

**2020**  
**Annual**  
**Report**

**ESPERION<sup>®</sup>**

# 2020

## will be remembered as the year everything changed.

While the world changed around us in obvious ways, Esperion changed as a company: We received our first marketing approvals for NEXLETOL® (bempedoic acid) Tablet and NEXLIZET® (bempedoic acid and ezetimibe) Tablet, moving us from a late-stage development company to a commercial organization and partner.

We launched our first products in the U.S. in March and June (respectively), secured additional approvals for both medicines in the European Union, the U.K. and Switzerland, and worked with our commercial partner Daiichi Sankyo Europe to launch in Germany, all as the world faced the impacts from COVID-19.

Just as everything in our lives became more complicated – errands, visits to family and friends, travel – so did managing a chronic disease. Not only are people with cardiovascular disease at increased risk of severe COVID-19, the pandemic has made it more difficult for them to manage their treatment. Medical services were disrupted around the world; 75% of countries reported that healthcare for noncommunicable diseases, including cardiovascular disease, has been disrupted during the pandemic.<sup>1</sup> In some cases, the only solution was to stop seeking care unless it was urgent, and about 40% of adults in the U.S. said they postponed medical care in the summer of 2020.<sup>2</sup>

Despite all of these difficulties, despite the fact that it would have been easier to put their health on hold for a few months, more than 21,000 patients went to their doctors and got a prescription for an Esperion medicine in 2020. We are grateful for the trust these patients and their physicians have placed in our treatments.

And although everything seems to have changed in 2020, **some things did not.** Our team at Esperion is as committed as ever to our purpose of lipid management for everybody.

If anything, the pandemic and the resulting disruption of the healthcare system has reinforced our belief in the need for new, easier medicines to treat high cholesterol.

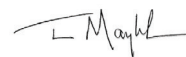
What we do remains the same: We work hard to make medicines that are easy to get, easy to take and easy to have. Our commitment to grow our pipeline was bolstered by the in-licensing of an oral PCSK9 inhibitor development program. We look forward to sharing more progress on our plans for this program later this year.

There were few changes to how we work and no “learning curve” for us to work virtually – we were already doing it. Our remote workforce was an advantage as we launched our products at the height of the pandemic last spring.

Undistracted, we continued our work for adult patients trying to manage their low-density lipoprotein cholesterol (LDL-C), especially those whose needs are not met by the status quo.

And, importantly, your support of our company has not changed. Just as we are grateful to the patients and physicians placing their trust in our products, we are grateful to our shareholders for your ongoing trust in

Esperion. We take pride in our accomplishments and look forward to achieving more together.



Tim M. Mayleben  
President and Chief  
Executive Officer

<sup>1</sup> WHO. “Rapid assessment of service delivery for NCDs during the COVID-19 pandemic” publication. <https://www.who.int/publications/m/item/rapid-assessment-of-service-delivery-for-ncds-during-the-covid-19-pandemic>. Published 29 May 2020. Accessed 11 Feb 2021. <sup>2</sup> U.S. Census Bureau. “Measuring Household Experiences during the Coronavirus Pandemic” Household Pulse Survey, Phase 1. <https://www.census.gov/data-tools/demo/hhp/assets/resources/phase-one-household-pulse-survey-tool-summary.xlsx>. Accessed 11 Feb 2021.

# Our belief: patients deserve better than the status quo

## Unmet Need

As The Lipid Management Company, the only publicly traded company fully focused on medicines to lower bad cholesterol, we constantly seek to better understand patients' experiences, especially the experiences of those whose needs aren't being met by current treatment options.

Up to

**20%**

of people who could be treated with a statin experience statin intolerance<sup>3</sup>

**>1/3**

of patients discontinue treatment with a statin within a year<sup>4</sup>

Nearly

**80%**

of very high-risk patients did not meet a guideline-recommended LDL-C target<sup>5</sup>

**8.7**

million patients in the U.S. don't reach their LDL-C goals despite taking a statin<sup>6</sup>

**9.6**

million patients in the U.S. with high LDL-C are not on statins, often due to tolerability concerns<sup>6</sup>



# MILLIONS OF PEOPLE NEED OUR HELP

In 2020, we supported the Familial Hypercholesterolemia (FH) Global Summit — the only conference dedicated to the care and treatment of inherited cardiovascular disorders, including FH and high lipoprotein(a) — which was held virtually for the first time.

We supported HealthyWomen in their survey “Women and High Blood Cholesterol.”

More than three-quarters of women who responded said side effects from statins made them not feel like themselves, and 78% would like a non-statin choice for managing bad cholesterol. Nearly a quarter of respondents said they do not regularly take their medicine for high cholesterol, leaving them at increased risk for cardiovascular events.

# Our business: making medicine easy

We work to discover, develop and commercialize innovative medicines and combinations with established medicines that are easy to get, easy to take and easy to have.

## 2020 Achievements

Esperion became a commercial company, gaining marketing authorizations in key geographies and launching NEXLETOL (bempedoic acid) Tablet\* and NEXLIZET (bempedoic acid and ezetimibe) Tablet\* in the U.S.

The two products also launched in Germany through our partner Daiichi Sankyo Europe, under the brand names NILEMDO® and NUSTENDI®.\*

**1ST** NEW ORAL  
MEDICINE TO LOWER  
LDL-C IN NEARLY  
**20 YEARS**  
FOR INDICATED PATIENTS

**8** MARKETING  
AUTHORIZATIONS  
FOR 2 PRODUCTS  
authorizations received in U.S., E.U., U.K. and Switzerland

\*NEXLETOL and NEXLIZET are approved as adjuncts to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypocholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C. The effect of NEXLETOL and NEXLIZET on cardiovascular morbidity and mortality has not been determined.

NILEMDO (bempedoic acid) is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin or, alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

NUSTENDI (bempedoic acid and ezetimibe) is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: in combination with a statin in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin in addition to ezetimibe, alone in patients who are either statin-intolerant or for whom a statin is contraindicated, and are unable to reach LDL-C goals with ezetimibe alone, in patients already being treated with the combination of bempedoic acid and ezetimibe as separate tablets with or without statin.

Sheldon Koenig was named chief operating officer in December, and his strategy and operations expertise will support Esperion's evolution into a commercial leader in cardiovascular medicine.

**We announced a partnership with Otsuka Pharmaceutical Co. to further develop and commercialize our products in Japan.**

The agreement includes more than \$600 million in milestones and development costs, plus 15-30% in royalties, making it the largest ever in Japan. Esperion received \$60 million in payments from Otsuka during 2020.

In November, we secured \$280 million in convertible debt financing to support the company's opportunity to grow, with diversified revenue streams on top of our strong cash position.



# Our science: cholesterol management beyond the status quo

Even as we launched NEXLETOL and NEXLIZET, we continued to gather and publish data on bempedoic acid at **key congresses and in key publications.**



CLEAR Outcomes, our ongoing Cardiovascular Outcomes Trial (CVOT) for bempedoic acid, is on track despite the pandemic and reached 50% of major adverse cardiac events (MACE) endpoints in the third quarter of 2020. In 2019, the trial had fully enrolled over 14,000 patients who are statin intolerant, a population with great unmet needs and few treatment options, and is designed to evaluate bempedoic acid's ability to reduce the risk of cardiovascular events in patients who have or are at high risk for cardiovascular disease. CLEAR Outcomes is on track to be completed in the second half of 2022.

## CLEAR Outcomes Trial

First-of-its-kind, landmark CVOT  
in patients with statin intolerance

Recruited patients in **32 countries**

**48%** of enrolled patients are women

On track to be completed in the  
**second half of 2022**

## Looking toward our future

**We in-licensed an oral PCSK9 inhibitor program, furthering Esperion's mission and leveraging our singular focus on oral, non-statin LDL-C lowering medicines.**

At the American Heart Association Scientific Sessions in November, a presentation of a pooled analysis from multiple studies showed NEXLETOL significantly lowered LDL-C with a mean reduction of 26.5% vs. placebo in people who cannot tolerate statins.

In late December, an analysis published in *Atherosclerosis* showed that a combination of bempedoic acid, ezetimibe and atorvastatin significantly lowered LDL-C by 60.5% vs. placebo.

In a pooled efficacy analysis published in *JAMA Cardiology*, NEXLETOL lowered LDL-C by a mean of 18% vs. placebo for patients on background statins and by a mean of 24% vs. placebo for patients with statin intolerance.

The analyses referenced here are investigational only and warrant further clinical research.

## Publications

### *Atherosclerosis:*

More than **90% of patients** treated with bempedoic acid, ezetimibe and atorvastatin triple therapy achieved guideline-recommended LDL-C levels

### *American Heart Association 2020 Scientific Sessions:*

NEXLETOL significantly lowered LDL-C with a mean **reduction of 26.5%** vs. placebo in pooled analysis of people who cannot tolerate statins

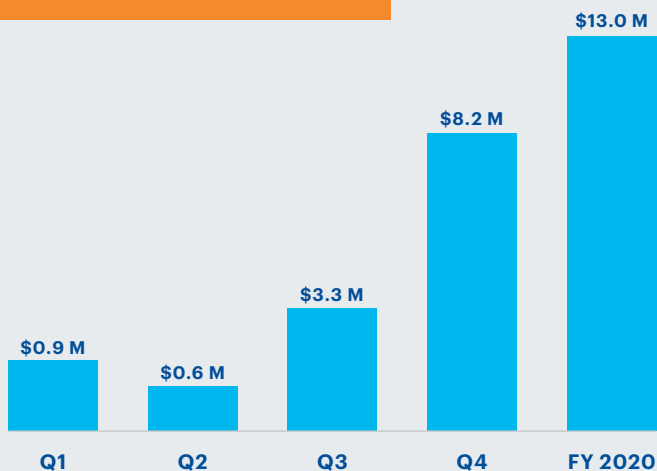


# Financial Results

During 2020, Esperion transitioned to a commercial company, recording our first-ever product sale from NEXLETOL at the end of the first quarter. With our partner Daiichi Sankyo Europe's launch in Germany, Esperion further diversified its revenue stream through recognition of the inaugural royalty revenues

for NILEMDO and NUSTENDI. To ensure the company was well positioned as the new year approached, Esperion took action to secure additional capital through a convertible debt financing, further strengthening the cash position for the future.

## 2020 Net Product Revenue

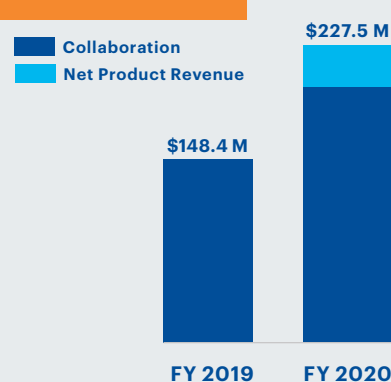


**U.S. Net Product Sales**  
Recorded 1st product sale in Q1

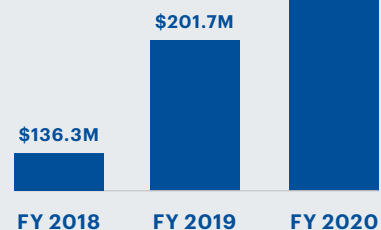
**Ex-U.S. Royalty Revenues**  
1st royalty from DSE in Q4

**Ex-U.S. Collaboration Milestones**  
>\$1 billion

## 2020 Revenue



## Cash, Cash Equivalents, Restricted Cash & Investment Securities Available for Sale





**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, 2020

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: 001-35986

**Esperion Therapeutics, Inc.**

(Exact Name of Registrant as Specified in its Charter)

Delaware

26-1870780

(State or Other Jurisdiction of Incorporation or Organization)

(I.R.S. Employer Identification No.)

3891 Ranchero Drive, Suite 150

Ann Arbor, MI 48108

(Address of principal executive office) (Zip Code)

Registrant's telephone number, including area code:

(734) 887-3903

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value	ESPR	NASDAQ Stock Market LLC

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. 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 Exchange Act. 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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes  No

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 the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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 Exchange Act.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

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

The aggregate market value of the voting stock held by non-affiliates of the registrant on June 30, 2020, based upon the closing price of \$51.31 of the registrant's common stock as reported on the NASDAQ Global Market, was \$1.41 billion. For purposes of foregoing calculation only, all directors and executive officers of the registrants are assumed to be affiliates of the registrant. This determination of affiliate status is not a determination for other purposes. As of February 1, 2021, there were 27,942,612 shares of the registrant's common stock, \$0.001 par value per share, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Part III of this Annual Report on Form 10-K incorporates by reference information from the definitive Proxy Statement for the registrant's 2021 Annual Meeting of Shareholders, which is expected to be filed with the Securities and Exchange Commission not later than 120 days after the Registrant's fiscal year ended December 31, 2020.

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## Summary of Material Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties that you should be aware of before making an investment decision, including those highlighted in the section entitled “Risk Factors.” These risks include, but are not limited to, the following:

- The current pandemic of the novel coronavirus (COVID-19) may have a material adverse effect on our business, financial condition, and results of operations.
- We depend almost entirely on the success of two products, bempedoic acid tablet and the bempedoic acid / ezetimibe combination tablet. There is no assurance that our commercialization efforts in the U.S. with respect to either product will be successful or that we will be able to generate revenues at the levels or within the timing we expect or at the levels or within the timing necessary to support our goals.
- We have limited operating history as a commercial company and limited experience in the marketing and sale of NEXLETOL® (bempedoic acid) tablet and NEXLIZET® (bempedoic acid and ezetimibe) tablets in the U.S.
- Our relationships with customers and third-party payors are subject to applicable anti-kickback, fraud and abuse, and other healthcare laws and regulations, and health information privacy and security laws, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings.
- Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.
- Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and may decrease the prices we may obtain for our approved drugs.
- The commercial success of our approved drugs, and of any future approved drugs, will depend upon, among other things, the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.
- We have obtained regulatory approval from the U.S. Food and Drug Administration, or FDA, the European Commission, or EC (which, with respect to the United Kingdom, converted to a Great Britain marketing authorization on January 1, 2021), and the Swiss Agency for Therapeutic Products, or Swissmedic, for both of our leading products as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia, or HeFH, or established atherosclerotic cardiovascular disease, or ASCVD, who require additional lowering of low density lipoprotein cholesterol, or LDL-C, but we cannot be certain that we will be able to obtain approval from regulatory authorities in other territories we or our ex-U.S. commercial partners decide to pursue, or successfully commercialize our products and any future product candidates. Additionally, we cannot be certain that we will be able to obtain approval of either of our products for any other indication or approval of any future product candidates.
- Failures or delays in the completion of our CLEAR cardiovascular outcomes trial, or CVOT, for bempedoic acid could result in increased costs to us and could delay, prevent or limit our ability to generate revenue and continue our business.
- Our approved drugs and any drug candidates for which we obtain marketing approval will be subject to ongoing enforcement of post-marketing requirements and we could be subject to substantial penalties, including withdrawal of our approved drugs or any future approved products from the market, if we fail to comply with all regulatory requirements or if we experience unanticipated problems with our approved drugs or any future approved products, when and if any of them are approved.
- We may need substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations.
- We may never achieve or maintain profitability.
- Manufacturing pharmaceutical products is complex and subject to product loss for a variety of reasons. We contract with third parties for the manufacture of bempedoic acid tablet and the bempedoic acid / ezetimibe combination tablet

for commercialization and clinical trials. This reliance on third parties increases the risk that we will not have sufficient quantities of our drugs or drug candidates or such quantities at an acceptable cost or quality, which could delay, prevent, or impair our development or commercialization efforts.

- If we are unable to adequately protect our proprietary technology or maintain issued patents which are sufficient to protect bempedoic acid and the bempedoic acid / ezetimibe combination tablet, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects.
- If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished.
- Servicing our debt may require a significant amount of cash.
- We may be at an increased risk of securities class action litigation.

The summary risk factors described above should be read together with the text of the full risk factors below, in the section entitled “Risk Factors” and the other information set forth in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations and future growth prospects.

## Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- our ability to successfully commercialize NEXLETOL® (bempedoic acid) tablet and NEXLIZET® (bempedoic acid and ezetimibe) tablets in the United States and any other jurisdictions where we may receive marketing approval in the future;
- our ability to obtain and maintain regulatory approval for our approved drugs or obtain and maintain regulatory approval for any of our current or future drug candidates, and any related restrictions, limitations, and/or warnings in the labels of NEXLETOL, NEXLIZET, NILEMDO™ (bempedoic acid) tablet and NUSTENDI™ (bempedoic acid and ezetimibe) tablet, or any of our current or future drug candidates that may receive marketing approval;
- the rate and degree of market acceptance for our approved drugs or any current or future drug candidate for which we may receive marketing approval;
- our ability and plans in continuing to build out our commercial infrastructure and successfully launch, market, and sell our approved drugs and any current or future drug candidate for which we may receive marketing approval;
- our ability to achieve clinical, regulatory or commercial milestones with our existing cash resources;
- the design, timing or outcome of our CVOT of bempedoic acid;
- our ability to realize the intended benefits of the commercial collaboration and license arrangement with Daiichi Sankyo Europe GmbH, or DSE, and Otsuka Pharmaceutical Co., Ltd., or Otsuka, and of our revenue interest purchase agreement with Eiger II SA LLC, or Oberland, an affiliate of Oberland Capital LLC;
- our ability to replicate positive results from a completed clinical study in a future clinical study;
- the potential benefits, effectiveness or safety of bempedoic acid and the bempedoic acid / ezetimibe combination tablets, as compared to statins and other low density lipoprotein cholesterol, or LDL-C, lowering therapies, either those currently available or those in development;
- our ability to respond and adhere to changes in regulatory requirements, including any requirement to conduct additional, unplanned clinical studies in connection with our pursuit of bempedoic acid and the bempedoic acid / ezetimibe combination tablets as LDL-C lowering therapies;
- guidelines relating to LDL-C levels and cardiovascular risk that are generally accepted within the medical community, including recent changes and any future changes to such guidelines;
- reimbursement policies, including any future changes to such policies or related legislative, executive, or administrative actions, and their impact on our ability to market, distribute and obtain payment for bempedoic acid and the bempedoic acid / ezetimibe combination tablets in the United States and in Europe, and, if approved, in other territories;
- the accuracy of our estimates of the size and growth potential of the LDL-C lowering market and the rate and degree of bempedoic acid and the bempedoic acid / ezetimibe combination tablets' market acceptance in the United States and in Europe, and, if approved, in other territories;

- our ability to comply with healthcare laws and regulations in the U.S. and any foreign countries, including, without limitation, those applying to the marketing and sale of commercial drugs;
- our ability to obtain and maintain intellectual property protection for bempedoic acid and the bempedoic acid / ezetimibe combination tablet without infringing on the intellectual property rights of others in the U.S., Europe and other territories;
- our ability to attract and retain key personnel, including scientific, clinical, commercial or management personnel;
- our plan and ability to establish strategic relationships or partnerships, as needed;
- our ability to meet our payment obligations under our revenue interest purchase agreement and to service the interest on our convertible notes and repay such notes, to the extent required;
- the impact of global economic and political developments on our business, including economic slowdowns or recessions that may result from the outbreak of COVID-19, which could harm our commercialization efforts, as well as the value of our common stock and our ability to access capital markets; and
- our ability to compete with other companies that are, or may be, developing or selling products that may compete with bempedoic acid and the bempedoic acid / ezetimibe combination tablet, in the United States and in Europe, and, if approved, in other territories.

These forward-looking statements are only predictions and we may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, so you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in Item 1A. Risk Factors, that could cause actual future results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Annual Report on Form 10-K and the documents that we have filed as exhibits to the Annual Report on Form 10-K with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by applicable law.



## PART I

*All brand names or trademarks appearing in this report are the property of their respective holders. Unless the context requires otherwise, references in this report to “Esperion” the “Company,” “we,” “us,” and “our” refer to Esperion Therapeutics, Inc.*

### Item 1. Business

#### Overview

We are the Lipid Management Company, a pharmaceutical company singularly focused on developing and commercializing affordable, oral, once-daily, non-statin medicines for patients struggling with elevated low-density lipoprotein cholesterol, or LDL-C. Our team of lipid experts are dedicated to lowering bad cholesterol through the discovery, development and commercialization of innovative medicines and their combinations with established medicines. Our first two products were approved by the U.S. Food and Drug Administration, or FDA, European Medicines Agency, or EMA, and Swiss Agency for Therapeutic Products, or Swissmedic, in 2020. Bempedoic acid and the bempedoic acid / ezetimibe combination tablets are oral, once-daily, non-statin, LDL-C lowering medicines for patients with atherosclerotic cardiovascular disease, or ASCVD, or heterozygous familial hypercholesterolemia, or HeFH.

On February 21, 2020, we announced that the FDA approved NEXLETOL as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or established ASCVD who require additional lowering of LDL-C. The effect of NEXLETOL on cardiovascular morbidity and mortality has not been determined. NEXLETOL is the first oral, once-daily, non-statin LDL-C lowering medicine approved since 2002 for indicated patients. NEXLETOL became commercially available in the U.S. on March 30, 2020.

On February 26, 2020, we announced that the FDA approved NEXLIZET as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or established ASCVD who require additional lowering of LDL-C. The effect of NEXLIZET on cardiovascular morbidity and mortality has not been determined. NEXLIZET is the first non-statin, LDL-C lowering fixed combination drug product ever approved. NEXLIZET became commercially available in the U.S. on June 4, 2020.

On April 6, 2020, we announced that the European Commission, or EC, approved NILEMDO (bempedoic acid) and NUSTENDI (bempedoic acid and ezetimibe) tablets for the treatment of hypercholesterolemia and mixed dyslipidemia, through the centralized marketing authorization procedure. The decision was applicable to all 27 European Union member states plus the United Kingdom (until December 31, 2020), Iceland, Norway and Liechtenstein. NILEMDO (bempedoic acid) and NUSTENDI (bempedoic acid and ezetimibe) are the branded product names for bempedoic acid and the bempedoic acid / ezetimibe combination tablets in Europe. NILEMDO is the first, oral, non-statin, LDL-C lowering medicine approved in Europe in almost two decades for indicated patients, and NUSTENDI is the first non-statin, LDL-C lowering combination medicine ever approved in Europe. In November 2020, we announced the commercial launch of NILEMDO and NUSTENDI in Germany. In December 2020, we announced the approval of NILEMDO and NUSTENDI in Switzerland. With respect to the United Kingdom, on January 1, 2021 all existing centralized marketing authorizations (which applied to our marketing authorizations for NILEMDO and NUSTENDI) were automatically converted to Great Britain marketing authorizations (under the Northern Ireland Protocol, centralized marketing authorizations remain valid for marketing products in Northern Ireland).

On April 17, 2020, we entered into a license and collaboration agreement, or the Otsuka Agreement, with Otsuka Pharmaceutical Co., Ltd., or Otsuka. Pursuant to the Otsuka Agreement, we granted Otsuka exclusive development and commercialization rights to bempedoic acid and the bempedoic acid / ezetimibe combination in Japan, or the Otsuka Territory. Otsuka will be responsible for all development, regulatory, and commercialization activities in Japan. In addition, Otsuka will fund all clinical development costs associated with the program in Japan. We estimate this amount to total up to \$100 million over the next few years. We received an upfront cash payment of \$60 million in April 2020 and will receive up to an additional \$450 million in total development and sales milestones. We will also receive tiered royalties ranging from 15 percent to 30 percent on net sales in Japan.

In 2019 we entered into a license and collaboration agreement with Daiichi Sankyo Europe GmbH, or DSE. Pursuant to the agreement, we have granted DSE exclusive commercialization rights to bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the European Economic Area and Switzerland, or the DSE Territory. DSE will be responsible for commercialization in the DSE Territory. We remain responsible for clinical development, regulatory and manufacturing activities for the licensed products globally, including in the DSE Territory. On June 18, 2020, we entered into an amendment to the license and collaboration agreement, or LCA Amendment, with DSE. In June 2020, we completed the transfer of the

MAAs for NILEMDO and NUSTENDI. Pursuant to the terms of the amendment, DSE paid us the second \$150 million milestone based on completion of the NUSTENDI MAA transfer rather than the first product sale in the EU. Prior to the execution of the LCA Amendment, the milestone payment was due upon the first commercial sale in Europe. Additionally, we and DSE have agreed to expand the territory in which DSE has exclusive commercialization rights to NILEMDO and NUSTENDI to include Turkey. DSE's designated affiliate in Turkey will be solely responsible, at its sole cost and expense, for all regulatory matters relating to such products in Turkey, including obtaining Regulatory Approval for such products in Turkey.

On December 3, 2020, we entered into a definitive agreement with Serometrix to in-license its oral, small molecule PCSK9 inhibitor program. Serometrix developed the oral proprotein convertase subtilisin/kexin type 9 inhibitors, or PCSK9 inhibitor, program with its proprietary technology to discover drugs for difficult protein targets. As part of the agreement, we made an upfront cash payment of \$12.5 million in December 2020 to Serometrix, with payments in future years tied to specific milestones.

We are conducting a global cardiovascular outcomes trial, or CVOT, —known as Cholesterol Lowering via Bempedoic Acid, an ACL-inhibiting Regimen (CLEAR) Outcomes. The trial is designed to evaluate whether treatment with bempedoic acid reduces the risk of cardiovascular events in patients who are statin averse and who have CVD or are at high risk for CVD. We initiated the CLEAR Outcomes CVOT in December 2016 and fully enrolled the study with over 14,000 patients in August 2019. The primary endpoint of the study is the effect of bempedoic acid on four types of major adverse cardiovascular events, or MACE (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, or coronary revascularization; also referred to as "four-component MACE"). CLEAR Outcomes is an event-driven trial and will conclude once the predetermined number of MACE endpoints occur. Based on estimated cardiovascular event rates, we expect to meet the target number of events in the second half of 2022. We intend to use positive results from this CVOT to support submissions for a CV risk reduction indication in the U.S., Europe and other territories.

## **Product Overview**

NEXLETOL is a first-in-class ATP Citrate Lyase, or ACL, inhibitor that lowers LDL-C by reducing cholesterol biosynthesis and up-regulating the LDL receptors. Completed Phase 3 studies conducted in more than 3,000 patients, with over 2,000 patients treated with NEXLETOL, demonstrated an average 18 percent placebo corrected LDL-C lowering when used in patients on moderate or high-intensity statins. NEXLETOL was approved by the FDA in February 2020 as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or established ASCVD who require additional lowering of LDL-C.

NEXLIZET contains bempedoic acid and ezetimibe and lowers elevated LDL-C through complementary mechanisms of action by inhibiting cholesterol synthesis in the liver and absorption in the intestine. Phase 3 data demonstrated NEXLIZET lowered LDL-C by a mean of 38 percent compared to placebo when added on to maximally tolerated statins. NEXLIZET was approved by the FDA in February 2020 as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or established ASCVD who require additional lowering of LDL-C.

NILEMDO is a first-in-class ACL inhibitor that lowers LDL-C by reducing cholesterol biosynthesis and up-regulating the LDL receptors. NILEMDO was approved by the EC in March 2020 for use in adults with primary hypercholesterolemia (heterozygous familial and non-familial) or mixed dyslipidemia, as an adjunct to diet in combination with a statin or statin with other lipid-lowering therapies in adult patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or alone or in combination with other lipid-lowering therapies as an adjunct to diet in adult patients who are statin-intolerant, or for whom a statin is contraindicated.

NUSTENDI contains bempedoic acid and ezetimibe and lowers elevated LDL-C through complementary mechanisms of action by inhibiting cholesterol synthesis in the liver and absorption in the intestine. NUSTENDI was approved by the EC in March 2020 for use in adults with primary hypercholesterolemia (heterozygous familial and non-familial) or mixed dyslipidemia, as an adjunct to diet in combination with a statin in adult patients unable to reach LDL-C goals with the maximum tolerated dose of a statin in addition to ezetimibe, alone in patients who are either statin-intolerant or for whom a statin is contraindicated, and are unable to reach LDL-C goals with ezetimibe alone, or as an adjunct to diet in adult patients already being treated with the combination of bempedoic acid and ezetimibe as separate tablets with or without statin.

### ***Mechanism of Action***

In November 2016, we announced the publication of "Liver-specific ATP Citrate Lyase inhibition by bempedoic acid decreases LDL-C and attenuates atherosclerosis," by Pinkosky et al., in *Nature Communications*. The paper outlines the

experiments and analyses undertaken by us and our collaborators to understand the mechanism of action for how bempedoic acid reduces LDL-C, including its specificity for the liver. Bempedoic acid is an adenosine triphosphate-citrate lyase, or ACL, inhibitor that lowers LDL-C by inhibition of cholesterol synthesis in the liver. ACL is an enzyme upstream of 3-hydroxy-3-methyl-glutaryl-coenzyme A, or HMG-CoA, reductase in the cholesterol biosynthesis pathway. Bempedoic acid and its active metabolite, ESP15228, require coenzyme A, or CoA, activation by very long-chain acyl-CoA synthetase 1, or ACSVL1, to ETC-1002-CoA and ESP15228-CoA, respectively. ACSVL1 is expressed primarily in the liver. Inhibition of ACL by ETC-1002-CoA results in decreased cholesterol synthesis in the liver and lowers LDL-C in blood via upregulation of low-density lipoprotein receptors.

### ***Cardiovascular Disease and Elevated LDL-C***

Cardiovascular disease, which includes heart attacks, strokes and other cardiovascular events, represents the number one cause of death globally. The American Heart Association, or AHA, estimates that more than 850,000 deaths in the United States were caused by cardiovascular disease on its 2020 Heart Disease and Stroke Statistics update.

Elevated LDL-C is well-accepted as a significant risk factor for cardiovascular disease. In the U.S. there are 96 million people, or more than 37 percent of the U.S. adult population, that have elevated levels of LDL-C. A consequence of elevated LDL-C is atherosclerosis, which is a disease characterized by the deposition of excess cholesterol and other lipids in the walls of arteries as plaque. The development of atherosclerotic plaques often leads to cardiovascular disease. The risk relationship between elevated LDL-C and cardiovascular disease was first defined by the Framingham Heart Study, which commenced in 1948 to define factors that contributed to the development of cardiovascular disease. The study enrolled participants who did not have any form of cardiovascular disease and followed them over a long period of time. Elevated LDL-C was identified early on as a key risk factor for the eventual development of cardiovascular disease.

The first marketed statin, lovastatin, was approved for use in the United States in 1987 as a therapy to lower elevated LDL-C levels. That same year, the National Cholesterol Education Program issued its first guidelines for the diagnosis and treatment of patients with elevated LDL-C. Over the subsequent 22 years, seven more statins were approved for use to lower elevated LDL-C levels.

In 1994 the first cardiovascular outcomes study with a statin was published. This study demonstrated a significant reduction in risk for total mortality and major cardiovascular events. A series of additional clinical outcomes studies with statins have each shown that lowering elevated LDL-C translated into reduced risk for major cardiovascular events. The relationship between the extent of LDL-C lowering and reduction in cardiovascular risk appeared to be linear, which has supported a hypothesis that lower LDL-C is associated with lower cardiovascular risk. This hypothesis was tested and proven in the TNT (Treating to New Targets) study where an on-treatment LDL-C level of 77 mg/dL associated with 80 mg of atorvastatin treatment translated into a statistically significant 22% reduction in risk of major cardiovascular events as compared with the 101 mg/dL on-treatment LDL-C level associated with 10 mg of atorvastatin.

### **Major Completed Clinical Outcomes Studies with Statin Therapies**

<b>Study name</b>	<b>4S</b>	<b>WOSCOPS</b>	<b>AFCAPS/ TexCAPS</b>	<b>TNT</b>	<b>JUPITER</b>
Study drug	Simvastatin	Pravastatin	Lovastatin	Atorvastatin	Rosuvastatin
No. of patients	4,444	6,595	6,605	10,001	17,803
Study design	Placebo controlled, monotherapy	Placebo controlled, monotherapy	Placebo controlled, monotherapy	Low dose vs high dose atorvastatin	Placebo controlled, monotherapy
Patient population	Secondary Prevention	Primary Prevention	Primary Prevention	Secondary Prevention	Primary Prevention
Baseline LDL-C (mg/dL)	188	192	156	98	108
LDL-C reduction	35%	26%	26%	21%	50%
CV RRR	35%	31%	37%	22%	44%

In November 2014, the results of the IMPROVE-IT (IMProved Reduction of Outcomes: Vytorin Efficacy International Trial) study were presented at the Scientific Sessions of the AHA. 18,144 patients with acute coronary syndrome were enrolled in IMPROVE-IT and were randomized to receive either 40 mg of simvastatin or 10 mg of ezetimibe/40 mg of simvastatin, and were followed until > 5,250 events (cardiovascular death, heart attack, documented unstable angina requiring hospitalization, coronary revascularization or stroke) occurred. The addition of ezetimibe to simvastatin resulted in a 6.4% relative risk

reduction (p=0.016) in the aggregate of the events described above. This was the first study to demonstrate incremental clinical benefit with a non-statin when added to a statin.

