$7,096, \$6,010 and \$4,905, respectively	91,924	100,243	152,223
Increase in fair value of Symphony Icon, Inc. purchase liability	—	—	2,101
Selling, general and administrative, including stock-based compensation of \$7,122, \$5,686 and \$4,567, respectively	56,835	63,754	66,090
Impairment loss on intangible asset	28,638	—	—
Total operating expenses	<u>180,628</u>	<u>166,488</u>	<u>222,313</u>
Income (loss) from operations	141,445	(103,279)	(130,624)
Interest expense	(20,676)	(20,777)	(6,984)
Interest and other income, net	3,350	3,508	1,954
Net income (loss) before taxes	124,119	(120,548)	(135,654)
Income tax benefit	6,014	—	12,661
Net income (loss)	<u>\$ 130,133</u>	<u>\$ (120,548)</u>	<u>\$ (122,993)</u>
Net income (loss) per common share, basic	<u>\$ 1.23</u>	<u>\$ (1.14)</u>	<u>\$ (1.17)</u>
Net income (loss) per common share, diluted	<u>\$ 1.16</u>	<u>\$ (1.14)</u>	<u>\$ (1.17)</u>
Shares used in computing net income (loss) per common share, basic	106,218	105,830	105,237
Shares used in computing net income (loss) per common share, diluted	116,747	105,830	105,237
Other comprehensive income (loss):			
Unrealized gain (loss) on investments	96	210	(27)
Comprehensive income (loss)	<u>\$ 130,229</u>	<u>\$ (120,338)</u>	<u>\$ (123,020)</u>

The accompanying notes are an integral part of these consolidated financial statements.

Lexicon Pharmaceuticals, Inc.

Consolidated Statements of Stockholders' Equity (Deficit)
(In thousands)

	<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Accumulated Deficit</u>	<u>Accumulated Other Comprehensive Gain (Loss)</u>	<u>Treasury Stock</u>	<u>Total</u>
	<u>Shares</u>	<u>Par Value</u>					
Balance at December 31, 2016	104,582	\$ 105	\$ 1,411,222	\$ (1,240,257)	\$ (195)	\$ (3,368)	\$ 167,507
Cumulative effect of change in accounting principle	—	—	1,991	(1,991)	—	—	—
Stock-based compensation	—	—	9,472	—	—	—	9,472
Issuance of common stock to designees of Symphony Icon Holdings LLC	660	—	10,499	—	—	—	10,499
Issuance of common stock under Equity Incentive Plans	469	1	5,485	—	—	—	5,486
Issuance of treasury stock	—	—	(3,143)	—	—	3,143	—
Repurchase of common stock	—	—	—	—	—	(1,679)	(1,679)
Net loss	—	—	—	(122,993)	—	—	(122,993)
Unrealized loss on investments	—	—	—	—	(27)	—	(27)
Balance at December 31, 2017	105,711	106	1,435,526	(1,365,241)	(222)	(1,904)	68,265
Cumulative effect of change in accounting principle	—	—	—	14,212	—	—	14,212
Stock-based compensation	—	—	11,696	—	—	—	11,696
Issuance of common stock under Equity Incentive Plans	451	—	732	—	—	—	732
Repurchase of common stock	—	—	—	—	—	(972)	(972)
Net loss	—	—	—	(120,548)	—	—	(120,548)
Unrealized gain on investments	—	—	—	—	210	—	210
Balance at December 31, 2018	106,162	106	1,447,954	(1,471,577)	(12)	(2,876)	(26,405)
Stock-based compensation	—	—	14,218	—	—	—	14,218
Issuance of common stock under Equity Incentive Plans	517	—	—	—	—	—	—
Repurchase of common stock	—	—	—	—	—	(941)	(941)
Net income	—	—	—	130,133	—	—	130,133
Unrealized gain on investments	—	—	—	—	96	—	96
Balance at December 31, 2019	<u>106,679</u>	<u>\$ 106</u>	<u>\$ 1,462,172</u>	<u>\$ (1,341,444)</u>	<u>\$ 84</u>	<u>\$ (3,817)</u>	<u>\$ 117,101</u>

The accompanying notes are an integral part of these consolidated financial statements.

Lexicon Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2019	2018	2017
Cash flows from operating activities:			
Net income (loss)	\$ 130,133	\$ (120,548)	\$ (122,993)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization	3,654	3,683	3,399
Impairment loss on intangible asset	28,638	—	—
Increase in fair value of Symphony Icon, Inc. purchase liability	—	—	2,101
Stock-based compensation	14,218	11,696	9,472
Loss on disposal of property and equipment	—	—	3
Amortization of debt issuance costs	1,465	1,336	599
Deferred tax benefit	(6,014)	—	(12,661)
Changes in operating assets and liabilities:			
(Increase) decrease in accounts receivable	(50,608)	(1,099)	166
(Increase) decrease in inventory	437	(2,732)	(1,948)
(Increase) decrease in prepaid expenses and other current assets	(2,652)	1,766	(557)
Decrease in other assets	429	144	33
Increase (decrease) in accounts payable and other liabilities	20,097	(19,913)	(11,875)
Decrease in deferred revenue	(25,990)	(22,940)	(51,133)
Net cash provided by (used in) operating activities	113,807	(148,607)	(185,394)
Cash flows from investing activities:			
Purchases of property and equipment	(70)	(95)	(228)
Purchases of investments	(322,385)	(119,987)	(267,873)
Maturities of investments	166,600	289,658	318,623
Net cash (used in) provided by investing activities	(155,855)	169,576	50,522
Cash flows from financing activities:			
Proceeds from issuance of common stock, net of fees	—	732	7,987
Repurchase of common stock	(941)	(972)	(1,679)
Proceeds from debt borrowings, net of fees	—	12,529	145,905
Repayment of debt borrowings	(1,285)	(14,533)	(2,280)
Net cash (used in) provided by financing activities	(2,226)	(2,244)	149,933
Net (decrease) increase in cash and cash equivalents	(44,274)	18,725	15,061
Cash and cash equivalents at beginning of year	80,386	61,661	46,600
Cash and cash equivalents at end of year	<u>\$ 36,112</u>	<u>\$ 80,386</u>	<u>\$ 61,661</u>
Supplemental disclosure of cash flow information:			
Cash paid for interest	\$ 19,211	\$ 16,465	\$ 5,870
Supplemental disclosure of noncash investing and financing activities:			
Common stock issued in satisfaction of Symphony Icon payment obligation	\$ —	\$ —	\$ 10,499

The accompanying notes are an integral part of these consolidated financial statements.

Lexicon Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements

December 31, 2019

1. Organization and Operations

Lexicon Pharmaceuticals, Inc. (“Lexicon” or the “Company”) is a Delaware corporation incorporated on July 7, 1995. Lexicon was organized to discover the functions and pharmaceutical utility of genes and use those gene function discoveries in the discovery and development of pharmaceutical products for the treatment of human disease.

Lexicon has financed its operations from inception primarily through sales of common and preferred stock, contract and milestone payments to it under strategic collaborations and other research and development collaborations, target validation, database subscription and technology license agreements, product sales, government grants and contracts and financing under debt and lease arrangements. The Company’s future success is dependent upon many factors, including, but not limited to, its ability to successfully commercialize XERMELO in the United States and the amount of revenues generated from such commercialization efforts; Ipsen Pharma SAS’s (“Ipsen”) ability to successfully commercialize XERMELO outside of the United States and Japan and Lexicon’s receipt of any milestone payments and royalties; the success of its ongoing nonclinical and clinical development efforts and ability to obtain necessary regulatory approvals of the drug candidates which are the subject of such efforts; its success in establishing new collaborations and licenses, including for the development and commercialization of sotagliflozin; general and industry-specific economic conditions which may affect research and development expenditures; and its ability to obtain and enforce patents and other proprietary rights in its discoveries, comply with federal and state regulations, and maintain sufficient capital to fund its activities. As a result of the aforementioned factors and the related uncertainties, there can be no assurance of the Company’s future success.

2. Summary of Significant Accounting Policies

Basis of Presentation: The accompanying consolidated financial statements include the accounts of Lexicon and its wholly-owned subsidiaries. Intercompany transactions and balances are eliminated in consolidation. In 2018, accounts payable included \$5.7 million related to its accrual for clinical studies. The Company has reclassified this amount to accrued liabilities in the consolidated balance sheet for comparable presentation of accounts payable and accrued liabilities.

Use of Estimates: The preparation of financial statements in conformity with U. S. generally accepted accounting principles (“GAAP”) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates.

Cash, Cash Equivalents and Short-Term Investments: Lexicon considers all highly-liquid investments with original maturities of three months or less to be cash equivalents. As of December 31, 2019 and December 31, 2018, short-term investments consist of U.S. treasury bills and corporate debt securities. The Company’s short-term investments are classified as available-for-sale securities and are carried at fair value, based on quoted market prices of the securities. The Company views its available-for-sale securities as available for use in current operations regardless of the stated maturity date of the security. Unrealized gains and losses on such securities are reported as a separate component of stockholders’ equity. Net realized gains and losses, interest and dividends are included in interest income. The cost of securities sold is based on the specific identification method.

Accounts Receivable: Lexicon records trade accounts receivable in the normal course of business related to the sale of products or services. The allowance for doubtful accounts takes into consideration such factors as historical write-offs, the economic climate and other factors that could affect collectibility. Write-offs are evaluated on a case by case basis.