The direct relationship between lower LDL-C levels and reduced risk for major cardiovascular events has been consistently demonstrated in greater than 30 clinical studies completed over 28 years involving more than 175,000 patients. As a result, physicians are highly focused on lowering LDL-C levels in their patients, and we believe there is a trend towards even more aggressive LDL-C lowering. For example, in the United States, increased attention has been placed on aggressive LDL-C management by organizations such as the AHA and the American College of Cardiology, or ACC. Additionally, both the Canadian Cardiovascular Society and the Joint British Societies have supported even lower LDL-C treatment targets for high-risk patients. This has led to the combination of statins with non-statin medicines such as ezetimibe and PCSK9 inhibitors for certain patients to reach their LDL-C goals.

In November 2018, the ACC and the AHA issued new guidelines for the treatment of elevated LDL-C. For the first time since 2013, the guidelines returned to including specific, numerical LDL-C treatment thresholds for patients. The guidelines directed physicians to continue to focus on LDL-C lowering to reduce risk in primary and secondary prevention patients, and maintain adequate LDL-cholesterol levels of: 70 mg/dL for patients at very high-risk for future cardiovascular events and 100 mg/dL for patients without a history of ASCVD. The guidelines call for using statins first to achieve LDL-C thresholds, and then consider adding non-statin medicines.

For the first time ever in an LDL-C guideline, the 2018 recommendations encouraged physicians to consider the cost-effectiveness of drug treatment options, specifically referencing the low cost-effectiveness of PCSK9 inhibitors. In addition, the guidelines also recommended that primary prevention patients with diabetes start with a moderate-intensity statin, increasing to a high-intensity statin if needed. Non-statin drugs could be added to achieve LDL-C lowering of  $\geq 50\%$ . Furthermore, in higher risk primary prevention patients who need aggressive LDL-C lowering, and in whom a high intensity statin is not acceptable or tolerated, adding non-statin medicines is reasonable. Also, instead of using the term “statin intolerance,” the new guidelines prefer the use of “statin-associated side effects.”

### 2018 AHA/ACC Guidelines on the Management of Blood Cholesterol

Patient Cardiovascular Disease Risk	LDL-C Threshold for Treatment
Patients with ASCVD	$\geq 70$ mg/dL after statins
Patients with LDL-C $\geq 190$ mg/dL at baseline and/or HeFH	$\geq 100$ mg/dL after statins
Patients with diabetes	$\geq 70$ mg/dL to initiate treatment
Patients with statin-associated side effects	Use of nonstatins (oral first) is recommended in patients who cannot tolerate statins

#### ***Patients with HeFH or established ASCVD who require additional lowering of LDL-C —Market Opportunity for Bempedoic Acid and the Bempedoic Acid / Ezetimibe Combination Tablet***

We have developed bempedoic acid and the bempedoic acid / ezetimibe combination tablet as an adjunct to diet and maximally tolerated statin therapy for patients with HeFH or established ASCVD who require additional lowering of LDL-C. The severity of elevated LDL-C in these patients, their level of CVD risk and their therapeutic options all widely vary.

We, with the assistance of a third-party global pharma sales and marketing consultancy group, conducted primary market research and developed a U.S. demand forecast model for bempedoic acid. Approximately 350 U.S. healthcare providers, consisting of cardiologists, endocrinologists and primary care physicians, were interviewed and the prevalence of hypercholesterolemia and diagnosis rates were estimated based on a review of the medical literature. It is estimated that approximately 8.7 million patients in the United States currently taking statins require additional LDL-C lowering.

Muscle pain and weakness are the most common side effects experienced by statin users and the most common causes for discontinuing therapy. Moreover, a significant proportion of patients remain on statin therapy despite experiencing muscle-related side effects, and require additional LDL-C lowering therapies to help them achieve their LDL-C treatment goals. Accordingly, we believe that in the presence of an oral, once-daily, non-statin LDL-C lowering therapy, the statin intolerant market could grow substantially. According to our research, approximately 9.6 million patients in the United States are not on statins, need additional LDL-C lowering, and it is estimated that most are only able to tolerate less than the lowest approved daily starting dose of their statin and are therefore considered to be statin intolerant.

## **Patients with Homozygous Familial Hypercholesterolemia (HoFH)**

A small subpopulation of patients with extremely elevated levels of LDL-C, estimated to be approximately 1,100 patients in the U.S. and 26,000 patients in the world, suffer from homozygous familial hypercholesterolemia, or HoFH. HoFH is a serious and rare genetic disease and patients with HoFH lack or have dysfunctional LDL-receptors and cannot remove LDL-particles and LDL-C from the blood. As a result, untreated HoFH patients typically have LDL-C levels in the range of 450 mg/dL to 1,000 mg/dL. Microsomal triglyceride transfer protein, or MTP inhibitors, a PCSK9 inhibitor and an apolipoprotein B, or ApoB, antisense oligonucleotide are approved therapies to lower elevated LDL-C levels in patients with a clinical or laboratory diagnosis of HoFH. Given the serious safety concerns with the MTP inhibitor and ApoB antisense oligonucleotide, specifically hepatotoxicity, the FDA has restricted their usage to this narrow subpopulation.

### **Statin Therapy**

Statins are the standard of care for patients with hypercholesterolemia today and are highly effective at lowering LDL-C. This class of drugs includes atorvastatin calcium, marketed as Lipitor®, the most prescribed LDL-C lowering drug in the world, representing well over 50% of all statin prescriptions in the U.S. and around the world.

Statins are selective, competitive inhibitors of HMG-CoA reductase, a rate-limiting enzyme in the cholesterol biosynthesis pathway in liver cells. Statin inhibition of cholesterol synthesis increases the number of LDL receptors on the surface of liver cells. This increase in LDL receptors increases uptake of LDL particles into liver cells from the blood, thus lowering LDL-C levels. Statins are also thought to have a potential effect on cholesterol synthesis in skeletal muscle. This effect could be linked to the myalgia associated with statin use as seen in certain patients with statin intolerance.

The benefits of statin use in lowering LDL-C levels and improving cardiovascular outcomes are well documented. Despite the effectiveness of statins and their broad market acceptance, there are over 18 million diagnosed U.S. patients on maximally tolerated statin therapy (approximately 9 million patients who are currently taking a statin and over 9 million patients who can't or won't take statins and for whom their maximally tolerated statin is no statin at all) who are unable to reach their LDL-C goal on their maximally tolerated statin therapy alone. In rare but extreme cases, statins can lead to muscle breakdown, kidney failure and death. For these reasons, we believe there is a need for new oral, once-daily, non-statin medicines to treat patients with elevated LDL-C.

### **Other Approved Therapies**

#### ***PCSK9 Inhibitors***

PCSK9 inhibitors inhibit PCSK9, an enzyme involved in the degradation of LDL receptors. PCSK9 inhibitors are injectable, monoclonal antibodies to lower LDL-C. In 2015, the FDA approved two PCSK9 inhibitors: alirocumab, which was developed by Sanofi and Regeneron Pharmaceuticals, and evolocumab, which was developed by Amgen, Inc. These therapies were originally approved as an adjunct to diet and maximally tolerated statin therapy for patients with HeFH and/or ASCVD that require additional lowering of LDL-C. Additionally, evolocumab was approved as an adjunct to diet and other LDL-C lowering therapies for patients with HoFH. In 2016, Pfizer discontinued development of its PCSK9 inhibitor, bococizumab, due to unanticipated attenuation of LDL-C lowering over time in its Phase 3 studies.

In February 2017, Amgen announced top-line results for the FOURIER (**F**urther Cardiovascular **O**utcomes **R**esearch with PCSK9 **I**nhibition in Subjects with **E**levated **R**isk) CVOT where evolocumab demonstrated a statistically significant 15 percent reduction in the risk of cardiovascular events. Full results of FOURIER were presented at the Scientific Sessions of the American College of Cardiology in March 2017 and were published in the New England Journal of Medicine in March 2017. In December 2017, based upon the results of the FOURIER study, the indications for the use of evolocumab were updated to include reduction in risk of myocardial infarction, stroke and coronary revascularization in adults with established cardiovascular disease, and for use alone or in combination with other lipid-lowering therapies to reduce LDL-C in adults with primary hyperlipidemia.

In March 2018, Regeneron Pharmaceuticals and Sanofi announced top-line results for the ODYSSEY Outcomes CVOT where alirocumab demonstrated a statistically significant 15 percent reduction in the risk of cardiovascular events. Full results of ODYSSEY Outcomes were presented at the Scientific Sessions of the ACC in March 2018 and were published in the New England Journal of Medicine in November 2018. In April 2019, the FDA approved alirocumab to reduce the risk of heart attack, stroke, and unstable angina requiring hospitalization in adults with established CVD. On December 10, 2019, Regeneron Pharmaceuticals and Sanofi announced their intent to simplify their antibody collaboration for alirocumab by restructuring into

a royalty-based agreement. Under the restructuring, which was effective April 2020, Regeneron has sole U.S. rights to alirocumab and Sanofi has sole ex-U.S. rights to alirocumab.

As described in currently approved U.S. prescribing information, PCSK9 inhibitors have demonstrated reductions of LDL-C when added on to maximally tolerated statin therapy in patients with HeFH and/or ASCVD of up to 64%. When PCSK9 inhibitors were used in patients with hypercholesterolemia considered to be statin intolerant, LDL-C levels were reduced by 45-56%. PCSK9 inhibitors' U.S. prescribing information also now includes an indication for the reduction in risk of myocardial infarction, stroke and coronary revascularization in patients with established cardiovascular disease. In addition, evolocumab and alirocumab are indicated for use alone or in combination with other lipid-lowering agents for patient with primary hyperlipidemia, including familial and nonfamilial hypercholesterolemia. Notwithstanding the LDL-C lowering efficacy of PCSK9 inhibitors, we believe their adoption by patients, physicians, and payors could be adversely impacted by their higher cost, notwithstanding recent price reductions, substantial prior authorization processes, and their injectable route of administration.

### **Additional Injectable PCSK9 Inhibitors in Development**

Novartis AG is developing inclisiran and the new drug application, or NDA, for inclisiran was submitted to the FDA in December 2019. Unlike the PCSK9 antibodies from Regeneron Pharmaceuticals and Sanofi and Amgen, inclisiran is a long-acting RNA interference therapeutic agent that inhibits the synthesis of PCSK9. Findings from clinical studies suggest that inclisiran may be dosed every 6 months, with a 3 month timeframe only between first and second dose. Like the PCSK9 antibodies, inclisiran is an injectable therapy that lowers LDL-C between 45% to 58% in Phase 3 clinical testing. In November 2019, Novartis AG acquired The Medicines Company. The Medicines Company initiated the ORION-4 trial in October 2018 which is designed to evaluate cardiovascular outcomes in 15,000 people being treated with inclisiran or placebo.

### **Triglyceride Lowering Therapy**

Icosapent ethyl is ethyl esters of the omega-3 fatty acid, eicosapentaenoic acid, or EPA, obtained from fish oil. Its potential mechanisms of action include increased  $\beta$ -oxidation, inhibition of acyl-CoA:1,2-diacylglycerol acyltransferase, or DGAT, decreased lipogenesis in the liver, and increased plasma lipoprotein lipase activity. Icosapent ethyl is an oral drug that is administered daily in 4 grams per day taken as four 0.5-gram capsules or two 1-gram capsules twice daily with food. In 2012, the FDA approved icosapent ethyl, which was developed by Amarin Corporation, an adjunct to diet to reduce triglyceride, or TG, levels in adult patients with severe ( $\geq 500$  mg/dL) hypertriglyceridemia. In clinical trials, icosapent ethyl lowered triglycerides by approximately 27 percent in clinical trials.

In September 2018, Amarin announced top-line results for the REDUCE-IT (Reduction of Cardiovascular Events Outcomes) CVOT where icosapent ethyl was added to patients on stable statin therapy who had their LDL-C under control (median LDL-C levels of 75 mg/dL). Icosapent ethyl demonstrated a statistically significant 25 percent reduction in risk of cardiovascular events. Full results of REDUCE-IT were presented at the AHA in November 2018, and were published in The New England Journal of Medicine in January 2019. In December 2019, Amarin received FDA approval for icosapent ethyl as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with TG levels ( $\geq 150$  mg/dL) and established cardiovascular disease or diabetes mellitus and two or more additional risk factors for cardiovascular disease.

### **Ongoing Clinical Studies**

#### *Global Cardiovascular Outcomes Trial—CLEAR Outcomes*

CLEAR Outcomes is a Phase 3, event driven, randomized, multicenter, double-blind, placebo-controlled clinical study designed to evaluate whether treatment of bempedoic acid reduces the risk of cardiovascular events in patients with statin intolerance who have cardiovascular disease or are at high risk for cardiovascular disease. The primary endpoint of the study is the effect of bempedoic acid on major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, or coronary revascularization; also referred to as "four-component MACE"). CLEAR Outcomes is designed to provide 90 percent power to detect an approximately 15 percent relative risk reduction in the primary endpoint in the bempedoic acid treatment group as compared to the placebo group and is expected to complete with a minimum of 1,620 patients experiencing the primary endpoint.

The study over-enrolled with over 14,000 patients with hypercholesterolemia and high cardiovascular disease risk at over 1,200 sites in 32 countries. Eligible patients at high risk (LDL-C  $>100$  mg/dL in primary prevention) for cardiovascular disease or with cardiovascular disease (LDL-C between 100 mg/dL to 190 mg/dL in secondary prevention) and who are only able to

tolerate less than the lowest approved daily starting dose of a statin and considered statin adverse, were randomized to receive bempedoic acid 180 mg once-daily or placebo. The expected average baseline LDL-C level in all patients is between 135 mg/dL and 140 mg/dL.

CLEAR Outcomes will conclude once the predetermined number of MACE endpoints occur. We initiated CLEAR Outcomes in December 2016 and completed enrollment in August 2019. The expected average treatment duration will be 3.75 years with a minimum treatment duration of approximately 2.25 years. Based on estimated cardiovascular event rates, we expect to meet the target number of events in the second half of 2022. The study is intended to support our submissions for a CV risk reduction indication in the U.S., Europe and other territories. During the third quarter of 2020, we accumulated 50% of the primary 4-component MACE endpoints.

## **Revenue**

We derive revenue through two primary sources: product sales and collaboration revenue. Product sales is related to our sales of NEXLETOL and NEXLIZET in the U.S. NEXLETOL was commercially available in the U.S. on March 30, 2020 and NEXLIZET was commercially available in the U.S. on June 4, 2020. Collaboration revenue consists of the collaboration payments made to us under our collaboration arrangements outside of the U.S. for the development and commercialization of our product candidates by our partners. Collaboration revenue also includes royalty revenue and sales of bulk tablets of our products to our collaboration partners.

During the year ended December 31, 2020, we recognized \$13.0 million in net product sales of NEXLETOL and NEXLIZET and \$214.6 million in collaboration revenue, primarily due to a \$150.0 million milestone payment from DSE and a \$60.0 million upfront payment from Otsuka. During the year ended December 31, 2019, we recognized \$148.4 million of revenue associated with the \$150.0 million upfront payment under our collaboration agreement with DSE. We recognized the remaining \$1.6 million during the year ended December 31, 2020, related to the performance obligation for the regulatory efforts to the MAA in the DSE Territory, which was transferred to DSE in June 2020.

If we fail to complete the development of bempedoic acid or the bempedoic acid / ezetimibe combination tablet, or any other product candidates we may develop, and secure additional approvals from regulatory authorities outside the U.S. and Europe, our ability to generate future revenue and our results of operations and financial position may be adversely affected.

## **Research and Development Expenses**

Research and development expenses for the year ended December 31, 2020, were \$146.9 million, which was primarily related to clinical development costs relating to the ongoing CLEAR Outcomes CVOT, product manufacturing supply prior to FDA and EMA approval and compensation related costs, including stock-based compensation.

## **Selling, General and Administrative**

We established our commercialization and distribution capabilities with the commercial launch of NEXLETOL and NEXLIZET in the U.S. and will continue to grow our commercial operations. We announced a collaboration agreement for the commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the DSE Territory in 2019 and the Otsuka Territory in 2020. We plan to continue to invest additional resources to develop our commercial infrastructure, such as hiring and training key commercial personnel and working with payors related to market access to expand the commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the United States as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or established ASCVD who require additional lowering of LDL-C.

We continue to engage in partnering discussions with potential third-party collaborators. We intend to seek approval and launch commercial sales of the bempedoic acid and the bempedoic acid / ezetimibe combination tablet in territories outside of the United States, Europe and Japan by establishing additional collaborations with one or more pharmaceutical company collaborators, depending on, among other things, the applicable indications, the related development costs and our available resources.

## **Manufacturing and Supply**

Bempedoic acid and the bempedoic acid / ezetimibe combination tablet are small molecule drugs that are synthesized from readily available raw materials using conventional chemical processes. We currently have no manufacturing facilities. We rely on contract manufacturers to produce both drug substances and drug products required for our commercial supply and clinical

studies. All lots of drug substance and drug product used in commercial supply and clinical studies are manufactured under current good manufacturing practices. We plan to continue to rely upon contract manufacturers and, potentially, collaboration partners to manufacture commercial quantities of the bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the United States and in Europe and, if approved, in territories outside of the United States and Europe.

### **Licenses and Collaboration Agreements**

In April 2008, we entered into an asset transfer agreement with Pfizer pursuant to which we acquired all intellectual property owned by Pfizer relating exclusively to the bempedoic acid program. We also entered into a license agreement providing a worldwide, exclusive, fully paid-up license of certain residual background intellectual property not transferred pursuant to the asset transfer agreement, and we granted Pfizer a worldwide, exclusive, fully paid-up license to certain patent rights owned or controlled by us relating to development programs other than bempedoic acid. The license to us covers the development, manufacturing and commercialization of bempedoic acid. There are no restrictions or limitations and we may grant sublicenses under the license agreements. Pfizer is not entitled to any royalties, milestones or any similar development or commercialization payments under the terms of the agreements, and the licenses granted are irrevocable and may not be terminated for any cause, including intentional breaches or breaches caused by gross negligence.

On January 2, 2019, we entered into a license and collaboration agreement, or LCA, with DSE. Pursuant to the agreement, we have granted DSE exclusive commercialization rights to bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the European Economic Area and Switzerland, or the DSE Territory. DSE will be responsible for commercialization in the DSE Territory. We remain responsible for clinical development, regulatory and manufacturing activities for the licensed products globally, including in the DSE Territory. On June 18, 2020, we entered into an amendment to the LCA Amendment with DSE to include Turkey. DSE's designated affiliate in Turkey will be solely responsible, at its sole cost and expense, for all regulatory matters relating to such products in Turkey, including obtaining Regulatory Approval for such products in Turkey.

On April 17, 2020, we entered into a license and collaboration agreement, or the Otsuka Agreement, with Otsuka Pharmaceutical Co., Ltd., or Otsuka. Pursuant to the Otsuka Agreement, we granted Otsuka exclusive development and commercialization rights to bempedoic acid and the bempedoic acid / ezetimibe combination tablet in Japan. Otsuka will be responsible for all development, regulatory, and commercialization activities in Japan. In addition, Otsuka will fund all clinical development costs associated with the program in Japan.

On December 3, 2020, we entered into a definitive agreement with Serometrix to in-license its oral, small molecule PCSK9 inhibitor program. Serometrix developed the oral PCSK9 inhibitor program with its proprietary technology to discover drugs for challenging protein targets.

For additional details on the DSE, Otsuka and Serometrix agreements, see Note 3 to our audited financial statements appearing elsewhere in this Annual Report on Form 10-K.

### **Intellectual Property**

We strive to protect and enhance the proprietary technologies that we believe are important to our business, including seeking and maintaining patents intended to cover our products and compositions, their methods of use and any other inventions that are important to the development of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain the proprietary position of bempedoic acid, the bempedoic acid / ezetimibe combination tablet and our other development programs.

As of December 31, 2020, our patent estate, including patents we own, on a worldwide basis, included approximately 24 issued United States patents and seven pending United States patent applications and over 20 issued patents and over 75 pending patent applications in other foreign jurisdictions. Of our worldwide patent estate, only a subset of our patents and pending patent applications relates to our bempedoic acid program.

Bempedoic acid is claimed in U.S. Patent No. 7,335,799 that is scheduled to expire in December 2025, which includes 711 days of patent term adjustment, and may be eligible for a patent term extension period of up to five years. We have requested a



five year patent term extension of U.S. Patent No. 7,335,799, and we believe that this patent could be the subject of an additional six month pediatric exclusivity period. In addition, U.S. Patent Nos. 9,000,041, 8,497,301, 9,624,152 and 10,118,881, which are scheduled to expire in December 2023, claim methods of using bempedoic acid. There are currently seven issued patents in countries outside the United States, including, Brazil, Canada, Europe, Japan and Mexico, that relate to bempedoic acid and its use. Furthermore, of the seven granted patents, we have two granted European patents that have been validated in numerous European countries including France, Germany, Great Britain, Ireland, Italy, the Netherlands, Spain, Sweden and Switzerland. We are seeking five year patent term extensions via supplementary protection certificates for 23 national patents validated from one of the granted European patents, which, if approved, could extend our patent protection in those countries until 2028.

In addition, we have three patent families in which we are pursuing patent protection for our bempedoic acid and bempedoic acid / ezetimibe combination tablet in combination with one or more statins. We have two pending U.S. patent applications and 19 pending applications outside the U.S. with claims directed to methods of treatment using the bempedoic acid / ezetimibe combination tablet. Additionally, we have one pending U.S. patent application and 23 pending applications outside of the U.S. directed to the manufacturing of our bempedoic acid / ezetimibe combination tablet. We also have one pending U.S. patent application and 18 pending applications outside the U.S., with claims directed to methods of treatment using a fixed dose combination of bempedoic acid and one or more statins.

In addition to the patents we own, we also hold an exclusive, worldwide, fully paid-up license on any residual background intellectual property not transferred from Pfizer pursuant to the asset transfer agreement.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing a non-provisional application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent. In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period. However, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. We have submitted a request for a patent term extension in the United States for U.S. Patent No. 7,335,799 and have been seeking supplementary protection certificates for one of the granted, counterpart European patents. However, the applicable authorities, including the FDA and the U.S. Patent and Trademark Office, or USPTO, in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also twenty years from the earliest effective filing date. Our issued U.S. patents, including patent term extensions we may be eligible for, will expire on dates ranging from 2021 to mid-2031. However, the actual protection afforded by a patent varies on a claim by claim basis for each applicable product, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Furthermore, the patent positions of biotechnology and pharmaceutical products and processes like those we intend to develop and commercialize are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in such patents has emerged to date in the U.S. The patent situation outside the U.S. is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries can diminish our ability to protect our inventions, and enforce our intellectual property rights and more generally, could affect the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Our ability to maintain and solidify our proprietary position for our drugs and technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of the patent applications that we may file or license from third parties will result in the issuance of any patents. The issued patents that we own or may receive in the future, may be challenged, invalidated or circumvented, and the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may be able to independently develop and commercialize similar drugs or duplicate our technology, business model or strategy without infringing our patents. Because of the extensive time required for clinical development and regulatory review of a drug we may develop, it is possible that, before any of our drugs can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of any such patent.

We may rely, in some circumstances, on trade secrets and unpatented know-how to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our consultants, vendors, collaborators, scientific advisors, contractors and other third parties and invention assignment agreements with our employees. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, vendors, collaborators, scientific advisors, contractors or other third parties use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For more information, please see “Risk Factors—Risks Related to our Intellectual Property.”

Our commercial success will also depend in part on not infringing the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our drugs or processes, obtain licenses or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize bempedoic acid, the bempedoic acid / ezetimibe combination tablet, or any other product candidates may have a material adverse impact on us. If third parties prepare and file patent applications in the U.S. that also claim technology to which we have rights, we may have to participate in an interference or derivation proceeding at the USPTO, to determine who is entitled to claim invention.

In addition, substantial scientific and commercial research has been conducted for many years in the areas in which we have focused our development efforts, which has resulted in third parties having a number of issued patents and pending patent applications. Patent applications in the U.S. and elsewhere are published only after eighteen months from the priority date. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Therefore, patent applications relating to drugs similar to bempedoic acid and any future drugs, discoveries or technologies we might develop may have already been filed by others without our knowledge.

## **Competition**

Our industry is highly competitive and subject to rapid and significant technological change. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. Key competitive factors affecting the commercial success of our product candidates are likely to be efficacy, safety and tolerability profile, reliability, convenience of dosing, price and reimbursement.

The market for cholesterol regulating therapies is especially large and competitive. The product candidates we are currently developing will face intense competition, either as monotherapies or as combination therapies.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a small number of our competitors. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. Finally, the development of new treatment methods for the diseases we are targeting could render our drugs non-competitive or obsolete. See “Risk Factors—Risks Related to Sales, Marketing, and Competition—Our market is subject to intense competition. If we are unable to compete effectively, our opportunity to generate revenue from the sale of bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the U.S., in Europe and, if approved, other territories will be materially adversely affected.”

## **Regulatory Matters**

### ***Government Regulation and Product Approval***

Government authorities in the United States at the federal, state and local level, and in other countries, extensively regulate, among other things, the research, and clinical development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, pricing, export and import of drug products such as those we are developing and have developed. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety, and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review, and approved by the regulatory authority.

Drugs are also subject to other federal, state, and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable regulatory requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the regulatory authority's refusal to approve pending applications, withdrawal of an approval, clinical holds, untitled or warning letters, voluntary product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, debarment, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

### **United States Drug Review and Approval**

#### ***United States Drug Development Process***

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, voluntary product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of extensive preclinical, sometimes referred to as nonclinical, laboratory tests, animal studies and formulation studies all performed in accordance with applicable regulations, including the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an Investigational New Drug, or IND, which must become effective before human clinical trials may begin and must be updated annually;
- performance of adequate and well-controlled human clinical trials in accordance with the applicable IND and other clinical trial-related regulations, sometimes referred to as Good Clinical Practices, or GCP, to establish the safety and efficacy of the proposed drug for its proposed indication;
- submission to the FDA of an NDA for a new drug;
- a determination by the FDA within 60 days of its receipt of a NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the active pharmaceutical ingredient, or API, and finished drug product are produced to assess compliance with current good manufacturing process, or cGMP;
- satisfactory completion of any FDA inspections of clinical trial sites, sponsor, and/or clinical research organizations to assess compliance with GCP and assure the integrity of clinical data in support of the NDA;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA; and

- FDA review and approval of the NDA.

Once a pharmaceutical product candidate is identified for development, it enters the nonclinical, also referred to as preclinical, testing stage. Nonclinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. An investigational new drug, or IND, sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical study, dosing procedures, subject selection and exclusion criteria, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical study lends itself to an efficacy evaluation. Some nonclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical study on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical studies due to safety concerns or non-compliance, and may be imposed on all drug products within a certain class of drugs. The FDA also can impose partial clinical holds, for example prohibiting the initiation of clinical studies of a certain duration or for a certain dose.

All clinical studies must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent. Further, an institutional review board, or IRB, must review and approve the plan for any clinical study before it commences at any institution. An IRB considers, among other things, whether the risks to individuals participating in the clinical study are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical study and the consent form that must be provided to each clinical study subject or his or her legal representative and must monitor the clinical study until completed.

Each new clinical protocol and any amendments to the protocol must be submitted to the IND for FDA review, and to the IRBs for approval. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

Human clinical studies are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The product is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing may be conducted in patients.
- *Phase 2.* Involves clinical studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage and schedule.
- *Phase 3.* Clinical studies are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical studies are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA and IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events, including any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator's brochure, or any findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the product candidate. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Concurrent with clinical studies, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested

and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

### ***NDA and FDA Review Process***

The results of product development, nonclinical studies and clinical studies, along with descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA for a new drug, requesting approval to market the product. The submission of an NDA is subject to the payment of a substantial user fee; a waiver of such fee may be obtained under certain limited circumstances. For example, the agency will waive the application fee for the first human drug application that a small business or its affiliate submits for review. The Company obtained a Small Business Waiver from the FDA related to bempedoic acid. There is also an annual prescription drug program fee for each approved prescription drug product on the market.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, as amended made into permanent law pursuant to Food and Drug Administration Safety and Innovation Act (FDASIA), an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be re-submitted with the additional information. The re-submitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also can require, or an NDA applicant may voluntarily propose, a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of a drug outweigh its risks. Elements of a REMS may include "dear doctor letters," a medication guide, and in some cases restrictions on distribution. These elements are negotiated as part of the NDA approval, and in some cases may delay the approval date. Once adopted, REMS are subject to periodic assessment and modification. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. An advisory committee is a panel of experts who provide advice and recommendations when requested by the FDA on matters of importance that come before the agency. The FDA is not bound by the recommendation of an advisory committee.

The approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical studies are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA will issue a complete response letter if the agency decides not to approve the NDA in its present form. The complete response letter usually describes all of the specific deficiencies that the FDA identified in the NDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical studies. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing.

### ***Post-Marketing Requirements***

Following approval of a new drug, a pharmaceutical company and the approved drug are subject to continuing regulation by the FDA, including, among other things, establishment registration and drug listing, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the drug, providing the regulatory authorities with updated safety and efficacy information, drug sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as off-label promotion), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs for off-label uses, the FDA takes the position that manufacturers may not market or promote such off-label uses. Modifications or enhancements to the drug or its labeling or

changes of the site or process of manufacturing are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process.

Prescription drug advertising is subject to federal, state, and foreign regulations. In the U.S., the FDA regulates prescription drug promotion, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drugs and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act, or the PDMA, a part of the FDCA. The Drug Supply Chain Security Act, or DSCSA, was enacted in 2013 with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the U.S. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period that is expected to culminate in November 2023. The law's requirements include the quarantine and prompt investigation of a suspect product to determine if it is illegitimate and notifying trading partners and the FDA of any illegitimate product. Drug manufacturers and their collaborators are also required to place a unique product identifier on prescription drug packages. This identifier consists of the National Drug Code, serial number, lot number, and expiration date, in the form of a 2-dimensional data matrix barcode that can be read by humans and machines.

In the U.S., once a drug is approved, its manufacturing is subject to comprehensive and continuing regulation by the FDA. FDA regulations require that drugs be manufactured in specific facilities per the NDA approval and in accordance with cGMP. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our approved drug and drug candidates in accordance with cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacturing and distribution of approved drugs 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 and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural, and documentation requirements with respect to manufacturing and quality assurance activities. NDA holders using contract manufacturers, laboratories, or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute drugs manufactured, processed, or tested by them. Discovery of problems with a drug after approval may result in restrictions on a drug, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the drug from the market, and may require substantial resources to correct.

The FDA also may require post-approval testing, sometimes referred to as Phase 4 testing, risk minimization action plans, and post-marketing surveillance to monitor the effects of an approved drug or place conditions on an approval that could restrict the distribution or use of the drug, such as the FDA has imposed and we have agreed to for NEXLETOL and NEXLIZET. Specifically, as part of our NEXLETOL and NEXLIZET approval, the FDA has required both a pharmacokinetics / pharmacodynamics, or PK/PD, and Phase 3 study evaluating bempedoic acid in patients with HeFH aged 10 years to less than 18 years, a worldwide descriptive study that collects prospective and retrospective data in women exposed to NEXLETOL and NEXLIZET during pregnancy to assess the risk of pregnancy and maternal complications, adverse effects on the developing fetus and neonate, and adverse effects on the infant through the first year of life, a lactation study to analyze milk in lactating women who have received therapeutic doses of NEXLETOL and NEXLIZET, and that we complete the ongoing CLEAR CVOT trial.

Discovery of previously unknown problems with a drug or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial, or administrative enforcement, untitled or warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a drug's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures, including a REMS or the conduct of post-marketing studies to assess a newly discovered safety issue. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our drug candidates under development.

### ***Other Regulatory Matters***

Manufacturing, sales, promotion, and other activities following drug approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the U.S., the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, or HHS, the Drug Enforcement Administration for

controlled substances, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments. In the U.S., sales, marketing, and scientific/educational programs must also comply with state and federal fraud and abuse laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010 (or collectively, the ACA). If drugs are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Drugs must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion, and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

We are subject to numerous foreign, federal, state, and local environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes. In addition, our leasing and operation of real property may subject us to liability pursuant to certain U.S. environmental laws and regulations, under which current or previous owners or operators of real property and entities that disposed or arranged for the disposal of hazardous substances may be held strictly, jointly, and severally liable for the cost of investigating or remediating contamination caused by hazardous substance releases, even if they did not know of and were not responsible for the releases.

The distribution of pharmaceutical drugs is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage, and security requirements intended to prevent the unauthorized sale of pharmaceutical drugs.