Inventory: Inventories are determined at the lower of cost or market value with cost determined under the specific identification method and may consist of raw materials, work in process and finished goods. Inventory consisted of the following as of December 31, 2019 and 2018 (in thousands):

	As of December 31,	
	2019	2018
Raw materials	\$ 3,182	\$ 3,564
Work-in-process	153	232
Finished goods	908	884
Total inventory	<u>\$ 4,243</u>	<u>\$ 4,680</u>

Concentration of Credit Risk: Lexicon’s cash equivalents, investments and accounts receivable represent potential concentrations of credit risk. The Company attempts to minimize potential concentrations of risk in cash equivalents and investments by placing investments in high-quality financial instruments. The Company’s accounts receivable are unsecured and are concentrated in pharmaceutical and biotechnology companies located in Europe and the United States. The Company has not experienced any significant credit losses to date. In 2019, customers in Germany and the United States represented 89% and 10% of revenue, respectively. In 2018, customers in Germany and the United States represented 53% and 40%, respectively. In 2017, customers in Germany, France and the United States represented 65%, 18% and 17% of revenue, respectively. At December 31, 2019, management believes that the Company has no significant concentrations of credit risk.

Segment Information and Significant Customers: Lexicon operates in one business segment, which primarily focuses on the discovery, development and commercialization of pharmaceutical products for the treatment of human disease. Substantially all of the Company’s revenues have been derived from drug discovery alliances, target validation collaborations for the development and, in some cases, analysis of the physiological effects of genes altered in knockout mice, technology licenses, subscriptions to its databases, product sales, government grants and contracts and compound library sales. In 2019, Sanofi-Aventis Deutschland GmbH (“Sanofi”) represented 89% of revenues and no other individual customer represented more than 10% of revenues. In 2018, Sanofi represented 53% of revenues and two independent specialty pharmacies, Biologics, Inc. and Diplomate Pharmacy, represented 25% and 14% of revenues, respectively. In 2017, Sanofi and Ipsen represented 65% and 18% of revenues, respectively.

Intangible Assets: Intangible assets, net consist of in-process research and development acquired in business combinations, which are reported at fair value, less accumulated amortization. Intangible assets with finite lives are amortized using the straight-line method over their estimated useful lives. During 2017, intangible assets relating to XERMELO of \$24.7 million were reclassified from indefinite-lived to finite-lived assets following the approval of XERMELO by the FDA. The Company has recorded \$1.8 million in amortization expense related to this asset in each of the years ended December 31, 2019 and 2018, respectively, and \$1.5 million for the year ended December 31, 2017. Amortization expense is recorded as cost of sales in the accompanying consolidated statements of comprehensive income (loss).

Estimated future amortization expense for intangible assets as of December 31, 2019 is as follows:

	For the Year Ending December 31
	(in thousands)
2020	\$ 1,766
2021	1,766
2022	1,766
2023	1,766
2024	1,766
Thereafter	10,886
	<u>\$ 19,716</u>

Property and Equipment: Property and equipment that is held and used is carried at cost and depreciated using the straight-line method over the estimated useful life of the assets which ranges from three to 40 years. Maintenance, repairs and minor replacements are charged to expense as incurred. Leasehold improvements are amortized over the shorter of the estimated useful life or the remaining lease term. Significant renewals and betterments are capitalized.

Impairment of Long-Lived Assets: Long-lived assets, right-of-use assets for leases and finite-lived intangible assets are reviewed for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of assets to be held and used is measured by comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount that the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. There were no impairments of long-lived assets, including finite-lived intangible assets, in 2019, 2018 or 2017.

Indefinite-lived intangible assets are also tested annually for impairment and whenever indicators of impairment are present. When performing the impairment assessment, the Company first assesses qualitative factors to determine whether it is necessary to recalculate the fair value of its intangible assets. If management believes, as a result of the qualitative assessment, that it is more likely than not that the fair value of the intangible assets is less than its carrying amount, the Company calculates the asset's fair value. If the carrying value of the asset exceeds its fair value, then the intangible asset is written down to its fair value. Lexicon determined that a triggering event occurred upon execution of the Termination Agreement with Sanofi (as defined in Note 13) and Lexicon's resulting decision to substantially reallocate resources from the development of certain programs, including LX1031 and LX1033 for irritable bowel syndrome, to the development of sotagliflozin. In connection with such triggering event, Lexicon determined that its LX1031 and LX1033 programs for irritable bowel syndrome, collectively an intangible asset, were considered to be impaired and recorded an impairment charge of \$28.6 million to IPR&D for the year ended December 31, 2019. The impairment reduced the remaining book value to zero. There were no impairments of indefinite-lived intangible assets in 2018 or 2017.

Goodwill Impairment: Goodwill is not amortized, but is tested at least annually for impairment at the reporting unit level. The Company has determined that the reporting unit is the single operating segment disclosed in its current financial statements. Impairment is the condition that exists when the carrying amount of goodwill exceeds its implied fair value. The first step in the impairment process is to determine the fair value of the reporting unit and then compare it to the carrying value, including goodwill. If the fair value exceeds the carrying value, no further action is required and no impairment loss is recognized. Additional impairment assessments may be performed on an interim basis if the Company encounters events or changes in circumstances that would indicate that, more likely than not, the carrying value of goodwill has been impaired. There was no impairment of goodwill in 2019, 2018 or 2017.

Revenue Recognition:

Product Revenues

Product revenues consist of commercial sales of XERMELO in the United States and sales of bulk tablets of XERMELO to Ipsen. Product revenues are recognized when the customer obtains control of the Company's product, which occurs upon delivery to the customer. The Company recognizes product revenue net of applicable reserves for variable consideration, including allowances for customer credits, estimated rebates, chargebacks, discounts, returns, distribution service fees, and government rebates, such as Medicare Part D coverage gap reimbursements in the United States, as discussed below. These estimates are based on the most likely amount method for relevant factors such as current contractual and statutory requirements, industry data and forecasted customer buying and payment patterns. Product shipping and handling costs are considered a fulfillment activity when control transfers to the Company's customers and such costs are included in cost of sales.

Customer Credits: The Company's customers are offered various forms of consideration, including allowances, service fees and prompt payment discounts. The Company expects that its customers will earn prompt payment discounts. As a result, the Company deducts the full amount of those discounts from total product sales when revenues are recognized. Service fees are also deducted from product sales as they are earned.

Rebates: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program. Rebate amounts are based upon contractual agreements or legal requirements with public sector (e.g., Medicaid) benefit providers. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or legal requirements with public sector benefit providers. The allowance for rebates is based on statutory discount rates and expected utilization. The Company's estimates for expected utilization of rebates are based on third party market research data and data received from the specialty pharmacies. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known unpaid rebates from the prior quarter. If actual future rebates vary from estimates, the Company may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Chargebacks: Chargebacks are discounts that occur when contracted customers purchase directly from a specialty pharmacy or distributor, who acts as a retailer. Contracted customers, which currently consist primarily of Public Health Service Institutions, non-profit clinics, and federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The specialty pharmacy or distributor, in turn, charges back to Lexicon the difference between the price paid by the specialty pharmacy or distributor and the discounted price paid to the specialty pharmacy or distributor by the customer. The allowance for chargeback is based on known sales to contracted customers.

Medicare Part D Coverage Gap: The Medicare Part D prescription drug benefit mandates manufacturers to fund a portion of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. The Company's estimates for the expected Medicare Part D coverage gap are based on data received from the specialty pharmacies and projections based on historical data. Funding of the coverage gap is generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters. If actual future funding varies from estimates, the Company may need to adjust prior period accruals, which would affect revenues in the period of adjustment.

Co-payment assistance: Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. The Company accrues a liability for co-payment assistance based on actual program participation and estimates of program redemption using data provided by third-party administrators.

Collaborative Agreements

The Company adopted ASU NO. 2014-09, "Revenue from Contracts with Customers", on January 1, 2018, using the modified retrospective method. In its adoption, the Company recorded a \$14.2 million cumulative-effect adjustment to its accumulated deficit related to a contract with the Texas Institute for Genomic Medicine. Subsequent to adoption, the Company was notified that all performance obligations related to the contract have been fulfilled.

Revenues under collaborative agreements include both license revenue and contract research revenue. The Company performs the following five steps in determining the amount of revenue to recognize as it fulfills its performance obligations under each of its agreements: (i) identify the contract(s) with a customer; (ii) identify the performance obligation in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation in the contract, and (v) recognize revenue when (or as) the Company satisfies the performance obligation. The Company applies this five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. The Company develops assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract.

At contract inception, the Company evaluates whether development milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal will not occur, the associated development milestone value is included in the transaction price. Development milestones that are not within the control of the Company or the licensee, including those requiring regulatory approval, are not considered probable of being achieved until those approvals are received. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue when (or as) the performance obligation is satisfied. At the end of each reporting period, the Company re-evaluates the probability of achievement of the development milestones and any related constraint, and if necessary, adjusts its estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues in the period of adjustment.

In agreements in which a license to the Company's intellectual property is determined distinct from other performance obligations identified in the agreement, the Company recognizes revenue when the license is transferred to the licensee and the licensee is able to use and benefit from the license.