The failure to comply with regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines, or other penalties, injunctions, voluntary recall or seizure of drugs, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of our approved drug or any future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes, or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our product; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

#### ***Patent Term Restoration and Marketing Exclusivity***

Depending upon the timing, duration and specifics of FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. We applied for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration dates, depending on the expected length of the clinical studies and other factors involved in the filing of the relevant NDA, however there can be no assurance that any such extension will be granted to us.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity

for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the nonclinical studies and adequate and well- controlled clinical studies necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of exclusivity in the United States. Pediatric exclusivity, if granted, provides an additional six months to an existing exclusivity or statutory delay in approval resulting from a patent certification. This six-month exclusivity, which runs from the end of other exclusivity protection or patent delay, may be granted based on the voluntary completion of a pediatric clinical study in accordance with a FDA-issued "Written Request" for such a clinical study.

Certain foreign countries permit extension of patent term for a newly approved drug and/or grant a period of data exclusivity and/or market exclusivity. For example, depending upon the timing and duration of the marketing authorization process in certain European countries, a newly approved drug may be eligible for a supplementary protection certification, or SPC, which can extend the basic patent right for the drug for a period up to five years.

### ***Coverage and Reimbursement***

Sales of NEXLETOL and NEXLIZET and any future approved drugs will depend, in part, on the extent to which such drugs will be covered by third-party payors, such as government health programs, commercial insurers, and managed healthcare organizations, as well as the level of reimbursement such third-party payors provide for our products. Patients and providers are unlikely to use NEXLETOL and NEXLIZET or any future approved drugs unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such drugs. These third-party payors are increasingly reducing reimbursements for medical drugs and services.

In the U.S., no uniform policy of coverage and reimbursement for drugs or biological products exists, and one payor's determination to provide coverage and adequate reimbursement for a product does not assure that other payors will make a similar determination. In the U.S., the principal decisions about reimbursement for new medicines are typically made by the CMS, an agency within the HHS, as the CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private third-party payors tend to follow Medicare coverage and reimbursement limitations to a substantial degree, but also have their own methods and approval process apart from Medicare determinations. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for NEXLETOL and NEXLIZET or any of our future drug candidates, if approved, are made on a payor-by-payor basis. As a result, the coverage determination process may be a time-consuming and costly process that will require us to provide scientific and clinical support for the use of NEXLETOL and NEXLIZET or any future approved drugs to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high.

Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution of generic drugs. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for NEXLETOL and NEXLIZET or any of our future drug candidates, if approved, or a decision by a third-party payor to not cover NEXLETOL and NEXLIZET or any of our future drug candidates could reduce physician usage of such drugs and have a material adverse effect on our sales, results of operations and financial condition.

The Medicaid Drug Rebate Program, or MDRP requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the MDRP, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate percentage on most branded prescription drugs of average manufacturer price, or AMP, and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, creating a new methodology by which rebates owed are calculated for drugs that are inhaled, infused, instilled, implanted, or injected, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates



on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Parts A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. These Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for NEXLETOL and NEXLIZET or any future drug candidates for which we may obtain marketing approval. However, any negotiated prices for NEXLETOL and NEXLIZET or any future drugs covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. The plan for the research was published in 2012 by the HHS, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures are made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of NEXLETOL and NEXLIZET or any of our future drug candidates for which we may obtain marketing approval, if any such drug or the condition that they are intended to treat are the subject of a trial. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's drug could adversely affect the sales of NEXLETOL and NEXLIZET or any of our future drug candidates for which we may obtain marketing approval. If third-party payors do not consider NEXLETOL and NEXLIZET or any future drugs to be cost-effective compared to other available therapies, they may not cover such drugs as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell such drugs on a profitable basis.

In recent years, additional laws have resulted in direct or indirect reimbursement reductions for certain Medicare providers, including:

- The Budget Control Act of 2011, or BCA, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2029 unless additional Congressional action is taken.
- The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for NEXLETOL and NEXLIZET or any future drug candidates for which we may obtain regulatory approval or the frequency with which NEXLETOL and NEXLIZET or any such drug candidate is prescribed or used.

### ***Other Healthcare Laws***

For our drugs and any future drug candidates that obtain regulatory approval and are marketed in the U.S., our arrangements with third-party payors, customers, and other third parties may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute NEXLETOL and NEXLIZET or any future products candidates for which we obtain marketing approval. In addition, we may be subject to health information privacy and security regulation by U.S. federal and state governments and foreign jurisdictions in which we conduct our business. In the U.S., these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below:

- The federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party on its behalf) to, knowingly and willfully offer, solicit, receive, or pay remuneration (including any kickback, bribe, or rebate), directly or indirectly, in cash or in kind, that is intended to induce or reward, or in return for, either the referral of an individual for, or the purchase, order, or recommendation of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs. Violations of this law are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, administrative civil monetary penalties, and exclusion from participation in government healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers, and formulary managers, on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances.
- The federal civil and criminal false claims laws, including the federal False Claims Act, impose criminal and civil penalties, and authorizes civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal healthcare program; making, using, or causing to be made or used, a false statement or record material to payment of a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the federal Anti-Kickback Statute are false or fraudulent claims for purposes of the False Claims Act. Our marketing and activities relating to the reporting of wholesaler or estimated retail prices for NEXLETOL and NEXLIZET or any future product candidates, the reporting of prices used to calculate Medicaid rebate information, and other information affecting federal, state, and third-party reimbursement for NEXLETOL and NEXLIZET or any future product candidates, and the sale and marketing of NEXLETOL and NEXLIZET and any future product candidates, are subject to scrutiny under this law.
- The anti-inducement law, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program.
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or

property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly or willfully falsifying, concealing or covering up by any trick or device a material fact, or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services relating to healthcare matters. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses and their business associates, that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms and required implementation of technical safeguards of such information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damage or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.
- The federal false statements statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services.
- Federal price reporting laws require drug manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products.
- The federal Physician Payments Sunshine Act, or Sunshine Act, enacted as part of the ACA, and its implementing regulations, require certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to the HHS under the Open Payments Program, information related to payments and other "transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners. In addition, many states also require the reporting of payments or other transfers of value. Many of these state laws differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.
- Analogous state and foreign laws and regulations, such as state anti-kickback, false claims laws, consumer protection, and unfair competition laws, which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales, and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers. Such laws are enforced by various state agencies and through private actions. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant federal government compliance guidance that otherwise restricts payments that may be made to healthcare providers and other potential referral sources, require drug manufacturers to report information related to pricing and marketing information, such as the tracking and reporting of gifts, compensations, and other remuneration and items of value provided to physicians and other healthcare providers and entities, require the registration of pharmaceutical sales representatives, and restrict marketing practices or require disclosure of marketing expenditures. State and foreign laws also govern the privacy and security of health information in certain circumstances. Such data privacy and security laws may differ from one another in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

In California, the California Consumer Privacy Act, or CCPA, was enacted in June 2018, became effective on January 1, 2020, and became subject to enforcement by the California Attorney General's office on July 1, 2020. The CCPA broadly defines personal information, and creates new individual privacy rights and protections for California consumers (as defined in the law), places increased privacy and security obligations on entities handling personal data of consumers or households, and provides for civil penalties for violations and a private right of action for data breaches. The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected

California residents with ways to opt-out of certain sales or transfers of personal information. While there is an exception for protected health information that is subject to HIPAA and clinical trial regulations, the CCPA may impact our business activities if we become a "Business" regulated by the scope of the CCPA.

In addition to the CCPA, new privacy and data security laws have been proposed in more than half of the states in the U.S. and in the U.S. Congress, reflecting a trend toward more stringent privacy legislation in the U.S., which trend may accelerate depending on the new U.S. presidential administration. The effects of the CCPA, and other similar state or federal laws, are potentially significant and may require us to modify our data processing practices and policies and to incur substantial costs and potential liability in an effort to comply with such legislation.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry. In November 2020, the OIG issued a Fraud Alert highlighting its view that pharmaceutical promotional speaker programs can pose a high risk of fraud and abuse. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other related governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, individual imprisonment, disgorgement, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, as well as additional oversight, and reporting obligations if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

## **European Union Regulatory Considerations**

### ***European Union Drug Development***

In the European Union, or EU, NILEMDO and NUSTENDI and any other of our product candidates are also subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the U.S., the various phases of preclinical and clinical research in Europe are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC, or the Directive, sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the Member State regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU Member States where the trial is to be conducted by two distinct bodies: the National Competent Authority, or NCA, and one or more Ethics Committees, or ECs. All suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the member state where they occurred.

In 2014, a new Clinical Trials Regulation 536/2014, or the Regulation, replacing the current Directive, was adopted. The new Regulation will become directly applicable in all EU Member States (without national implementation) following confirmation of the full functionality of the Clinical Trials Information System, the centralized EU portal and database for clinical trials foreseen by the new Regulation, through an independent audit. This is currently expected to occur in December 2021. The new Regulation seeks to simplify and streamline the approval of clinical trials in the EU. For example, the sponsor shall submit a single application for approval of a clinical trial via the EU Portal. As part of the application process, the sponsor shall propose a reporting Member State, who will coordinate the validation and evaluation of the application. The reporting Member State shall consult and coordinate with the other Member States in which the clinical trial is to take place (such Member States being referred to as the Member States Concerned). If an application is rejected, it can be amended and resubmitted through the EU Portal. If an approval is issued, the sponsor can start the clinical trial in all Member States Concerned. However, a Member State Concerned can, in limited circumstances, declare an "opt-out" from an approval. In such a case, the clinical trial cannot be conducted in that Member State. The Regulation also aims to streamline and simplify the

rules on safety reporting and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to the EU Database.

The UK has implemented Directive 2001/20/EC into national law through the Medicines for Human Use (Clinical Trials) Regulations, so UK regulation of clinical trials is currently aligned with EU regulations. Whether the UK will amend its legislation to align more closely with the new EU Regulation once that comes into effect is as yet unknown.

### ***European Union Drug Review and Approval***

In the EEA, medicinal products can only be commercialized after obtaining an EU marketing authorization. There are two types of marketing authorizations.

The first is the centralized marketing authorization, which is issued by the European Commission through the Centralized Procedure, or CP, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP of the EMA. A centralized marketing authorization is valid throughout the entire territory of the EEA. The CP is mandatory for certain types of drugs, such as biotechnology medicinal drugs, advanced-therapy medicines (gene-therapy, somatic cell-therapy or tissue-engineered medicines), orphan medicinal drugs, and medicinal drugs containing a new active substance indicated for the treatment of HIV or AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions, and viral diseases. The CP is optional for drugs containing a new active substance not yet authorized in the EEA, or for drugs that constitute a significant therapeutic, scientific, or technical innovation or which are in the interest of public health in the EU.

National marketing authorizations, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for drugs not falling within the mandatory scope of the CP. Where a drug has already been authorized for marketing in a member state of the EEA, this national authorization can be recognized in other Member States through the Mutual Recognition Procedure. If the drug has not received a national authorization in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which authorization is sought, one of which is selected by the applicant as the Reference Member State (RMS). The competent authority of the RMS prepares a draft assessment report, a draft summary of the drug characteristics (SPC), and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Concerned Member States) for their approval. If the Concerned Member States raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the drug is subsequently granted a national marketing authorization in all the Member States (i.e., in the RMS and the Concerned Member States).

Under the above described procedures, before granting the marketing authorization, the EMA or the Competent Authorities of the Member States of the EEA make an assessment of the risk benefit balance of the product on the basis of scientific criteria concerning its quality, safety, and efficacy.

On June 23, 2016, the electorate in the UK voted in favor of leaving the EU (commonly referred to as Brexit). Thereafter, on March 29, 2017, the country formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The UK formally left the EU on January 31, 2020. A transition period began on February 1, 2020, during which EU pharmaceutical law remained applicable to the UK and ended on December 31, 2020. Since the regulatory framework for pharmaceutical products in the UK covering quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the UK, as the UK legislation now has the potential to diverge from EU legislation. It remains to be seen how Brexit will impact regulatory requirements for medicinal products and devices in the UK in the long-term. The MHRA has recently published detailed guidance for industry and organizations to follow now the transition period is over, which will be updated as the UK's regulatory position on medicinal products and medical devices evolves over time.

Now that the UK has left the EU, Great Britain, will no longer be covered by centralized marketing authorizations (under the Northern Irish Protocol, centralized EU authorizations will continue to be recognized in Northern Ireland). All medicinal products with a current centralized authorization, including NILEMDO and NUSTENDI, were automatically converted to GB marketing authorizations on January 1, 2021. For a period of two years from January 1, 2021, the MHRA may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new Great Britain marketing authorization. A separate application will, however, still be required. The MHRA also has the power to have regard to marketing authorizations approved in EEA Member States through Decentralized or Mutual Recognition Procedures with a view to more quickly granting a marketing authorization in the UK or GB.

### ***Post-Approval Controls***

The holder of a marketing authorisation must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorisation. Such risk-minimization measures or post-authorisation obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorisation safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions.

All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

### ***Manufacturing***

Medicinal products may only be manufactured in the EU, or imported into the EU from another country, by the holder of a manufacturing authorisation from the competent national authority. The manufacturer or importer must have a qualified person who is responsible for certifying that each batch of product has been manufactured in accordance with EU standards of cGMP before releasing the product for commercial distribution in the EU or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with cGMP.

### ***Pricing and Reimbursement***

Governments influence the price of medicinal products in the EU through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription medicines, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

### ***Rest of the World Regulation***

In addition to regulations in the United States, we are subject to a variety of foreign regulations governing clinical studies and commercial sales and distribution of our product candidates to the extent we choose to sell any products outside of the United States. While we have obtained FDA approval for NEXLETOL and NEXLIZET, and approval from the EC and Swissmedic for NILEMDO and NUSTENDI, and whether or not we obtain FDA, EC, or Swissmedic approval for any future product candidate, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical studies or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical studies, product licensing, pricing and reimbursement vary greatly from country to country. As in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution would apply to any product that is approved outside the United States.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

### **Human Capital Resources**

In order to achieve the goals and expectations of our Company, it is crucial that we continue to attract and retain top talent. To facilitate talent attraction and retention, we strive to make Esperion a safe and rewarding workplace, with opportunities for our employees to grow and develop in their careers, supported by strong compensation, benefits and health and wellness

programs, and by programs that build connections between our employees. As of December 31, 2020, we had 479 full-time employees. Thirty-two of our employees have Ph.D. degrees, eight have M.D. degrees and fourteen have PharmD degrees. 86 of our employees are engaged in research and development activities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

The success of our business is fundamentally connected to the well-being of our employees. Accordingly, we are committed to their health, safety and wellness. We provide our employees and their families with access to a variety of innovative, flexible and convenient health and wellness programs, including benefits that provide protection and security so they can have peace of mind concerning events that may require time away from work or that impact their financial well-being; that support their physical and mental health by providing tools and resources to help them improve or maintain their health status and encourage engagement in healthy behaviors; and that offer choice where possible so they can customize their benefits to meet their needs and the needs of their families. In response to the COVID-19 pandemic, we implemented changes that we determined were in the best interest of our employees, as well as the communities in which we operate, and which comply with government regulations. This included implementing a work-from-home policy for all employees who are able to perform their duties remotely and restricting all nonessential travel.

We provide robust compensation and benefits programs to help meet the needs of our employees. In addition to salaries, these programs include potential annual discretionary bonuses, stock awards, a 401(k) Plan, healthcare and insurance benefits, health savings and flexible spending accounts, paid time off, family leave, and flexible work schedules, among others. In addition to our broad-based equity award programs, we have used targeted equity-based grants with vesting conditions to facilitate retention of personnel, particularly those with critical drug development skills and experience.

## **Facilities**

Our corporate headquarters are located in Ann Arbor, Michigan where we lease and occupy approximately 19,400 square feet of office space. We believe that our existing facilities are adequate for our current needs.