For agreements that include sales-based royalties, including milestones based on a level of sales, the license is deemed to be the predominant item to which the royalties relate and the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

The Company may receive payments from its licensees based on billing schedules established in each contract. Upfront payments and fees are recorded as deferred revenue upon receipt or when due, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these agreements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional.

Cost of Sales: Cost of sales consists of third-party manufacturing costs, freight and indirect overhead costs associated with sales of XERMELO. The Company began capitalizing inventory during 2017 once the FDA approved XERMELO as the related costs were expected to be recoverable through the commercialization of the product. Costs incurred prior to approval of XERMELO have been recorded as research and development expense in the consolidated statements of comprehensive income (loss). As a result, cost of sales for approximately the next twelve months will reflect a lower average per unit cost of materials. Product shipping and handling costs are included in cost of sales. Cost of sales also includes the amortization of the intangible asset for XERMELO using the straight-line method over the estimated useful life of 14 years.

Research and Development Expenses: Research and development expenses consist of costs incurred for company-sponsored as well as collaborative research and development activities. These costs include direct and research-related overhead expenses and are expensed as incurred. Technology license fees for technologies that are utilized in research and development and have no alternative future use are expensed when incurred. Substantial portions of the Company's preclinical and clinical trials are performed by third-party laboratories, medical centers, contract research organizations and other vendors. For preclinical studies, the Company accrues expenses based upon estimated percentage of work completed and the contract milestones remaining. For clinical studies, expenses are accrued based upon the number of patients enrolled and the duration of the study. The Company's estimates of the clinical study costs and costs to transition activities from Sanofi for development of sotagliflozin for type 2 diabetes, heart failure and chronic kidney disease was based on estimates of the services to be received and efforts to be expended pursuant to contracts with multiple vendors and the CRO that will conduct and manage the clinical studies on its behalf. The Company monitors patient enrollment, the progress of clinical studies and related activities to the extent possible through internal reviews of data reported to the Company by the vendors and clinical site visits. The Company's estimates depend on the timeliness and accuracy of the data provided by the vendors regarding the status of each program and total program spending. The Company periodically evaluates the estimates to determine if adjustments are necessary or appropriate based on information it receives.

Stock-Based Compensation: The Company recognizes compensation expense in its statements of comprehensive income (loss) for share-based payments, including stock options and restricted stock units issued to employees, based on their fair values on the date of the grant, with the compensation expense recognized over the period in which an employee is required to provide service in exchange for the stock award. Stock-based compensation expense for awards without performance conditions is recognized on a straight-line basis. Stock-based compensation expense for awards with performance conditions is recognized over the period from the date the performance condition is determined to be probable of occurring through the time the applicable condition is met. As of December 31, 2019, stock-based compensation cost for all outstanding unvested options and restricted stock units was \$24.0 million, which is expected to be recognized over a weighted-average period of 1.1 years.

The fair value of stock options is estimated at the date of grant using the Black-Scholes method. The Black-Scholes option-pricing model requires the input of subjective assumptions. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options. For purposes of determining the fair value of stock options, the Company segregates its options into two homogeneous groups, based on exercise and post-vesting employment termination behaviors, resulting in different assumptions used for expected option lives. Historical data is used to estimate the expected option life for each group. Expected volatility is based on the historical volatility in the Company's stock price. The following weighted-average assumptions were used for options granted in the years ended December 31, 2019, 2018 and 2017, respectively:

	Expected Volatility	Risk-free Interest Rate	Expected Term	Dividend Rate
December 31, 2019:				
Employees	88%	2.2%	4	0 %
Officers and non-employee directors	77%	2.6%	8	0 %
December 31, 2018:				
Employees	58%	2.6%	4	0 %
Officers and non-employee directors	63%	2.8%	8	0 %
December 31, 2017:				
Employees	61%	1.7%	4	0 %
Officers and non-employee directors	70%	2.2%	8	0 %

Income Taxes: The Company recognizes deferred tax liabilities and assets for the expected future tax consequences of events that have been recognized differently in the financial statements and tax returns. The Company uses the liability method in accounting for income taxes. Under this method, deferred tax liabilities and assets are determined based on the difference between the financial statement carrying amounts and tax bases of liabilities and assets using enacted tax rates and laws in effect in the years in which the differences are expected to reverse. Deferred tax assets are evaluated for realization based on a more-likely-than-not criteria in determining if a valuation allowance should be provided.

The Company maintains a valuation allowance on net operating losses and other deferred tax assets. Accordingly, the Company has not reported any tax benefit relating to the remaining net operating loss carryforwards and income tax credit carryforwards that are available for utilization in future periods. On a periodic basis, the valuation allowance is reassessed on deferred income tax assets, weighing positive and negative evidence to assess the recoverability of the deferred tax assets. In 2019, the Company reassessed the valuation allowance and considered negative evidence, including the cumulative losses over the three years ended December 31, 2019, and positive evidence, including the income during the year ended December 31, 2019 and projections of future income. After assessing both the negative evidence and the positive evidence, the Company concluded that it should continue to maintain the valuation allowance on net operating losses and other deferred tax assets as of December 31, 2019 given the significance of the weight of the negative evidence. Based on recent financial performance and future projections, the Company could record a reversal of all, or a portion of the valuation allowance associated with U.S. deferred tax assets in future periods. However, any such change is subject to actual performance and other considerations that may present positive or negative evidence at the time of the assessment. The total deferred tax asset balance subject to the valuation allowance was approximately \$333.6 million at December 31, 2019.

Significant judgment is required in making these assessments to maintain or reverse valuation allowances and, to the extent future expectations change the Company would have to assess the recoverability of these deferred tax assets at that time. The Tax Cuts and Jobs Act (the "2017 Tax Act") was enacted on December 22, 2017. The 2017 Tax Act significantly changes U.S. corporate income tax laws, including a reduction of the U.S. corporate income tax rate from 35 percent to 21 percent, reduction of certain tax credits, limitations on, or deductibility of interest expense and executive compensation, and limitations on the use of net operating loss carryforwards.

Net Income (Loss) per Common Share: Net income (loss) per common share is computed using the weighted average number of shares of common stock outstanding. Shares associated with convertible debt, stock options and restricted stock units that could potentially dilute earnings per share in the future are not included in the computation of diluted earnings per share because they are antidilutive.

3. Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, "Leases." ASU 2016-02 requires companies that lease assets to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in its balance sheet. The pronouncement also requires additional disclosures about the amount, timing and uncertainty of cash flows arising from leases. This pronouncement was effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. This ASU was required to be adopted using a modified retrospective approach. Management adopted ASU 2016-02 on the effective date of January 1, 2019 and elected the practical expedient that allows entities to not apply the new guidance in the comparative periods they present in their financial statements in the year of adoption. Consequently, prior year financial information has not been updated and the disclosures required under the new standard have not been provided for periods prior to January 1, 2019. Upon adoption, the Company recognized \$2.1 million for right-of-use assets and corresponding liabilities on the consolidated balance sheet,

primarily related to leases of office space. The adoption of this ASU on January 1, 2019 did not have a material impact on Lexicon's consolidated financial statements.

Pronouncements Not Yet Adopted. In November 2018, the FASB issued ASU No. 2018-18, "Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606". This targeted amendment to Topic 808 clarifies that certain transactions resulting from a collaborative agreement should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer for a good or service that is a distinct unit-of-account. This amendment is effective for fiscal years, and interim periods within years presented, beginning after December 15, 2019, and should be applied retrospectively to the date of initial application of Topic 606. The Company has applied the provisions of Topic 606 to account for its transactions for collaboration arrangements, including recognition, measurement, presentation and disclosure requirements, and does not expect adoption of this ASU to have a material impact on its consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04, "Intangibles-Goodwill and Other," which is intended to simplify the subsequent measurement of goodwill. The pronouncement allows an entity, during its annual or interim goodwill impairment evaluation, to compare the fair value of a reporting unit with its carrying amount. An impairment charge is immediately recognized by which the carrying amount exceeds the fair value. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2019. The Company does not expect adoption of this ASU to have a material impact on its consolidated financial statements.

4. Cash and Cash Equivalents and Investments

The fair value of cash and cash equivalents and investments held at December 31, 2019 and 2018 are as follows:

	As of December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
Cash and cash equivalents	\$ 36,112	\$ —	\$ —	\$ 36,112
Securities maturing within one year:				
U.S. treasury securities	235,463	94	(10)	235,547
Total short-term investments	\$ 235,463	\$ 94	\$ (10)	\$ 235,547
Total cash and cash equivalents and investments	\$ 271,575	\$ 94	\$ (10)	\$ 271,659

	As of December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
Cash and cash equivalents	\$ 80,386	\$ —	\$ —	\$ 80,386
Securities maturing within one year:				
U.S. treasury securities	73,983	—	(9)	73,974
Corporate debt securities	5,695	—	(3)	5,692
Total short-term investments	\$ 79,678	\$ —	\$ (12)	\$ 79,666
Total cash and cash equivalents and investments	\$ 160,064	\$ —	\$ (12)	\$ 160,052

There were no realized gains or losses for the years ended December 31, 2019 and 2018.

5. Fair Value Measurements

The Company uses various inputs in determining the fair value of its investments and measures these assets on a recurring basis. Assets and liabilities recorded at fair value in the consolidated balance sheets are categorized by the level of objectivity associated with the inputs used to measure their fair value. The following levels are directly related to the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities:

- Level 1 – quoted prices in active markets for identical assets, which include U.S. treasury securities
- Level 2 – other significant observable inputs (including quoted prices for similar investments, market corroborated inputs, etc.), which include corporate debt securities
- Level 3 – significant unobservable inputs

The inputs or methodology used for valuing securities are not necessarily an indication of the credit risk associated with investing in those securities. The following tables provide the fair value measurements of applicable Company assets and liabilities that are measured at fair value on a recurring basis according to the fair value levels defined above as of December 31, 2019 and 2018.

Assets and Liabilities at Fair Value				
As of December 31, 2019				
	Level 1	Level 2	Level 3	Total
(in thousands)				
Assets				
Cash and cash equivalents	\$ 36,112	\$ —	\$ —	\$ 36,112
Short-term investments	235,547	—	—	235,547
Total cash and cash equivalents and investments	<u>\$ 271,659</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 271,659</u>

Assets and Liabilities at Fair Value				
As of December 31, 2018				
	Level 1	Level 2	Level 3	Total
(in thousands)				
Assets				
Cash and cash equivalents	\$ 80,386	\$ —	\$ —	\$ 80,386
Short-term investments	73,974	5,692	—	79,666
Total cash and cash equivalents and investments	<u>\$ 154,360</u>	<u>\$ 5,692</u>	<u>\$ —</u>	<u>\$ 160,052</u>

The Company did not have any Level 3 assets or liabilities at December 31, 2019 or 2018. Transfers between levels are recognized at the actual date of circumstance that caused the transfer. There were no transfers between Level 1 and Level 2 during the periods presented.

The Company also has assets that under certain conditions are subject to measurement at fair value on a non-recurring basis. These assets include goodwill associated with the acquisitions of Coelacanth Corporation in 2001 and Symphony Icon in 2010 and intangible assets associated with the acquisition of Symphony Icon in 2010. For these assets, measurement at fair value in periods subsequent to their initial recognition is applicable if one or more is determined to be impaired.

Refer to Note 9, Debt Obligations, for fair value measurements of debt obligations.

6. Property and Equipment

Property and equipment at December 31, 2019 and 2018 are as follows:

	Estimated Useful Lives In Years	As of December 31,	
		2019	2018
		(in thousands)	
Computers and software	3-5	\$ 4,587	\$ 4,557
Furniture and fixtures	5-7	5,629	5,644
Laboratory equipment	3-7	3,279	3,378
Leasehold improvements	3-7	417	416
Buildings	15-40	59,212	59,212
Land	—	2,664	2,664
Total property and equipment		75,788	75,871
Less: Accumulated depreciation and amortization		(61,741)	(60,006)
Net property and equipment		\$ 14,047	\$ 15,865

7. Income Taxes

Lexicon recognizes deferred tax liabilities and assets for the expected future tax consequences of events that have been recognized differently in the financial statements and tax returns. Under this method, deferred tax liabilities and assets are determined based on the difference between the financial statement carrying amounts and tax bases of liabilities and assets using enacted tax rates and laws in effect in the years in which the differences are expected to reverse. Deferred tax assets are evaluated for realization based on a more-likely-than-not criteria in determining if a valuation allowance should be provided.

The components of Lexicon's deferred tax assets (liabilities) at December 31, 2019 and 2018 are as follows:

	As of December 31,	
	2019	2018
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	\$ 193,270	\$ 206,789
Research and development tax credits	46,306	47,087
Orphan drug credits	24,524	24,524
Capitalized research and development	58,596	71,047
Stock-based compensation	5,340	4,641
Deferred revenue	—	5,458
Interest	—	3,625
Other	5,533	6,044
Total deferred tax assets	333,569	369,215
Deferred tax liabilities:		
Deferred tax liability related to acquisition of Symphony Icon	(4,140)	(10,525)
Other	(3)	(2)
Total deferred tax liabilities	(4,143)	(10,527)
Less: valuation allowance	(329,426)	(364,702)
Net deferred tax liabilities	\$ —	\$ (6,014)

Deferred tax assets associated with net operating losses (NOLs), deferred revenue and interest decreased in 2019 due to the Termination Agreement (as defined in Note 13) with Sanofi. Refer to Note 13, Collaboration and License Agreements, for additional information. The \$4.1 million deferred tax liability relates to the tax impact of future amortization or possible impairments associated with intangible assets acquired with Symphony Icon, which are not deductible for tax purposes.

A reconciliation of the statutory tax rate to the effective tax rate for the years ended December 31, 2019, 2018 and 2017 consists of the following:

	Year Ended December 31,		
	2019	2018	2017
	(in thousands)		
Expected income tax expense (benefit) at 21%, 21% and 35%, respectively	\$ 26,065	\$ (25,315)	\$ (47,479)
State income taxes, net of federal benefit	445	(809)	(2,324)
Equity compensation	1,688	1,059	1,447
Research and development credit	—	(978)	(1,993)
Orphan drug credit	—	—	(189)
Deferred true-up	—	—	(5,316)
Tax rate change	—	—	169,464
Symphony Icon fair value adjustment	—	—	735
Change in valuation allowance	(35,276)	25,928	(126,634)
Other ⁽¹⁾	1,064	115	(372)
Income tax benefit	<u>\$ (6,014)</u>	<u>\$ —</u>	<u>\$ (12,661)</u>

⁽¹⁾ Other is primarily comprised of expiring Research and Development credits for the year ended December 31, 2019.

At December 31, 2019, Lexicon had both federal and state NOL carryforwards of approximately \$879.7 million and \$83.0 million, respectively. In 2019, federal NOLs decreased by \$62.2 million primarily due to utilization against taxable income. The state NOL carryforwards decreased due to a legislative change from pre-apportionment to post-apportionment reporting in New Jersey. The federal and state NOL carryforwards will begin to expire in 2022. The Company's R&D tax credit carryforwards of approximately \$46.3 million begin to expire in 2020. The orphan drug credit relates to a credit that is calculated as a percentage of expenditures for development of XERMELO, which has received Orphan Drug designation from the FDA. Utilization of the NOL, R&D credit and orphan drug credit carryforwards may be subject to a significant annual limitation due to ownership changes that have occurred previously or could occur in the future provided by Section 382 of the Internal Revenue Code. Although NOLs were utilized in 2019, based on the federal tax law limits and the Company's cumulative loss position, Lexicon concluded it was appropriate to establish a full valuation allowance for its net deferred tax assets until an appropriate level of profitability is sustained. During the year ended December 31, 2019, the valuation allowance decreased \$35.3 million, primarily due to the Company's utilization of NOLs and decreases to deferred revenue and interest deferred tax assets.

Lexicon recorded an income tax benefit of \$6.0 million in the year ended December 31, 2019 despite reporting pretax income for the year. The result reflects the impact of the impairment of intangible assets associated with Symphony Icon and the benefit from the utilization of federal NOLs for which a tax benefit had not previously been recognized, partially offset by nondeductible expenses. There were no income tax benefits in the year ended December 31, 2018. Income tax benefits of \$12.7 million were recorded for the year ended December 31, 2017. Of the \$12.7 million tax benefits, \$8.7 million is the release of a valuation allowance as a result of the ability to estimate the reversal of the deferred tax liability related to the intangible associated with XERMELO and \$4.0 million was recorded to remeasure the deferred tax liability associated with the remaining indefinite-lived intangible asset associated with Symphony Icon at the newly enacted U.S. corporate income tax rate. As of December 31, 2019 and 2018, the Company did not have any unrecognized tax benefits.

The Company is primarily subject to U.S. federal and New Jersey and Texas state income taxes. The tax years 1995 to current remain open to examination by U.S. federal authorities and 2004 to current remain open to examination by state authorities. The Company's policy is to recognize interest and penalties related to income tax matters in income tax

expense. As of December 31, 2019 and 2018, the Company had no accruals for interest or penalties related to income tax matters.

8. Goodwill

On July 12, 2001, Lexicon completed the acquisition of Coelacanth Corporation in a merger. Coelacanth, now Lexicon Pharmaceuticals (New Jersey), Inc., formed the core of the Company's division responsible for small molecule compound discovery. The results of Lexicon Pharmaceuticals (New Jersey), Inc. are included in the Company's results of operations for the period subsequent to the acquisition. Goodwill associated with the acquisition of \$25.8 million, which represents the excess of the \$36.0 million purchase price over the fair value of the underlying net identifiable assets, was assigned to the consolidated entity, Lexicon.

On July 30, 2010, Lexicon exercised its Purchase Option and completed the acquisition of Symphony Icon, Inc. Goodwill associated with the acquisition of \$18.7 million, which represents the assets recognized in connection with the deferred tax liability acquired and did not result from excess purchase price, was assigned to the consolidated entity, Lexicon.

Goodwill is not subject to amortization, but is tested at least annually for impairment at the reporting unit level, which is the Company's single operating segment. The Company performed an impairment test of goodwill on its annual impairment assessment date. This test did not result in an impairment of goodwill.

9. Debt Obligations

Convertible Notes. In November 2014, Lexicon completed an offering of \$87.5 million in aggregate principal amount of its 5.25% Convertible Senior Notes due 2021 (the "Convertible Notes"). The conversion feature did not meet the criteria for bifurcation as required by generally accepted accounting principles and the entire principal amount was recorded as long-term debt on the Company's consolidated balance sheets.