## **Legal Proceedings**

On January 12, 2016, a purported stockholder of our company filed a class action lawsuit in the United States District Court for the Eastern District of Michigan, against us and Tim Mayleben, captioned *Kevin L. Dougherty v. Esperion Therapeutics, Inc., et al.* (No. 16-cv-10089). The lawsuit alleges that we and Mr. Mayleben violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 by allegedly failing to disclose in an August 17, 2015, public statement that the FDA would require a cardiovascular outcomes trial before approving our lead product candidate. The lawsuit seeks, among other things, compensatory damages in connection with an allegedly inflated stock price between August 18, 2015, and September 28, 2015, as well as attorneys' fees and costs. On May 20, 2016, an amended complaint was filed in the lawsuit and on July 5, 2016, we filed a motion to dismiss the amended complaint. On December 27, 2016, the court granted our motion to dismiss with prejudice and entered judgment in our favor. On January 24, 2017, the plaintiffs in this lawsuit filed a motion to alter or amend the judgment. In May 2017, the court denied the plaintiff's motion to alter or amend the judgment. On June 19, 2017, the plaintiffs filed a notice of appeal to the Sixth Circuit Court of Appeals and on September 14, 2017, they filed their opening brief in support of the appeal. The appeal was fully briefed on December 7, 2017, and it was argued before the Sixth Circuit on March 15, 2018. On September 27, 2018, the Sixth Circuit issued an opinion in which it reversed the district court's dismissal and remanded for further proceedings. On October 11, 2018, we filed a petition for rehearing en banc and, on October 23, 2018, the Sixth Circuit of Appeals directed plaintiffs to respond to that petition. On December 3, 2018, the Sixth Circuit denied our petition for en banc rehearing, and on December 11, 2018, the case was returned to the federal district court by mandate from the Sixth Circuit. On December 26, 2018, we filed our answer to the amended complaint, and on March 28, 2019, we filed our amended answer to the amended complaint. On September 15, 2020, we filed a motion for summary judgment, and the plaintiffs filed a motion for partial summary judgment, and on October 23, 2020, the parties filed oppositions to both motions for summary judgment. On November 20, 2020, we and plaintiffs filed replies in support of our respective motions. We are unable to predict the outcome of this matter and are unable to make a meaningful estimate of the amount or range of loss, if any, that could result from an unfavorable outcome.

On December 15, 2016, a purported stockholder of our company filed a derivative lawsuit in the Court of Chancery of the State of Delaware against Tim Mayleben, Roger Newton, Mary McGowan, Nicole Vitullo, Dov Goldstein, Daniel Janney, Antonio Gotto Jr., Mark McGovern, Gilbert Omenn, Scott Braunstein, and Patrick Enright. Our company is named as a nominal defendant. The lawsuit alleges that the defendants breached their fiduciary duties to the company when they made or approved improper statements on August 17, 2015, regarding our lead product candidate's path to FDA approval, and failed to ensure that reliable systems of internal controls were in place at our company. On February 8, 2019, we and the defendants filed a motion to dismiss the derivative lawsuit. On April 23, 2019, the plaintiff filed an opposition to the motion to dismiss the derivative lawsuit, and we filed a reply brief on May 15, 2019. On November 6, 2019, the court held a hearing on the motion to dismiss.

On February 13, 2020, the court granted our motion to dismiss with prejudice and entered judgment in our favor. On March 16, 2020, the plaintiff filed a notice of appeal to the Supreme Court of Delaware. On June 1, 2020, the plaintiff filed his opening brief on appeal to the Supreme Court of Delaware. On July 1, 2020, the Company and the defendants filed an answering brief, and on July 16, 2020, the plaintiff filed a reply brief. On October 14, 2020, the Supreme Court of Delaware held oral arguments on the appeal. On October 29, 2020, the Supreme Court of Delaware issued an order affirming the judgment of the Court of Chancery.

In the future, we may become party to legal matters and claims arising in the ordinary course of business, the resolution of which we do not anticipate would have a material adverse impact on our financial position, results of operations or cash flows.

#### **Available Information**

Our website address is [www.esperion.com](http://www.esperion.com). Our Annual Reports 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 available free of charge through the investor relations page of our internet website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. Alternatively, these reports may be accessed at the SEC's website at [www.sec.gov](http://www.sec.gov).

#### **Item 1A. Risk Factors**

*Except for the historical information contained herein or incorporated by reference, this report and the information incorporated by reference contains forward-looking statements that involve risks and uncertainties. These statements include projections about our accounting and finances, plans and objectives for the future, future operating and economic performance and other statements regarding future performance. These statements are not guarantees of future performance or events. Our actual results could differ materially from those discussed in this report. Factors that could cause or contribute to these differences include, but are not limited to, those discussed in the following section, as well as those discussed in Part II, Item 7 entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this report and in any documents incorporated in this report by reference.*

*You should consider carefully the following risk factors, together with all of the other information included or incorporated in this report. If any of the following risks, either alone or taken together, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.*

#### **Risks Related to the COVID-19 Pandemic**

***The current pandemic of COVID-19, including recurring surges and waves of infection, and the future outbreak of other highly infectious or contagious diseases, could have a material adverse impact on our business, financial condition and results of operations, including our commercial launch of NEXLETOL and NEXLIZET, our commercial launch of NILEMDO and NUSTENDI led by DSE in Germany, our intended commercial launch of NILEMDO and NUSTENDI led by DSE in other EU countries, our ongoing CLEAR Outcomes trial, and operations and sales in general.***

Broad-based business or economic disruptions could adversely affect our ongoing or planned research and development and commercialization activities. For example, in December 2019, an outbreak of a novel strain of coronavirus spread to the majority of countries around the world, including the U.S. To date, the COVID-19 pandemic has caused significant disruptions to the U.S. and global economy and has contributed to significant volatility and negative pressure in financial markets. The global impact of the outbreak continues to evolve as additional cases of the virus are identified, public health officials learn more about the spread of the virus and the efficacy of containment measures, and vaccines against the virus are developed and distributed. Many countries, including certain states and cities in the U.S., have reacted by instituting varying levels of quarantine and social distancing requirements, restrictions on travel, and mandatory closures of and/or occupancy limits for businesses. Although some of these restrictions have been and may from time to time be eased or lifted, in response to local surges and new waves of infection, some countries, states, and local governments have reinstated, or may reinstate, these restrictions, and additional, more restrictive orders, proclamations, and/or directives may be issued in the future. In response to the spread of SARS-CoV-2 and COVID-19, our commercial and medical organizations are following internal guidelines and respective state guidelines when interacting with physicians and customers.



As a result of the current pandemic, or future pandemics, we may not be able to meet expectations with respect to the net product sales of NEXLETOL and NEXLIZET or attain or maintain profitability and positive cash-flow from operations. Our ongoing CVOT for bempedoic acid and the timing for the review and approval of expanded indications for their effect on cardiovascular events may be impacted as well. So far, most of our manufacturing partners and CROs have continued to produce at anticipated levels despite these COVID-19 challenges.

The extent to which the COVID-19 pandemic, or the future outbreak of any other highly infectious or contagious diseases, impacts our business, including our commercialization efforts, preclinical studies, and clinical trial operations, will depend on continuously changing circumstances, which are highly uncertain and cannot be predicted with confidence, such as the duration of such pandemic including future waves of infection or the broad availability of an effective vaccine, the actions taken to contain the pandemic or mitigate its impact, and the direct and indirect economic effects of the pandemic and containment measures, among others. The ongoing fluidity of this situation precludes any prediction as to the full impact of the COVID-19 pandemic, but it could have a material adverse effect on our business, financial condition, and results of operations. The COVID-19 pandemic may also have the effect of heightening many of the risks described herein, including the below:

- Our ability to successfully launch, commercialize, and generate net product sales from NEXLETOL and NEXLIZET may be adversely affected by the economic impact of the COVID-19 pandemic. Physicians' offices and other medical institutions continue to have limited access for non-patients, which includes our sales personnel. In addition, social distancing requirements and precautionary measures due to COVID-19 have impacted the ability of our sales personnel to interact in-person with physicians and customers. As a result, in many circumstances we have needed to limit our interactions with physicians and payors and adapt our launch strategies and tactics to include a virtual model, including developing and deploying various technology-enabled platforms for virtual engagement such as remote detailing, digital and non-personal marketing channels, and social media. These circumstances may adversely affect the ability of our sales professionals and our partner's sales professionals to effectively market NEXLETOL, NEXLIZET, NILEMDO and NUSTENDI to physicians and the rates of uptakes for NEXLETOL, NEXLIZET, NILEMDO and NUSTENDI, which may have a negative impact on our sales and our market penetration. In addition, patient visits with physicians have decreased as a result of COVID-19, due to travel restrictions, social distancing requirements, prioritization of healthcare resources to address the pandemic, and/or fear of exposure to the virus, which could have a material adverse impact on new patient starts and overall patient treatment volume. Market disruption and rising unemployment caused by the COVID-19 pandemic may lead to delays in obtaining insurance coverage and reimbursement of newly approved products.
- Business interruptions from the current or future pandemics may adversely impact the third parties we solely rely on to sufficiently manufacture bempedoic acid tablets and the bempedoic acid / ezetimibe combination tablets and to produce our product candidates in quantities we require, which may impair the commercialization of NEXLETOL, NEXLIZET, NILEMDO and NUSTENDI and our CLEAR Outcomes CVOT.
- We have implemented precautionary measures to protect the health and safety of our employees, partners, and patients during the COVID-19 pandemic, including encouraging our personnel to work remotely for all employees who are able to perform their duties remotely, and requiring adherence to onsite occupancy limits and appropriate safety measures designed to comply with federal, state, and local guidelines. Our business operations may be further disrupted if any of our employees, officers, or board of directors contract an illness related to COVID-19 and are unable to perform their duties.
- Health regulatory agencies globally may experience disruptions in their operations as a result of the COVID-19 pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or be under-resourced and, as a result, review, inspection, and other timelines may be materially delayed.
- Health regulatory agencies may refuse to accept data from our clinical trials due to mitigation strategies we utilize in response to the COVID-19 pandemic and current regulatory guidance, which could delay, limit, or prevent marketing approval of our drugs or drug candidates.
- The trading prices for our common stock and other pharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. In addition, a recession, depression, or other sustained adverse market event resulting from the COVID-19 pandemic could materially and adversely affect our business and the value of our common stock.

While it is not possible at this time to estimate the entirety of the impact that the COVID-19 pandemic will have on our business or operations, the continued spread or future waves of COVID-19, measures taken by governments, actions taken to protect employees, and the broad impact of the pandemic on all business activities may materially and adversely affect our preclinical activities, clinical development progress, data and timelines, commercialization efforts including any revenue from sales, supply chain continuity, and general business operations, and our business, prospects, financial condition, and results of operations could be materially harmed as a result.

## **Risks Related to our Business and Commercialization**

### **Risks Related to Business Development and Commercialization**

*We depend almost entirely on the success of two products, bempedoic acid and the bempedoic acid / ezetimibe combination tablet. There is no assurance that our commercialization efforts in the U.S. and DSE's effort in Europe with respect to either product will be successful or that we will be able to generate revenues at the levels or within the timing we expect or at the levels or within the timing necessary to support our goals.*

To date, we have generated \$13.0 million in revenues from the sale of products in the U.S. Our lead products, NEXLETOL (bempedoic acid) tablet and NEXLIZET (bempedoic acid and ezetimibe) tablets, were approved by the FDA in February 2020. NEXLETOL became commercially available in the U.S. in March 2020 and NEXLIZET became commercially available in the U.S. in June 2020. On April 6, 2020, we announced that the EC approved NILEMDO (bempedoic acid) and NUSTENDI (bempedoic acid and ezetimibe) tablets for the treatment of hypercholesterolemia and mixed dyslipidemia. The decision is applicable to all 27 European Union member states plus the United Kingdom, Iceland, Norway and Liechtenstein. NILEMDO (bempedoic acid) and NUSTENDI (bempedoic acid and ezetimibe) are the branded product names for bempedoic acid and the bempedoic acid / ezetimibe combination tablets in Europe. In November 2020, we announced the commercial launch of NILEMDO and NUSTENDI in Germany. In December 2020, we announced the approval of NILEMDO and NUSTENDI in Switzerland. There is no assurance that the commercial launches will be successful or that additional launches will occur on the timing we anticipate. We may encounter delays or hurdles related to our launches that affect timing.

Our business currently depends heavily on our ability to successfully commercialize NEXLETOL and NEXLIZET in the U.S. to treat patients as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or established ASCVD who require additional lowering of LDL-C. We may never be able to successfully commercialize the products or meet our expectations with respect to revenues. Prior to our launch in March 2020, we had never marketed, sold or distributed for commercial use any pharmaceutical product. There is no guarantee that the infrastructure, systems, processes, policies, personnel, relationships and materials we have built to launch and commercialize either product in the U.S. will be sufficient for us to achieve success at the levels we expect. Additionally, healthcare providers may not accept a new treatment paradigm for patients with HeFH or established ASCVD who require additional lowering of LDL-C. We may also encounter challenges related to reimbursement of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, even if we have positive early indications from payors, including potential limitations in the scope, breadth, availability, or amount of reimbursement covering each product. Similarly, healthcare settings or patients may determine that the financial burdens of treatment are not acceptable. Our results may also be negatively impacted if we have not adequately sized our field teams or our physician segmentation and targeting strategy is inadequate or if we encounter deficiencies or inefficiencies in our infrastructure or processes. Any of these issues could impair our ability to successfully commercialize bempedoic acid and the bempedoic acid / ezetimibe combination tablet or to generate substantial revenues or profits or to meet our expectations with respect to the amount or timing of revenue or profits. Any issues or hurdles related to our commercialization efforts may materially adversely affect our business, results of operations, financial condition and prospects. There is no guarantee that we will be successful in our launch or commercialization efforts with respect to bempedoic acid and the bempedoic acid / ezetimibe combination tablet.

*We have obtained regulatory approval from the FDA, the EC, and Swissmedic for both of our leading product candidates as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or established ASCVD who require additional lowering of LDL-C, but we cannot be certain that we will be able to obtain approval from regulatory authorities in other territories we decide to pursue, or successfully commercialize our products and any future product candidates. Additionally, we cannot be certain that we will be able to obtain approval either of our candidates for any other indication or approval of any future product candidates.*

Bempedoic acid and the bempedoic acid / ezetimibe combination tablet may require substantial additional clinical development, testing, and regulatory approvals before we are permitted to commence their commercialization in markets

outside of the U.S. and Europe for an LDL-C lowering indication. The clinical studies, manufacturing and marketing of our products and any future product candidates are subject to extensive and rigorous review and regulation by numerous government authorities in the U.S. and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through preclinical testing and clinical studies that the product candidate is safe and effective for use in each target indication. This process can take many years and require the expenditure of substantial resources, and may include post-marketing studies and surveillance. Of the large number of drugs in development in the U.S., only a small percentage successfully complete the approval process at the FDA, EMA or any other foreign regulatory agency, and are commercialized. Accordingly, we cannot assure you that bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any other of our product candidates we may develop will be successfully developed or commercialized.

We are not permitted to market our product candidates in the U.S. or in Europe for any other indication until we receive approval of an NDA supplement from the FDA, MAA from the EC, or in any other foreign countries until we receive the requisite approval from such countries. Additionally, we may decide to submit a supplemental NDA or MAA in the future for bempedoic acid and the bempedoic acid / ezetimibe combination tablet for other indications, such as a CVD risk reduction indication. As a condition to submitting an NDA supplement or MAA for bempedoic acid to treat patients with hypercholesterolemia for a CVD risk reduction indication, we have initiated and intend to complete the CLEAR Outcomes CVOT.

Obtaining approval of an NDA or MAA is a complex, lengthy, expensive and uncertain process, and the FDA or EMA may delay, limit or deny approval of bempedoic acid and the bempedoic acid / ezetimibe combination tablet for many reasons, including, among others:

- the FDA, EMA or any other regulatory authorities may change their approval policies or adopt new regulations, including with respect to whether LDL-C lowering is a surrogate endpoint for initial approval of bempedoic acid and the bempedoic acid / ezetimibe combination tablet;
- the FDA, EMA or any other regulatory authorities may change their approval policies for an LDL-C lowering indication for bempedoic acid and the bempedoic acid / ezetimibe combination tablet if there is a shift in the future standard-of-care for statin intolerant patients with hypercholesterolemia;
- the FDA, EMA, or any other regulatory authorities may change their approval policies with regard to a CVD risk reduction indication;
- we may not be able to demonstrate that bempedoic acid and the bempedoic acid / ezetimibe combination tablet are safe and effective in treating patients with hypercholesterolemia to the satisfaction of the FDA, EMA or any other regulatory agency;
- the results of our clinical studies may not meet the level of statistical or clinical significance required by the FDA or EMA for marketing approval;
- the magnitude of the treatment effect must also be clinically meaningful along with the drug's safety for a favorable benefit/risk assessment by the FDA, EMA or any other regulatory agency;
- the FDA, EMA or any other regulatory agency may change in the future the number, design, size, duration, patient enrollment criteria, exposure of patients, or conduct or implementation of our clinical studies;
- the FDA, EMA or any other regulatory agency may require that we conduct additional clinical studies;
- the FDA, EMA or any other regulatory agency may not approve the formulation, specifications or labeling of bempedoic acid and the bempedoic acid / ezetimibe combination tablet;
- the clinical research organizations, or CROs, that we retain to conduct our clinical studies may take actions outside of our control that materially adversely impact our clinical studies;
- the FDA, EMA or any other regulatory agency may find the data from preclinical studies and clinical studies insufficient to demonstrate that the clinical and other benefits of bempedoic acid and the bempedoic acid / ezetimibe combination tablet outweigh the safety risks;

- the FDA, EMA or any other regulatory agency may disagree with our interpretation of data from our preclinical studies and clinical studies;
- the FDA, EMA or any other regulatory agency may not accept data generated at our clinical study sites;
- if our NDAs are reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our applications or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical studies, limitations in approved labeling or distribution and use restrictions;
- the FDA, EMA or any other regulatory agency may require the development of a REMS as a condition of approval or post-approval; or
- the FDA, EMA or any other regulatory agency may not approve the manufacturing processes or facilities of third-party manufacturers with which we contract.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market bempedoic acid and the bempedoic acid / ezetimibe combination tablet. Moreover, because our business is almost entirely dependent upon these product candidates, any setback in our pursuit of its regulatory approval would have a material adverse effect on our business and prospects.