The Convertible Notes are governed by an indenture (the "Indenture"), dated as of November 26, 2014, between the Company and Wells Fargo Bank, N.A., as trustee. The Convertible Notes bear interest at a rate of 5.25% per year, payable semiannually in arrears on June 1 and December 1 of each year, beginning on June 1, 2015. The Convertible Notes mature on December 1, 2021. The Company may not redeem the Convertible Notes prior to the maturity date, and no sinking fund is provided for the Convertible Notes.

Holders of the Convertible Notes may convert their Convertible Notes at their option at any time prior to the close of business on the business day immediately preceding the maturity date. Upon conversion, the Company will deliver for each \$1,000 principal amount of converted Convertible Notes a number of shares of its common stock equal to the conversion rate, as described in the Indenture. The conversion rate is initially 118.4553 shares of common stock per \$1,000 principal amount of Convertible Notes (equivalent to an initial conversion price of \$8.442 per share of common stock). The conversion rate is subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date, the Company will increase the conversion rate for a holder who elects to convert its Convertible Notes in connection with such a corporate event in certain circumstances.

If the Company undergoes a fundamental change, holders may require the Company to repurchase for cash all or any portion of their Convertible Notes at a fundamental change repurchase price equal to 100% of the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

In connection with the issuance of the Convertible Notes, the Company incurred \$3.4 million of debt issuance costs. The debt issuance costs are amortized as interest expense over the expected life of the Convertible Notes using the effective interest method. The Company determined the expected life of the debt was equal to the seven-year term of the Convertible Notes. As of December 31, 2019, the balance of unamortized debt issuance costs was \$0.9 million, which offsets long-term debt on the consolidated balance sheets. As of December 31, 2019, the carrying value of the Convertible Notes was \$86.6 million.

The fair value of the Convertible Notes was \$64.8 million as of December 31, 2019 and was determined using Level 2 inputs based on the indicative pricing published by certain investment banks or trading levels of the Convertible Notes, which are not listed on any securities exchange or quoted on an inter-dealer automated quotation system.

Mortgage Loan. In August 2018, a wholly owned subsidiary of Lexicon entered into a term loan and security agreement, refinancing the previously existing mortgage on its facilities in The Woodlands, Texas (the “Property”). The Company recorded the refinancing as a debt extinguishment, with no recognition of gain or loss on the transaction. The loan agreement provides for a \$12.9 million mortgage on the Property and has a two-year term with a 10-year amortization. The mortgage loan bears interest at a rate per annum equal to the greater of (a) the 30-day LIBOR rate plus 5.5% and (b) 7.5% and provides for a balloon payment of \$10.3 million due in August 2020. Lexicon incurred \$0.4 million of debt issuance costs in connection with the mortgage loan, which offsets the current portion of long-term debt on the consolidated balance sheets and will be amortized as interest expense over the two-year term of the loan agreement. As of December 31, 2019, the balance of unamortized debt issuance costs was \$0.1 million. The consolidated balance sheet includes mortgage debt, the carrying value of the debt, of \$11.0 million as of December 31, 2019. The buildings and land that serve as collateral for the mortgage loan are included in property and equipment at \$59.2 million and \$2.7 million, respectively, before accumulated depreciation, as of December 31, 2019. The fair value of Lexicon’s mortgage loan approximates its carrying value. The fair value of Lexicon’s mortgage loan was determined using Level 2 inputs using discounted cash flow analysis, based on the Company’s estimated current incremental borrowing rate.

In January 2020, Lexicon’s wholly owned subsidiary entered into a real estate purchase and sale agreement under which Lexicon agreed to sell its facilities in The Woodlands, Texas. Such sale is subject to normal and customary closing conditions, including a study period, which extends until April 9, 2020, during which the purchaser may conduct inspections, analyses and other studies of the property and may terminate the agreement in its discretion. Such sale is also subject to the negotiation and execution by the parties of a leaseback agreement for a period of six months with respect to a portion of the property concurrently with closing.

BioPharma Term Loan. In December 2017, Lexicon entered into a loan agreement with BioPharma Credit PLC and BioPharma Credit Investments IV Sub LP under which \$150 million was funded in December 2017 (the “BioPharma Term Loan”). The BioPharma Term Loan matures in December 2022, bears interest at 9% per year, subject to additional interest if an event of default occurs and is continuing, and is payable quarterly.

The BioPharma Term Loan is subject to mandatory prepayment provisions that require prepayment upon a change of control or receipt of proceeds from certain non-ordinary course transfers of assets. The Company may prepay the BioPharma Term Loan in whole at its option at any time. Any prepayment of the BioPharma Term Loan is subject to customary make-whole premiums and prepayment premiums.

The Company’s obligations under the BioPharma Term Loan are secured by a first lien security interest in substantially all of the assets of the Company and certain of its subsidiaries, other than its facilities in The Woodlands, Texas. The loan agreement contains certain customary representations and warranties, affirmative and negative covenants and events of default applicable to the Company and certain of its subsidiaries, including among other things, covenants restricting dispositions, fundamental changes in our business, mergers or acquisitions, indebtedness, encumbrances, distributions, investments, transactions with affiliates and subordinated debt. If an event of default occurs and is continuing, all amounts outstanding under the BioPharma Term Loan may be declared immediately due and payable.

In connection with the BioPharma Term Loan, the Company incurred \$4.1 million of debt issuance costs. The debt issuance costs are amortized as interest expense over the expected life of the BioPharma Term Loan using the effective interest method. The Company determined the expected life of the debt was equal to the five-year term of the BioPharma Term Loan. As of December 31, 2019, the balance of unamortized debt issuance costs was \$2.4 million, which offsets long-term debt on the consolidated balance sheets. As of December 31, 2019, the carrying value of the BioPharma Term Loan was \$147.6 million.

The fair value of the BioPharma Term Loan approximates its carrying value. The fair value of the BioPharma Term Loan was determined using Level 2 inputs using discounted cash flow analysis, based on the Company’s estimated current incremental borrowing rate.

The following table includes the aggregate scheduled future principal payments of the Company's long-term debt as of December 31, 2019:

	For the Year Ending December 31
	(in thousands)
2020	\$ 11,130
2021	87,500
2022	150,000
2023	—
2024	—
Thereafter	—
Total debt	248,630
Less deferred financing costs	(3,447)
Less current portion	(11,012)
Total long-term debt	\$ 234,171

10. Commitments and Contingencies

Operating Lease Obligations: A Lexicon subsidiary leases office space in Basking Ridge, New Jersey under a lease agreement, the term of which began in June 2015 and terminates in December 2022. As disclosed in Note 3, Lexicon adopted ASU 2016-02, "Leases", on January 1, 2019. As of December 31, 2019, the office space lease right-of-use (ROU) asset had a balance of \$1.7 million, which is included in other assets in the consolidated balance sheet, and current and non-current liabilities relating to the ROU asset were \$0.6 million and \$1.1 million, respectively, which are included in accrued liabilities and other long-term liabilities in the consolidated balance sheet, respectively. The discount rate used to record the office space lease was Lexicon's estimated borrowing rate of 9%. Lexicon elected to apply the short-term lease exception to all leases one year or less.

The following table reconciles the undiscounted cash flows of the operating lease liability to the recorded lease liability at December 31, 2019:

	(in thousands)
2020	\$ 620
2021	632
2022	645
2023	—
2024	—
Thereafter	—
Total undiscounted operating lease liability	1,897
Less: amount of lease payments representing interest	(242)
Present value of future lease payments	1,655
Less: short-term operating lease liability	(553)
Long-term operating lease liability	\$ 1,102

Employment Arrangements: Lexicon has entered into employment arrangements with certain of its corporate officers. Under the arrangements, each officer receives a base salary, subject to adjustment, with an annual discretionary bonus based upon specific objectives to be determined by the compensation committee. The employment arrangements are at-will and some contain non-competition agreements. Some of the arrangements also provide for certain severance payments for either six or 12 months and, in some cases, payment of a specified portion of the officer's bonus target for such year, in the event of a specified termination of the officer's employment.

Legal Proceedings: On January 28, 2019, a purported securities class action complaint captioned Daniel Manopla v. Lexicon Pharmaceuticals, Inc., Lonnel Coats, Jeffrey L. Wade and Pablo Lapuerta, M.D. was filed against the Company and certain of its officers in the U.S. District Court for the Southern District of Texas, Houston Division. A first amended complaint was filed on July 30, 2019 and Lexicon filed a motion to dismiss such first amended complaint on September 30, 2019. The plaintiff filed an opposition to Lexicon's motion to dismiss on November 14, 2019 and Lexicon filed a reply in support of its motion to dismiss on December 13, 2019. The lawsuit purports to be a class action brought on behalf of purchasers of the Company's securities during the period from March 11, 2016 through July 29, 2019. The complaint alleges that the defendants violated federal securities laws by making materially false and misleading statements and/or omissions concerning data from its Phase 3 clinical trials of sotagliflozin in type 1 diabetes patients and the prospects of FDA approval of sotagliflozin for the treatment of type 1 diabetes. The complaint purports to assert claims for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. The complaint seeks, on behalf of the purported class, an unspecified amount of monetary damages, interest, fees and expenses of attorneys and experts, and other relief.

In addition, Lexicon is from time to time party to claims and legal proceedings that arise in the normal course of its business and that it believes will not have, individually or in the aggregate, a material adverse effect on its results of operations, financial condition or liquidity.

11. Equity Incentive Awards

Equity Incentive Plans

2017 Equity Incentive Plan: In September 1995, Lexicon adopted the 1995 Stock Option Plan, which was subsequently amended and renamed the 2017 Equity Incentive Plan (the "Equity Incentive Plan").

The Equity Incentive Plan provides for the grant of incentive stock options to employees and nonstatutory stock options to employees, directors and consultants of the Company. The plan also permits the grant of stock bonus awards, restricted stock awards, restricted stock unit awards, stock appreciation rights and performance stock awards. Incentive and nonstatutory stock options have an exercise price of 100% or more of the fair market value of the Company's common stock on the date of grant. Most stock options granted under the Equity Incentive Plan become vested and exercisable over a period of four years; however some have been granted with different vesting schedules. Stock options granted under the Equity Incentive Plan have a term of ten years from the date of grant.

The total number of shares of common stock that may be issued pursuant to stock awards under the Equity Incentive Plan shall not exceed in the aggregate 20,000,000 shares at December 31, 2019. In the first quarter of 2020, the Company amended the 2017 Equity Incentive Plan, subject to stockholder approval, to increase the aggregate number of shares that may be issued under the plan to 30,000,000 shares. As of December 31, 2019, options to purchase 7,456,905 shares and 2,801,928 restricted stock units were outstanding, 1,909,515 shares had been issued upon the exercise of stock options, 1,968,979 shares had been issued pursuant to restricted stock units and 113,940 shares had been issued pursuant to stock bonus awards or restricted stock awards granted under the Equity Incentive Plan.

2017 Non-Employee Directors' Equity Incentive Plan: In February 2000, Lexicon adopted the 2000 Non-Employee Directors' Stock Option Plan, which was subsequently amended and renamed the 2017 Non-Employee Directors' Equity Incentive Plan (the "Directors' Plan"). Under the Directors' Plan, non-employee directors may be granted awards under the plan with an aggregate grant date fair value of no more than \$500,000 during any calendar year, taken together with any cash fees paid to such non-employee director in compensation for service on Lexicon's board of directors during such calendar year. Stock options granted under the Directors' Plan have an exercise price equal to the fair market value of the Company's common stock on the date of grant and a term of ten years from the date of grant.

The total number of shares of common stock that may be issued pursuant to stock awards under the Directors' Plan shall not exceed in the aggregate 600,000 shares. As of December 31, 2019, stock options to purchase 237,850 shares were outstanding, none had been issued upon the exercise of stock options, 27,728 restricted stock units were outstanding and 103,208 shares had been issued pursuant to restricted stock awards granted under the Directors' Plan.

Stock Option Activity: The following is a summary of stock option activity under Lexicon's equity incentive plans:

(in thousands, except exercise price data)	2019		2018		2017	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at beginning of year	6,152	\$ 10.68	4,961	\$ 11.17	4,834	\$ 11.24
Granted	2,435	5.06	1,916	10.00	892	14.31
Exercised	—	—	(97)	7.55	(458)	11.97
Expired	(212)	9.95	(239)	14.21	(157)	26.42
Forfeited	(680)	10.42	(389)	12.04	(150)	13.84
Outstanding at end of year	<u>7,695</u>	8.95	<u>6,152</u>	10.68	<u>4,961</u>	11.17
Exercisable at end of year	<u>4,275</u>	\$ 10.56	<u>3,620</u>	\$ 10.72	<u>3,077</u>	\$ 10.95

The weighted average estimated grant date fair value of stock options granted during the years ended December 31, 2019, 2018 and 2017 were \$3.18, \$5.63 and \$8.59, respectively. The total intrinsic value of stock options exercised during the years ended December 31, 2018 and 2017 were \$0.2 million and \$2.0 million, respectively. The weighted average remaining contractual term of stock options outstanding and exercisable was 6.8 and 5.3 years, respectively, as of December 31, 2019. At December 31, 2019, the aggregate intrinsic value of the outstanding stock options was \$0.2 million. At December 31, 2019, there was no intrinsic value of exercisable stock options.

Stock Bonus and Restricted Stock Unit Activity:

During the year ended December 31, 2019, Lexicon granted its non-employee directors 27,728 restricted stock units and during the year ended December 31, 2018 and 2017, granted its non-employee directors 20,512 and 10,248 shares, respectively, of restricted stock awards. The restricted stock in 2019, 2018 and 2017 had weighted average grant date fair values of \$5.67, \$7.80 and \$15.61 per share, respectively. Vesting of restricted stock units occurs on the first anniversary of the grant date and vesting of restricted stock awards is immediate.

During the years ended December 31, 2019, 2018 and 2017, Lexicon granted its employees restricted stock units in lieu of or in addition to annual stock option awards. These restricted stock units vest in three to four annual installments. The total fair value of shares vested in 2019, 2018 and 2017 was \$2.9 million, \$3.3 million and \$4.7 million, respectively.

The following is a summary of restricted stock units activity under Lexicon's stock-based compensation plans for the year ended December 31, 2019:

	Weighted Average Grant Date Fair Value	
	Shares	
	(in thousands)	
Outstanding at December 31, 2018	1,286	\$ 10.17
Granted	2,446	5.05
Vested	(517)	9.60
Forfeited	(385)	6.50
Outstanding at December 31, 2019	<u>2,830</u>	\$ 6.35

Aggregate Shares Reserved for Issuance

As of December 31, 2019, an aggregate of 10,524,411 shares of common stock were reserved for issuance upon exercise of outstanding stock options and vesting of outstanding restricted stock units and 5,979,947 additional shares were available for future grants under Lexicon's equity incentive plans. The Company has a policy of using either authorized and unissued shares or treasury shares, including shares acquired by purchase in the open market or in private transactions, to satisfy equity award exercises.

12. Benefit Plan

Lexicon maintains a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code. The plan covers substantially all full-time employees. Participating employees may defer a portion of their pretax earnings, up to the Internal Revenue Service annual contribution limit. Beginning in 2000, the Company was required to match employee contributions according to a specified formula. The matching contributions totaled \$1.2 million, \$1.0 million and \$1.0 million in the years ended December 31, 2019, 2018 and 2017, respectively. Company contributions are vested based on the employee's years of service, with full vesting after four years of service.

13. Collaboration and License Agreements

Lexicon has derived substantially all of its revenues from drug discovery and development alliances, target validation collaborations for the development and, in some cases, analysis of the physiological effects of genes altered in knockout mice, product sales, government grants and contracts, technology licenses, subscriptions to its databases and compound library sales.

Sanofi. In November 2015, Lexicon entered into a Collaboration and License Agreement, which was subsequently amended in July 2017 (collectively, the "Sanofi Agreement"), with Sanofi for the worldwide development and commercialization of Lexicon's diabetes drug candidate sotagliflozin. In December 2016, Sanofi terminated its rights under the Sanofi Agreement with respect to Japan.

Effective as of September 9, 2019 (the "Settlement Date"), Lexicon entered into a Termination and Settlement Agreement and Mutual Releases (the "Termination Agreement") with Sanofi, pursuant to which the Sanofi Agreement was terminated and associated disputes between Lexicon and Sanofi were settled.

Under the terms of the Termination Agreement, Lexicon regained all rights to sotagliflozin and assumed full responsibility for the worldwide development and commercialization of sotagliflozin in all indications. Sanofi paid Lexicon \$208 million in September 2019, \$26 million in March 2020 (less amounts withheld by Sanofi offsetting certain third party costs and internal costs incurred by Sanofi and asserted by Sanofi to be payable by Lexicon under the terms of the Termination Agreement) and is obligated to pay an additional \$26 million within twelve months of the Settlement Date, and neither party will owe additional payments pursuant to the Sanofi Agreement. The parties have cooperated in the transition of responsibility for ongoing clinical studies and other activities, and each party is responsible for its own expenses associated with such transition, subject to certain exceptions. The following is a summary description of the Sanofi Agreement without giving effect to the Termination Agreement.

Under the Sanofi Agreement, Lexicon had granted Sanofi an exclusive, worldwide (excluding Japan), royalty-bearing right and license under its patent rights and know-how to develop, manufacture and commercialize sotagliflozin. Subject to specified exceptions, neither party could (a) perform clinical development activities relating to any other compound which inhibits sodium-glucose cotransporters type 1 or type 2 or (b) commercialize any such compounds in the United States, countries of the European Union and certain other specified countries, in each case during the royalty terms applicable in such countries. Among the specified exceptions was a right Lexicon retained to pursue the development of its development candidate LX2761, with respect to which Lexicon granted Sanofi certain rights of first negotiation specified in the Sanofi Agreement.