The development and approvals required for the approval of the bempedoic acid / ezetimibe combination tablet are substantially identical to those for bempedoic acid, and the risks relating to the clinical development and approval of bempedoic acid apply equally to the bempedoic acid / ezetimibe combination tablet. Any failure in our development of bempedoic acid would materially and adversely affect our ability to develop, seek approval for and commercialize the bempedoic acid / ezetimibe combination tablet for the planned indications. In addition, even if bempedoic acid succeeds in its clinical development and is approved for one or more indications, there can be no assurance that the bempedoic acid / ezetimibe combination tablet would be developed successfully and approved for the same indications or at all, and vice versa.

***We have limited experience as a commercial company and the marketing and sale of bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any future approved drugs may be unsuccessful or less successful than anticipated.***

While we have initiated the commercial launch of our approved drugs in the U.S. and DSE has initiated the commercial launch in Germany, we have limited experience as a commercial company and there is limited information about our ability to successfully overcome many of the risks and uncertainties encountered by companies commercializing drugs in the biopharmaceutical industry. To execute our business plan, in addition to successfully marketing and selling bempedoic acid and the bempedoic acid / ezetimibe combination tablet, we will need to successfully:

- establish and maintain our relationships with healthcare providers who will be treating the patients who may receive our drugs and any future drugs;
- obtain adequate pricing and reimbursement for bempedoic acid and the bempedoic acid / ezetimibe combination tablet and any future drugs;
- develop and maintain successful strategic alliances; and
- manage our spending as costs and expenses increase due to clinical trials, marketing approvals, and commercialization.

If we are unsuccessful in accomplishing these objectives, we may not be able to successfully commercialize bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any future drug candidates, raise capital, expand our business, or continue our operations.

***The commercialization of the bempedoic acid / ezetimibe combination tablet in the U.S. and Europe, and, if approved in other territories, depends on the continued availability of ezetimibe.***

The bempedoic acid / ezetimibe combination tablet is dependent on the continued availability of ezetimibe in the marketplace, and there can be no assurance that the current availability of ezetimibe will continue. The producers of ezetimibe

are under no obligation to continue producing, commercializing or making ezetimibe available to patients, or to continue producing ezetimibe in any particular quantity, which could prevent our ability to obtain ezetimibe. For example, such producers may encounter manufacturing or other production issues and fail to produce enough ezetimibe, and this could cause our commercialization efforts to fail or be significantly delayed.

***Our reliance on sole source third-party suppliers could harm our ability to commercialize bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any drug candidates that may be approved in the future.***

We have scaled up our manufacturing process for bempedoic acid and the bempedoic acid / ezetimibe combination tablet in anticipation of greater drug requirements for commercialization. We do not currently own or operate manufacturing facilities for the production of bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any future drug candidates that may be approved in the future. We rely on sole source third-party suppliers to manufacture and supply bempedoic acid and the bempedoic acid / ezetimibe combination tablet which may not be able to produce sufficient inventory to meet commercial demand in a cost-efficient, timely manner, or at all. Our third-party suppliers may not be required to, or may be unable to, provide us with any guaranteed minimum production levels or have sufficient dedicated capacity for our drugs. As a result, there can be no assurances that we will be able to obtain sufficient quantities of bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any drug candidates that may be approved in the future, which could have a material adverse effect on our business as a whole.

***Even though we have received marketing approval for bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the U.S. and Europe, and even if we receive such approval in other markets, we may still face future development and regulatory difficulties.***

Even though we have received marketing approval for bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the U.S. and Europe, and even if we receive such approval in other markets, regulatory authorities may still impose significant restrictions on bempedoic acid or the bempedoic acid / ezetimibe combination tablet's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies, such as a CVOT. Bempedoic acid and the bempedoic acid / ezetimibe combination tablet will also be subject to ongoing FDA requirements governing the packaging, storage, labeling, advertising and promotion of the product, recordkeeping and submission of safety updates and other post-marketing information. The FDA has significant post-marketing authority, including, for example, the authority to require labeling changes based on new safety information and to require post-marketing studies or clinical studies to evaluate serious safety risks related to the use of a drug product. For example, as part of our NEXLETOL and NEXLIZET approval, the FDA has required both a PK/PD and Phase 3 study evaluating bempedoic acid in patients with HeFH aged 10 years to less than 18 years, a worldwide descriptive study that collects prospective and retrospective data in women exposed to NEXLETOL and NEXLIZET during pregnancy to assess the risk of pregnancy and maternal complications, adverse effects on the developing fetus and neonate, and adverse effects on the infant through the first year of life, a lactation study to analyze milk in lactating women who have received therapeutic doses of NEXLETOL and NEXLIZET, and that we complete the ongoing CLEAR CVOT trial.

The EMA and other foreign regulatory authorities may impose similar requirements on bempedoic acid or the bempedoic acid / ezetimibe combination tablet as those described above with respect to the FDA.

Manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practices and other regulations. If we or a regulatory agency discover problems with bempedoic acid or the bempedoic acid / ezetimibe combination tablet, such as adverse events of unanticipated severity or frequency, or problems with the facility where bempedoic acid or the bempedoic acid / ezetimibe combination tablet is manufactured, a regulatory agency may impose restrictions on bempedoic acid or the bempedoic acid / ezetimibe combination tablet, the manufacturer or us, including requiring withdrawal of bempedoic acid or the bempedoic acid / ezetimibe combination tablet from the market or suspension of manufacturing. If we, bempedoic acid or the bempedoic acid / ezetimibe combination tablet or the manufacturing facilities for bempedoic acid or the bempedoic acid / ezetimibe combination tablet fail to comply with applicable regulatory requirements, a regulatory agency may, among other things:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw marketing approval;

- suspend any ongoing clinical studies;
- refuse to approve pending applications or supplements to applications submitted by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or request that we initiate a product recall.

***Relationships with healthcare providers and physicians and third-party payors are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and third-party payors in the U.S. and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute, the False Claims Act, laws and regulations related to the reporting of payments to physicians and teaching hospitals, and HIPAA, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to the below.

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering, paying or providing any remuneration (including any kickback, bribe, or rebate), directly or indirectly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution.
- Federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery.
- The Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it.

- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose, among other things, requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.
- The federal Physician Payment Sunshine Act of 2010, as amended by the Health Care and Education Reconciliation Act, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to any payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners.
- Additional federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. For instance, state anti-kickback and false claims laws may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients. Laws related to insurance fraud may provide claims involving private insurers. State laws may require pharmaceutical or medical device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources. State and local laws may also require the licensure of sales representatives and require drug or device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information. Further data privacy and security laws and regulations in foreign jurisdictions that may be more stringent than those in the U.S. (such as the European Union, which adopted the GDPR, which became effective in May 2018). Analogous state laws may additionally govern 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.

Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies often scrutinize interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

The failure to comply with any of these laws or regulatory requirements subjects entities to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the

operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations, guidance or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the U.S. will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

***Formulary Coverage, Pricing, and Reimbursement policies could limit our ability to sell bempedoic acid or the bempedoic acid / ezetimibe combination tablet.***

Sales of our products will depend, in part, on the extent to which our products will be covered and reimbursed by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. Adequate coverage and reimbursement from third party payors are critical to new product acceptance. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent our products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree.

Significant uncertainty exists in the U.S. as to the coverage and reimbursement status of bempedoic acid and the bempedoic acid / ezetimibe combination tablet. Market acceptance and sales of bempedoic acid and the bempedoic acid / ezetimibe combination tablet will depend, in part, on the extent to which our products in the U.S. will be covered and reimbursed by third-party payors, such as government health care programs, commercial insurance, and managed healthcare organizations and may be affected by healthcare reform measures. Adequate coverage and reimbursement from third party payors are critical to new product acceptance. Third-party payors decide which medications they will pay for and establish reimbursement levels for those medications. No uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third party payors. These third-party payors are increasingly reducing reimbursement levels for medical products and services. The process for determining whether a third-party payor will provide coverage for a drug product typically is separate from the process for setting the price of a drug product or for establishing the reimbursement rate that a payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the approved drugs for a particular indication. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a therapeutic is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.



Cost containment is a primary concern in the U.S. healthcare industry and elsewhere. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. The U.S. federal government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, utilization management and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for bempedoic acid and the bempedoic acid / ezetimibe combination tablet or a decision by a third-party payor to not cover bempedoic acid and the bempedoic acid / ezetimibe combination tablet could reduce physician usage of the products and could have a material adverse effect on our sales, results of operations and financial condition.

We cannot be sure that reimbursement will be available for bempedoic acid or the bempedoic acid / ezetimibe combination tablet and, if reimbursement is available, the level of such reimbursement. Reimbursement may impact the demand for, or the price of, bempedoic acid or the bempedoic acid / ezetimibe combination tablet. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize bempedoic acid or the bempedoic acid / ezetimibe combination tablet.

There may also be delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services.

In addition, increasingly, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging prices. We cannot be sure that coverage will be available for any products or product candidate that we, or any future collaborator, commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from one country to another. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any of our products or product candidates for which we, or any future collaborator, obtain regulatory approval could significantly harm our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

In some foreign countries, particularly in Canada and European countries, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or pricing approval in some countries, we may be required to conduct a clinical study that compares the cost-effectiveness of bempedoic acid and the bempedoic acid / ezetimibe combination tablet with other available therapies. If reimbursement for bempedoic acid or the bempedoic acid / ezetimibe combination tablet is unavailable in any country in which we seek reimbursement, if it is limited in scope or amount, if it is conditioned upon our completion of additional clinical studies, or if pricing is set at unsatisfactory levels, our operating results could be materially adversely affected.

***Recent federal legislation may increase pressure to reduce prices of certain pharmaceutical products paid for by Medicare, which could materially adversely affect our revenue and our results of operations.***

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the scope of coverage and the price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may cause a similar reduction in payments from private payors. This legislation may pose an even greater risk to bempedoic acid and the bempedoic acid / ezetimibe combination tablet than some other pharmaceutical products because a significant portion of the target patient population for bempedoic acid and the bempedoic acid / ezetimibe combination tablet would likely be over 65 years of age and, therefore, many such patients will be covered by Medicare.

In March 2010, ACA became law in the United States. The goal of the ACA is to reduce the cost of healthcare and substantially change the way healthcare is financed by both governmental and private insurers. The ACA, among other things, increases minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs and biologic products, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70%, effective January 1, 2019, by the Bipartisan Budget Act of 2018) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA, including decreasing the tax-based shared responsibility payment imposed on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate," to \$0 effective January 1, 2019 as part of the Tax Cuts and Jobs Act, or TCJA. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseparable feature of the ACA, and therefore because the mandate was effectively nullified, the remaining provisions of the ACA are invalid as well. On December 18, 2019 the Fifth Circuit U.S. Court of Appeals held the individual mandate is unconstitutional, but remanded the case to the lower court to reconsider its earlier invalidation of the full law. In March 2020, the U.S. Supreme Court agreed to hear this case and oral arguments were held on November 10, 2020. The Supreme Court's decision in this case is forthcoming. Pending review, the ACA remains in effect, but it is unclear at this time what effect the latest ruling will have on the ACA long term. Litigation and legislation related to the ACA are likely to continue, with unpredictable and uncertain results. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business. It is unclear how this decision and any subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA and our business. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2030 unless additional Congressional action is taken. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, as well as subsequent legislation, these reductions have been suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. Proposed legislation, if passed, would extend this suspension until the end of the pandemic.

Further, some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. Since January 2017, President Trump signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One such Executive Order directed federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. The Trump administration concluded that cost-sharing reduction, or CSR, payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until those appropriations are made. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. On August 14, 2020, the U.S. Court of Appeals for the Federal Circuit ruled in two separate cases that the federal government is liable for the full amount of unpaid CSRs for the years preceding and including 2017. For CSR claims made by health insurance companies for years 2018 and later, further litigation will be required to determine the amounts due, if any. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than \$12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. This decision was appealed to the U.S. Supreme Court, which on April 27, 2020, reversed the U.S. Court of Appeals for the Federal Circuit's decision and remanded the case to the U.S. Court of Federal Claims, concluding the government has an obligation to pay these risk corridor payments under the relevant formula. To date, at least \$6 billion has been paid out to health plans and insurers, and follow-up class action and other litigation is pending. The viability of the federal and state marketplaces and subsequent impacts on providers, and potentially our business, are not yet known. The Bipartisan Health Care Stabilization Act of 2017 as well as the follow-on Bipartisan Health Care Stabilization Act of 2018 were introduced to appropriate funds to stabilize CSR payments; however, the future of this effort is unclear.

There has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. The Trump administration's budget proposal for fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. On December 27, 2018, the District Court for the District of Columbia invalidated a reimbursement formula change under the 340B drug pricing program, and CMS subsequently altered the FYs 2019 and 2018 reimbursement formula on specified covered outpatient drugs ("SCODs"). The court ruled this change was not an "adjustment" which was within the Secretary's discretion to make but was instead a fundamental change in the reimbursement calculation. However, most recently, on July 31, 2020, the U.S. Court of Appeals for the District of Columbia Circuit overturned the district court's decision and found that the changes were within the Secretary's authority. On September 14, 2020, the plaintiffs-appellees filed a Petition for Rehearing En Banc (i.e., before the full court), but was denied on October 16, 2020. The 340B drug pricing program imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. It is unclear how these developments could affect covered hospitals who might purchase our future products and affect the rates we may charge such facilities for our approved products in the future, if any.

Further, the Trump administration previously released a plan to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. On July 24, 2020 and September 13, 2020, President Trump announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. The FDA also released a final rule which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Under the final rule, States and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the FDA for review and authorization. On September 25, 2020, CMS stated drugs imported by States under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Separately, the FDA also issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code, or NDC, for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country.

Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021 and ending December 31, 2027. The Interim Final Rule has not been finalized and is subject to revision and challenge. Additionally, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. HHS has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. Although a number of these measures and other proposed measures will require authorization through additional legislation to

become effective, and the Biden administration may change or reverse executive actions taken by the previous administration, Congress has indicated that it will continue to seek new legislative measures to control drug costs.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product and medical device pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and medical devices to purchase and which suppliers will be included in their prescription drug and other healthcare programs.

We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. It is unclear how the Biden administration will prioritize and execute initiatives to contain healthcare costs. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for our products and any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

We expect that changes and challenges to the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies, and additional downward pressure on the price that we receive for our products and any future approved product.

Finally, the availability of generic LDL-C lowering treatments may also substantially reduce the likelihood of reimbursement for branded counterparts or other competitive LDL-C lowering therapies, such as bempedoic acid or the bempedoic acid / ezetimibe combination tablet. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed.

***The U.K.'s exit from the EU may have a negative effect on global economic conditions, financial markets, and our business.***

In June 2016, the U.K. held a referendum in which voters approved an exit from the EU, commonly referred to as "Brexit." The announcement of Brexit caused significant volatility in global stock markets and currency exchange rate fluctuations that resulted in the strengthening of the U.S. dollar against foreign currencies in which we conduct business. The strengthening of the U.S. dollar relative to other currencies may adversely affect our operating results. This withdrawal has created political and economic uncertainty, particularly in the U.K. and the EU, where we currently conduct clinical trials and intend to seek marketing approvals in the future. During the Brexit transition period, which ended on December 31, 2020, the U.K. continued to follow all of the EU's rules and maintained its current trading relationship with the EU. The U.K. and EU have signed a EU-UK Trade and Cooperation Agreement, or the TCA, which became provisionally applicable on January 1, 2021 and will become formally applicable once ratified by both the U.K. and the EU. The TCA sets out the arrangements between the U.K. and EU on trade in certain areas (e.g. goods and some services, energy, fisheries, social security coordination); however there is still uncertainty over how its terms will play out in practice and there are still key aspects of the U.K.'s relationship with the EU which are not covered by the TCA, such as in respect of financial services. We expect that uncertainty over the terms of the TCA and other future agreements between the U.K. and EU will continue to cause political and economic uncertainty, which could harm our business and financial results. The withdrawal will, among other outcomes, disrupt the free movement of goods, services and people between the U.K. and the EU, and result in increased legal and regulatory complexities, as well as potential higher costs of conducting business in Europe. Until there is greater understanding on how the terms of the TCA will play out in practice, and until the terms of other potential agreements that the U.K. may eventually enter into with the EU are known, it is not possible to determine the extent of the impact that the U.K.'s departure from the EU and/or any related matters may have on us; however, any of these effects of Brexit, and others we cannot anticipate, could adversely affect our business, business opportunities, results of operations, financial condition, and cash flows. Likewise, similar actions taken by European and other countries in which we operate could have a similar or even more profound impact.