Under the Sanofi Agreement, Sanofi paid Lexicon an upfront payment of \$300 million. In addition, Lexicon was eligible to receive from Sanofi (a) up to an aggregate of \$110 million upon the achievement of four development milestones relating to the results of certain Phase 3 clinical trials of sotagliflozin in type 2 diabetes patients, (b) up to an aggregate of \$220 million upon the achievement of four regulatory milestones relating to the first commercial sale following regulatory approval of sotagliflozin for type 1 and type 2 diabetes, respectively, in each of the United States and Europe, of which two milestones representing the substantial majority of such aggregate amount relate to type 2 diabetes and the remaining two milestones relate to type 1 diabetes, (c) \$100 million upon the achievement of a milestone based on the results of either of two outcomes studies in type 2 diabetes patients, the completion of which would likely occur after initial regulatory approval of sotagliflozin in type 2 diabetes, and (d) up to an aggregate of \$990 million upon the achievement of six commercial milestones that will be achieved upon reaching specified levels of sales. The Company believed that each of the development and regulatory milestones under the Sanofi Agreement was substantive. Due to the uncertainty surrounding the achievement of the future development and regulatory milestones, these payments were deemed constrained and were not recognized as revenue. Commercial milestones would have been accounted for as royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria were met. Lexicon was also entitled to tiered, escalating royalties ranging from low double digit percentages to forty percent of net sales of sotagliflozin, based on indication and territory, with royalties for the higher band of

such range attributable to net sales for type 1 diabetes in the United States, and subject in each case to customary royalty reduction provisions.

Lexicon continued to be responsible for all clinical development activities relating to type 1 diabetes and 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 United States. Under the terms of its co-promotion option, Lexicon would have funded forty percent of the commercialization costs relating to such co-promotion activities. Sanofi was responsible for all clinical development and commercialization of sotagliflozin for the treatment of type 2 diabetes worldwide and would have been solely responsible for the commercialization of sotagliflozin for the treatment of type 1 diabetes outside the United States. Lexicon shared in the funding of a portion of the planned type 2 diabetes development costs over the first three years of the collaboration, up to an aggregate of \$100 million, which was satisfied in 2018. Sanofi would have booked sales worldwide in all indications.

The parties were responsible for using commercially reasonable efforts to perform their development and commercialization obligations pursuant to mutually approved development and commercialization plans.

The parties' activities under the Sanofi Agreement were governed by a joint steering committee and certain other governance committees which reflected equal or other appropriate representation from both parties. If the applicable governance committee was not able to make a decision by consensus and the parties were not able to resolve the issue through escalation to specified senior executive officers of the parties, then Sanofi would have final decision-making authority, subject to limitations specified in the Sanofi Agreement.

The Sanofi Agreement would have expired upon the expiration of all applicable royalty terms for all licensed products in all countries. The royalty term for each licensed product in each country was the period commencing on the effective date of the Sanofi Agreement and ending on the latest of expiration of specified patent coverage, expiration of specified regulatory exclusivity and 10 years following the first commercial sale in the applicable country. Either party could terminate the Sanofi Agreement in the event of an uncured material breach by the other party. Prior to completion of the core development activities for type 2 diabetes specified in the development plan, Sanofi could terminate the Sanofi Agreement on a country-by-country and licensed product-by-licensed product basis, in the event of (a) notification of a material safety issue relating to the licensed product or the class of sodium-glucose cotransporters type 1 or type 2 inhibitors resulting in a recommendation or requirement that Lexicon or Sanofi cease development, (b) failure to achieve positive results with respect to certain clinical trial results, (c) the occurrence of specified fundamental adverse events or (d) the exploitation of the licensed product infringing third party intellectual property rights in specified major markets and Sanofi is unable to obtain a license to such third party intellectual property rights.

The Company considered the following as its performance obligations with respect to the revenue recognition of the \$300 million upfront payment:

- The exclusive worldwide license granted to Sanofi to develop and commercialize sotagliflozin;
- The development services Lexicon is performing for sotagliflozin relating to type 1 diabetes; and
- The funding Lexicon will provide for development relating to type 2 diabetes.

The Company determined that the license had stand-alone value because it was an exclusive license that gave Sanofi the right to develop and commercialize sotagliflozin or to sublicense its rights. In addition, sotagliflozin is currently in development and it was possible that Sanofi or another third party could conduct clinical trials without assistance from Lexicon. As a result, the Company considered the license and the development services under the Sanofi Agreement to be separate performance obligations. The Company recognized the portion of the transaction price allocated to the license immediately because Lexicon delivered the license and earned the revenue at the inception of the arrangement. The Company was recognizing as revenue the amount allocated to the development services for type 1 diabetes over the period of time Lexicon performed services, which was expected to be through 2027, and recognized as revenue the obligation to provide funding for development services for type 2 diabetes over the period of time Lexicon provided the funding, which was completed in 2018.

The Company determined that the initial transaction price was the \$300 million upfront payment because it was the only payment that was fixed and determinable at the inception of the arrangement. There was considerable uncertainty at the date of the agreement as to whether Lexicon would earn milestone payments or royalty payments. As such, the Company did not include those payments in the allocable consideration. The Company allocated the transaction price based on the relative best estimate of selling price of each performance obligation. The Company estimated the selling price of the license deliverable by applying a probability-based income approach utilizing an appropriate discount rate. The significant inputs the Company used to determine the projected income of the license included: exercising the option to co-promote, estimated future

product sales, estimated cost of goods sold, estimated operating expenses, income taxes, and an appropriate discount rate. The Company estimated the selling price of the development services for type 1 diabetes by using internal estimates of the cost to hire third parties to perform the services over the expected period to perform the development. The Company estimated the obligation to provide funding for type 2 diabetes by using internal estimates of the expected cash flows and timing for \$100 million in funding.

As a result of the allocation of the Sanofi Agreement, the Company recognized \$126.8 million of the \$300 million upfront payment for the license in 2015. The Company was recognizing the \$113.8 million allocated to the development services performance obligation and the \$59.4 million allocated to the funding performance obligation over the estimated period of performance as the development and funding occurred. The Termination Agreement was accounted for as a modification under ASC 606. Upon execution of the Termination Agreement in September 2019, the Company recognized the remaining \$23.5 million allocated to Lexicon's performance obligations as revenue and reduced its remaining deferred revenue balance accordingly. In addition, the Company recognized revenue of \$260 million, representing the full cash consideration from the Termination Agreement. The Company has no remaining performance obligations to Sanofi. Revenue recognized under the collaboration agreements with Sanofi was \$286 million, \$33.2 million and \$60.1 million for the years ended December 31, 2019, 2018 and 2017, respectively.

Ipsen. In October 2014, Lexicon entered into a License and Collaboration Agreement, which was subsequently amended in March 2015 (collectively, the "Ipsen Agreement"), with Ipsen for the development and commercialization of XERMELO outside of the United States and Japan (the "Licensed Territory").

Under the Ipsen Agreement, Lexicon granted Ipsen an exclusive, royalty-bearing right and license under its patent rights and know-how to commercialize XERMELO in the Licensed Territory. Ipsen is responsible for using diligent efforts to commercialize XERMELO in the Licensed Territory pursuant to a mutually approved commercialization plan. Subject to certain exceptions, Lexicon was responsible for conducting clinical trials required to obtain regulatory approval for XERMELO for carcinoid syndrome in the European Union, including those contemplated by a mutually approved initial development plan, and has the first right to conduct most other clinical trials of XERMELO. Lexicon was responsible for the costs of all clinical trials contemplated by the initial development plan. The costs of additional clinical trials will be allocated between the parties based on the nature of such clinical trials. Under the Ipsen Agreement, Ipsen has paid Lexicon an aggregate of \$47.2 million through December 31, 2019, consisting of \$24.5 million in upfront payments, a \$6.4 million milestone upon the acceptance of the filing submitted by Ipsen to the European Medicines Agency for XERMELO as an adjunct to somatostatin analog therapy for the long-term treatment of carcinoid syndrome, a \$5.1 million milestone upon Ipsen's receipt of approval from the European Commission for the marketing of XERMELO in all member states of the European Union, Norway and Iceland, a \$3.8 million milestone upon Ipsen's first commercial sale in Germany, a \$3.8 million milestone upon Ipsen's first commercial sale in the United Kingdom, a \$1.3 million milestone upon Ipsen's receipt of approval from Health Canada and a \$2.3 million milestone upon Ipsen's first commercial sale in Canada. In addition, Lexicon is eligible to receive from Ipsen (a) up to an aggregate of approximately \$9.6 million upon the achievement of specified regulatory and commercial launch milestones and (b) up to an aggregate of €72 million upon the achievement of specified sales milestones. Milestone payments are deemed constrained. Lexicon is also entitled to tiered, escalating royalties ranging from low twenties to mid-thirties percentages of net sales of XERMELO in the Licensed Territory, subject to a credit for amounts previously paid to Lexicon by Ipsen for the manufacture and supply of such units of XERMELO. Lexicon and Ipsen have entered into a commercial supply agreement pursuant to which Lexicon supplies Ipsen's commercial requirements of XERMELO, and Ipsen pays an agreed upon transfer price for such commercial supply.

The Company considered the following as its performance obligations with respect to the revenue recognition of the \$24.5 million upfront payment:

- The exclusive license granted to Ipsen to develop and commercialize XERMELO in the Licensed Territory;
- The development services Lexicon is performing for XERMELO;
- The obligation to participate in committees which govern the development of XERMELO until commercialization; and
- The obligation to supply commercial supply of XERMELO, under a commercial supply agreement.

The Company determined that the license had stand-alone value because it is an exclusive license that grants Ipsen the right to develop and commercialize XERMELO or to sublicense its rights. In addition, at the time of the agreement, it would have been possible for Ipsen or another third party to conduct clinical trials without assistance from Lexicon. As a result, the Company considers the license and the development services under the Agreement to be separate performance obligations. The Company recognized the portion of the transaction price allocated to the license immediately because Lexicon delivered the

license and earned the revenue at the inception of the arrangement. The Company is recognizing as revenue the amount allocated to the development services and the obligation to participate in committees over the period of time Lexicon performs services, which was completed in 2018.

The Company determined that the commercial supply agreement is a contingent deliverable at the onset of the Agreement. There was inherent uncertainty in obtaining regulatory approval at the time of the agreement, thus, making the applicability of the commercial supply agreement outside the control of Lexicon and Ipsen. As a result, the Company has determined the commercial supply agreement does not meet the definition of a performance obligation that needs to be accounted for at the inception of the arrangement. The Company has also determined that there is no significant and incremental discount related to the commercial supply agreement that should be accounted for at the inception of the arrangement.

The Company determined that the initial transaction price was the \$24.5 million upfront payments because they were the only payments that were fixed and determinable at the inception of the arrangement. There was considerable uncertainty at the date of the agreement as to whether Lexicon would earn milestone payments, royalty payments or payments for finished drug product. As such, the Company did not include those payments in the transaction price. The Company allocated the transaction price based on the relative best estimate of selling price of each performance obligation. The Company estimated the selling price of the license deliverable by applying a probability-based income approach utilizing an appropriate discount rate. The significant inputs the Company used to determine the projected income of the license included: estimated future product sales, estimated cost of goods sold, estimated operating expenses, income taxes, and an appropriate discount rate. The Company estimated the selling price of the development services by using internal estimates of the cost to hire third parties to perform the services over the expected period to perform the development. The Company estimated the selling price of the obligation to participate in committees by using internal estimates of the number of internal hours and salary and benefits costs to perform these services.

As a result of the allocation, the Company recognized \$21.2 million of the \$24.5 million upfront payment for the license in 2014, and an additional \$1.4 million in 2015 upon entering into the amendment. The Company recognized the \$1.7 million allocated to the development services deliverable over the estimated period of performance as development occurs, and recognized the \$0.1 million allocated to the committee participation deliverable ratably over the estimated period of performance. Milestone payments that are contingent upon the achievement of a substantive milestone are deemed constrained. If or when the constraint is determined to be resolved, the Company will re-evaluate the overall transaction price and recognize an adjustment on a cumulative catch-up basis in the period that the adjustment was evaluated. During 2019, the milestone earned when Ipsen made its first commercial sale in Canada was determined to be a distinct performance obligation relating to the development activities and accordingly, was recognized as revenue without further allocation to the remaining performance obligations. Revenue recognized under the Agreement was \$4.9 million, \$4.6 million and \$16.2 million for the years ended December 31, 2019, 2018 and 2017, respectively. Revenue for the years ended December 31, 2019, 2018 and 2017 include \$0.3 million, \$0.3 million and \$0.1 million, respectively, of royalties from Ipsen. Revenue for the years ended December 31, 2019, 2018 and 2017 include \$1.3 million, \$1.6 million and \$0.8 million, respectively, from sales of bulk tablets of XERMELO to Ipsen.

14. Earnings (Loss) Per Share

The following is a summary of Lexicon's earnings (loss) per share calculations and reconciliations of basic to diluted earnings (loss) per share:

(In thousands, except per share amounts)	Year Ended December 31,		
	2019	2018	2017
Numerator:			
Net income (loss)	\$ 130,133	\$ (120,548)	\$ (122,993)
Add interest expense on Convertible Notes	5,067	—	—
Adjusted net income (loss)	\$ 135,200	\$ (120,548)	\$ (122,993)
Denominator:			
Shares used in computing net income (loss) per common share, basic	106,218	105,830	105,237
Add effect of potential dilutive securities			
Share based awards	164	—	—
Convertible Notes	10,365	—	—
Shares used in computing net income (loss) per common share, diluted	116,747	105,830	105,237
Net income (loss) per share - basic	\$ 1.23	\$ (1.14)	\$ (1.17)
Net income (loss) per share - diluted	\$ 1.16	\$ (1.14)	\$ (1.17)

For periods presented with a net loss, the weighted average number of shares outstanding are the same for both basic and diluted net loss per common share. The average number of shares associated with stock options and restricted stock units that were excluded from diluted earnings per share that would potentially dilute earnings per share in the future was 8,206,390, 7,438,134 and 5,907,643, respectively, for the years ended December 31, 2019, 2018 and 2017. For periods presented with a net loss, the shares associated with the Convertible Notes are not included in the computation of diluted earnings per share because they are antidilutive.

15. Selected Quarterly Financial Data (Unaudited)

The table below sets forth certain unaudited statements of comprehensive income (loss) data, and net income (loss) per common share data, for each quarter of 2019 and 2018:

(in thousands, except per share data)

	Quarter Ended			
	March 31	June 30	September 30	December 31
	(Unaudited)			
2019				
Revenues (1)	\$ 9,216	\$ 9,682	\$ 294,448	\$ 8,727
Income (loss) from operations	\$ (17,469)	\$ (18,545)	\$ 224,676	\$ (47,217)
Net income (loss)	\$ (21,797)	\$ (23,018)	\$ 226,086	\$ (51,138)
Net income (loss) per common share, basic	\$ (0.21)	\$ (0.22)	\$ 2.13	\$ (0.48)
Net income (loss) per common share, diluted	\$ (0.21)	\$ (0.22)	\$ 1.95	\$ (0.48)
Shares used in computing net income (loss) per common share, basic	106,054	106,272	106,272	106,272
Shares used in computing net income (loss) per common share, diluted	106,054	106,272	116,640	106,272
2018				
Revenues	\$ 25,374	\$ 13,798	\$ 6,966	\$ 17,071
Loss from operations	\$ (37,713)	\$ (30,272)	\$ (22,927)	\$ (12,367)
Net loss	\$ (41,821)	\$ (34,549)	\$ (27,396)	\$ (16,782)
Net loss per common share, basic and diluted	\$ (0.40)	\$ (0.33)	\$ (0.26)	\$ (0.16)
Shares used in computing net loss per common share, basic and diluted	105,668	105,848	105,881	105,920

(1) Revenues for the three months ended September 30, 2019 include \$260 million from the Sanofi Termination Agreement, as defined in Note 13.

For periods presented with a net loss, the weighted average number of shares outstanding are the same for both basic and diluted net loss per common share. For these periods, shares associated with convertible debt, stock options and restricted stock units are not included in the weighted average number of shares of common stock outstanding because they are antidilutive.

CORPORATE SUMMARY

EXECUTIVE OFFICERS

LONNEL COATS

President and Chief Executive Officer

PABLO LAPUERTA, M.D.

Executive Vice President and
Chief Medical Officer

ALAN J. MAIN, PH.D.

Executive Vice President,
Commercial Supply Operations

ALEXANDER A. SANTINI

Executive Vice President
and Chief Commercial Officer

PRAVEEN TYLE, PH.D.

Executive Vice President,
Research and Development

JEFFREY L. WADE

Executive Vice President,
Corporate and Administrative Affairs
and Chief Financial Officer

BRIAN T. CRUM

Vice President and General Counsel

JAMES F. TESSMER

Vice President, Finance
and Accounting

BOARD OF DIRECTORS

RAYMOND DEBBANE

Chairman

President and Chief Executive Officer,
The Invus Group, LLC

PHILIPPE J. AMOUYAL

Managing Director,
The Invus Group, LLC

SAMUEL L. BARKER, PH.D.

Former President, U.S. Pharmaceutical
Group, Bristol-Myers Squibb Company

LONNEL COATS

President and Chief Executive Officer,
Lexicon Pharmaceuticals, Inc.

ROBERT J. LEFKOWITZ, M.D.

Investigator, Howard Hughes Medical
Institute and James B. Duke Professor of
Medicine and Professor of Biochemistry
Duke University Medical Center:
Recipient of 2012 Nobel Prize in Chemistry

ALAN S. NIES, M.D.

Former Senior Vice President,
Clinical Sciences,
Merck & Co., Inc.

FRANK P. PALANTONI

Chief Executive Officer,
Laboratory M2

CHRISTOPHER J. SOBECKI

Managing Director,
The Invus Group, LLC

JUDITH L. SWAIN, M.D.

Visiting Professor of Medicine,
National University of Singapore
and Chief Medical Officer,
Physiowave, Inc.

CORPORATE HEADQUARTERS

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TRANSFER AGENT

Computershare
PO Box 30170
College Station, TX 77845
(877) 854-4583
www-us.computershare.com/investor

ANNUAL REPORT

Our 2019 annual report on Form 10-K is
available, without charge, upon request
by contacting our Investor Relations
Department at (281) 863-3000.

ANNUAL MEETING

Our annual meeting of shareholders will be
held at 8:00 a.m. CDT on April 23, 2020 at
Lexicon's corporate headquarters at:
8800 Technology Forest Place
The Woodlands, TX 77381

This annual report to shareholders contains forward-looking statements relating to Lexicon's commercial products and clinical and preclinical development programs and the potential therapeutic and commercial potential of those commercial products and drug candidates. These statements involve risks, uncertainties and other important factors that 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 risks, uncertainties and other important factors is contained in the section entitled "Risk Factors" and elsewhere in our annual report on Form 10-K for the year ended December 31, 2019, as filed with the Securities and Exchange Commission and included as part of this annual report to shareholders.



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