For example, since the regulatory framework in the U.K. covering the quality, safety and efficacy of medicinal products, clinical trials, marketing authorizations, commercial sales and distribution of medicinal products is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime with respect to our products and the approval of our future product candidates in the U.K. For instance, the U.K. will now no longer be covered by the centralized procedure for obtaining EEA-wide marketing authorizations for medicinal products, and a separate process for authorization of drug products will be required in the U.K., resulting in an authorization covering the U.K. or GB only. All medicinal products with a current centralized authorization, including NILEMDO and NUSTENDI, were automatically converted to GB marketing authorizations on January 1, 2021. In addition, the announcement of Brexit and the withdrawal of the U.K. from the EU have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these effects of Brexit, among others, could adversely affect our business, our results of operations, liquidity, and financial condition.

***Data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.***

In the event we decide to continue to enroll subjects in our ongoing or future clinical trials, we may be subject to additional privacy restrictions. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the EU General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR increased our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. Further, Brexit has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated.

In addition, California recently enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA will require covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA went into effect on January 1, 2020, and the California Attorney General may bring enforcement actions for violations beginning July 1, 2020. The CCPA was amended on September 23, 2018, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

***Our future success depends on our ability to retain members of our executive management team, and to attract, retain and motivate qualified personnel.***

We are highly dependent on members of our senior management team. We have entered into employment agreements with these individuals, but any employee may terminate his or her employment with us. Although we do not have any reason to believe that we will lose the services of these individuals in the foreseeable future, the loss of the services of these individuals might impede the achievement of our research, development and commercialization objectives. We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Recruiting and retaining qualified scientific personnel and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific personnel from universities and research institutions. Failure to succeed in clinical studies may make it more challenging to recruit and retain qualified scientific personnel.

### **Risks Related to Sales, Marketing, and Competition**

***Our market is subject to intense competition. If we are unable to compete effectively, our opportunity to generate revenue from the sale of bempedoic acid or the bempedoic acid / ezetimibe combination tablet in the U.S., in Europe and, if approved, in other territories will be materially adversely affected.***

The LDL-C lowering therapies market is highly competitive and dynamic and dominated by the sale of inexpensive generic versions of statins. In 2017, generic statins, ezetimibe, and fixed combination drugs accounted for about 93% of U.S. prescriptions within the cholesterol / LDL-C lowering market. Our success will depend, in part, on our ability to obtain a share of the market, initially, for patient populations consistent with the labeling of our products in jurisdictions where we obtain regulatory approval. Potential competitors in North America, Europe and elsewhere include major pharmaceutical companies, specialty pharmaceutical companies, biotechnology firms, universities and other research institutions and government agencies. Other pharmaceutical companies may develop LDL-C lowering therapies for patients that compete with bempedoic acid and the bempedoic acid / ezetimibe combination tablet that do not infringe the claims of our patents, pending patent applications or other proprietary rights, which could materially adversely affect our business and results of operations.

Lipid lowering therapies currently on the market that would compete with bempedoic acid and the bempedoic acid / ezetimibe combination tablet include the following:

- Inexpensive generic versions of statins;
- Inexpensive generic versions of ezetimibe, a cholesterol absorption inhibitor;
- Injectable PCSK9 inhibitors such as Praluent® (alirocumab) and Repatha® (evolocumab), marketed by Regeneron/Sanofi and Amgen Inc. respectively;
- Bile acid sequestrants such as Welchol® (colesevelam), marketed by Daiichi Sankyo Inc.;
- MTP inhibitors, such as JXTAPID® (lomitapide), marketed by Amryt Pharma Plc.;
- Apo B Anti-Sense therapy, such as KYNAMRO® (mipomersen), marketed by Kastle Therapeutics LLC;
- Inexpensive generic versions of combination tablet therapies, such as ezetimibe and simvastatin;
- Triglyceride lowering therapy such as Vascepa® (icosapent ethyl), marketed by Amarin Corporation; and
- Other lipid-lowering monotherapies (including cheaper generic versions), such as Tricor® (fenofibrate) and Niaspan® (niacin extended release), both of which are marketed by AbbVie, Inc.

Several other pharmaceutical companies have other LDL-C lowering therapies in development that may be approved for marketing in the U.S. or outside of the U.S.

Many of our potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience discovering and developing drug candidates, obtaining FDA and other marketing approvals of

products and commercializing those products. Accordingly, our competitors may be more successful than we may be in obtaining regulatory approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than bempedoic acid or the bempedoic acid / ezetimibe combination tablet, and may render bempedoic acid or the bempedoic acid / ezetimibe combination tablet obsolete or non-competitive before we can recover the expenses of developing and commercializing it. The bempedoic acid and bempedoic acid / ezetimibe combination tablet may also compete with unapproved and off-label LDL-C lowering treatments, and following the expiration of additional patents covering the LDL-C lowering market, we may also face additional competition from the entry of new generic drugs. We anticipate that we will encounter intense and increasing competition as new drugs enter the market and advanced technologies become available.

***The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found to have improperly promoted off-label uses, we may become subject to significant liability.***

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as bempedoic acid or the bempedoic acid / ezetimibe combination tablet. In particular, a product may not be promoted for uses that are not approved by the FDA or other regulatory agencies as reflected in the product's approved labeling. For instance, we received marketing approval for bempedoic acid and the bempedoic acid / ezetimibe combination tablet as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or established ASCVD who require additional lowering of LDL-C, the first indication we pursued. Physicians may in their practice prescribe bempedoic acid and the bempedoic acid / ezetimibe combination tablet to their patients in a manner that is inconsistent with the approved label, potentially including as a therapy in addition to statins. If we are found to have promoted such off-label uses, we may become subject to public advisory or enforcement letters, reputational damage, and significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion under both the Federal Anti-kickback Statute and False Claims Act and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of bempedoic acid and the bempedoic acid / ezetimibe combination tablet to ensure it remains consistent with its approved labeling, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

***Even as we have received marketing approval for bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the U.S. and Europe, we may never receive regulatory approval to market bempedoic acid or the bempedoic acid / ezetimibe combination tablet outside of the U.S. and Europe.***

In order to market any product outside of the U.S. and Europe, we must establish and comply with the numerous and varying efficacy, safety and other regulatory requirements of the countries in which we intend to market our product. Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ from that required to obtain FDA or EMA approval. The marketing approval processes in other countries may include all of the risks detailed above regarding FDA approval in the U.S. as well as other risks, or vice versa. In particular, in many countries outside of the U.S. and Europe, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others. Failure to obtain marketing approval in other countries or any delay or other setback in obtaining such approval would impair our ability to commercialize bempedoic acid or the bempedoic acid / ezetimibe combination tablet in such foreign markets. Any such impairment would reduce the size of our potential market, which could have a material adverse impact on our business, results of operations and prospects.

***Even as we have received marketing approval for bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the U.S. and Europe, they may not achieve broad market acceptance, which would limit the revenue that we generate from their sales.***

The commercial success of bempedoic acid or the bempedoic acid / ezetimibe combination tablet in the U.S. and Europe, and, if approved, by other regulatory authorities, in other countries in which we pursue regulatory approval, will depend upon the awareness and acceptance of bempedoic acid and the bempedoic acid / ezetimibe combination tablet among the medical community, including physicians, patients and healthcare payors. Market acceptance of bempedoic acid and the bempedoic acid / ezetimibe combination tablet will depend on a number of factors, including, among others:

- bempedoic acid and the bempedoic acid / ezetimibe combination tablet's demonstrated ability to treat statin intolerant patients for LDL-C lowering or CV risk reduction as an add-on for patients already on statin therapy, as compared with other available therapies;
- the relative convenience and ease of administration of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, including as compared with other treatments for patients for LDL-C lowering or CV risk reduction;
- the prevalence and severity of any adverse side effects such as muscle pain or weakness;
- limitations or warnings contained in the labeling approved for bempedoic acid or the bempedoic acid / ezetimibe combination tablet by the FDA;
- availability of alternative treatments, including a number of competitive therapies already approved for LDL-C lowering or CV risk reduction, including PCSK9 inhibitors, or expected to be commercially launched in the near future;
- pricing and cost effectiveness;
- the effectiveness of our, in Europe, DSE's, and in Japan, Otsuka's, sales and marketing strategies, as well as the effectiveness of any other future collaborators;
- our ability to increase awareness of bempedoic acid or the bempedoic acid / ezetimibe combination tablet through marketing efforts;
- our ability to obtain sufficient third-party coverage or reimbursement; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If bempedoic acid or the bempedoic acid / ezetimibe combination tablet does not achieve an adequate level of acceptance by patients, physicians and payors, we may not generate sufficient revenue from bempedoic acid and the bempedoic acid / ezetimibe combination tablet to become or remain profitable. Our efforts to educate the medical community and third-party payors about the benefits of bempedoic acid and the bempedoic acid / ezetimibe combination tablet may require significant resources and may never be successful.

***Even though we have obtained marketing approval for bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the U.S. and Europe, physicians and patients using other LDL-C lowering therapies may choose not to switch to our products.***

Physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective, safe or convenient treatments enter the market. In addition, patients often acclimate to the brand or type of therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of reimbursement for existing therapies. If physicians or patients are reluctant to switch from existing therapies to bempedoic acid and the bempedoic acid / ezetimibe combination tablet, our operating results and financial condition would be materially adversely affected.

### **Risks Related to Our Business**

***We have expanded and expect to continue to expand our sales, marketing and distribution capabilities, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.***

We are an early-stage commercial company with recently established capabilities for marketing, sales, market access and distribution. We expect that in the future we will continue to increase our workforce and the scope of our operations, including as we build our commercial sales capabilities. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational and financial systems and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure; or give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to



significant costs and may divert financial resources from other projects, such as the commercialization and development of bempedoic acid or the bempedoic acid / ezetimibe combination tablet. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than anticipated, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize bempedoic acid or the bempedoic acid / ezetimibe combination tablet and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

***Our internal computer systems, or those of our third-party clinical research organizations or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our bempedoic acid or the bempedoic acid / ezetimibe combination tablet commercialization and development programs.***

Despite the implementation of security measures, our internal computer systems and those of our third-party clinical research organizations and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical study data for bempedoic acid or the bempedoic acid / ezetimibe combination tablet could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or our products and product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of bempedoic acid or the bempedoic acid / ezetimibe combination tablet could be delayed and the commercialization of our products could be impacted.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and patients, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. We may experience threats to our data and systems, including malicious codes and viruses, phishing and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our third-party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

***Our employees may engage in misconduct or other improper activities, including violating applicable regulatory standards and requirements or engaging in insider trading, which could significantly harm our business.***

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA and applicable non-U.S. regulators, provide accurate information to the FDA and applicable non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of, including trading on, information obtained in the course of clinical studies, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a

code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

***The increasing use of social media platforms presents new risks and challenges.***

Social media is increasingly being used to communicate about our drugs, clinical development programs, and the diseases our drugs and drug candidates are being developed to treat, and we are utilizing what we believe is appropriate social media in connection with our commercialization efforts for bempedoic acid and the bempedoic acid / ezetimibe combination tablet and we intend to do the same for our future products, if approved. Social media practices in the pharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us. For example, there is a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business.

***The effects of enacted tax legislation and other legislative, regulatory, and administrative developments to our business are uncertain. Increased costs related to such developments could adversely affect our financial condition and results of operations.***

On December 22, 2017, the TCJA was signed into law. The TCJA made major changes to the taxation of corporations, including reduction of the corporate tax rate from 35% to 21%, limitation of the tax deduction for interest expense to 30% of adjusted taxable income (except for certain small businesses), limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carrybacks, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Further, on March 27, 2020, the CARES Act was signed into law, which, among other things, suspends the 80% limitation on the deduction for net operating losses in taxable years beginning before January 1, 2021, permits a 5-year carryback of net operating losses arising in taxable years beginning after December 31, 2017 and before January 1, 2021, and generally caps the limitation on the deduction for net interest expense at 50% of adjusted taxable income for taxable years beginning in 2019 and 2020. It cannot be predicted whether, when, in what form, or with what effective dates, tax laws, regulations, and rulings may be enacted, promulgated, or issued, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law.

***Our ability to use our net operating loss carryforwards may be subject to limitation.***

At December 31, 2020, we had United States federal net operating loss carryforwards of approximately \$700.7 million and state net operating loss carryforwards of approximately \$530.3 million. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an “ownership change,” the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. In general, an “ownership change” will occur if there is a cumulative change in our ownership by “5-percent shareholders” that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. As a result of prior equity issuances and other transactions in our stock, we have previously experienced “ownership changes” under section 382 of the Code and comparable state tax laws in those years. While these ownership changes could potentially impact our ability to use tax loss carryforwards from before the ownership change dates in any given year, based upon current tax law, we do not anticipate these limitations hindering our ability to utilize the losses over time if the Company generates sufficient taxable income over the carryforward period. We may also experience ownership changes in the future as a result of future transactions in our stock. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards or other pre-change tax attributes to offset United States federal and state taxable income is subject to further limitations.

***We or the third parties upon whom we depend may be adversely affected by natural disasters or global health crises and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Natural disasters or global health crises, including the COVID-19 pandemic, could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition, and prospects. If a natural disaster, global health crisis, power outage, or other event occurred that prevented us from using all or a significant portion of our

headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted our operations or the operations of our vendors, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster, health crisis, or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business.

### **Risks Related to Clinical Development, Regulatory Review, and Approval of Our Drugs and Future Drug Candidates**

***Failures or delays in the completion of our CLEAR Outcomes CVOT for bempedoic acid could result in increased costs to us and could delay, prevent or limit our ability to generate revenue and continue our business.***

In December 2016, we initiated the CLEAR Outcomes CVOT. The completion of the CLEAR Outcomes CVOT or any of our other ongoing or future clinical studies can be delayed or prevented for a number of reasons, including, among others:

- the FDA, EMA or any other regulatory authority may not agree to the study design or overall program;
- the FDA, EMA or any other regulatory authority may place a clinical study on hold;
- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs and study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;
- inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical studies;
- difficulties or delays obtaining institutional review board, or IRB, approval to conduct a clinical study at a prospective site or sites;
- severe or unexpected drug-related side effects experienced by patients in a clinical study, including instances of muscle pain or weakness or other side effects;
- reports from preclinical or clinical testing of other cardiometabolic therapies that raise safety or efficacy concerns; and
- difficulties retaining patients who have enrolled in a clinical study but may be prone to withdraw due to rigors of the study, lack of efficacy, side effects, personal issues or loss of interest.

Clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical study may be suspended or terminated by us, the FDA, the EMA, the IRBs at the sites where the IRBs are overseeing a clinical study, a data safety monitoring committee, or DMC, overseeing the clinical study at issue or any other regulatory authorities due to a number of factors, including, among others:

- failure to conduct the clinical study in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical study operations or study sites by the FDA, EMA or any other regulatory authorities that reveals deficiencies or violations that require us to undertake corrective action, including the imposition of a clinical hold;
- unforeseen safety issues;
- changes in government regulations or administrative actions;
- problems with clinical supply materials; and
- lack of adequate funding to continue the clinical study.

***Positive results from completed Phase 1, Phase 2 and Phase 3 clinical studies of bempedoic acid and the bempedoic acid / ezetimibe combination tablet are not necessarily predictive of the results of our ongoing CLEAR Outcomes CVOT of bempedoic acid or any other of our future clinical studies, nor do they guarantee approval of bempedoic acid and the bempedoic acid / ezetimibe combination tablet by the FDA, EMA or any other regulatory agency for additional indications such as a CVD risk reduction indication. If we cannot replicate the positive results from our completed Phase 1, Phase 2 and***

***Phase 3 clinical studies of bempedoic acid and the bempedoic acid / ezetimibe combination tablet in our CVOT or other future clinical studies, we may be unable to successfully develop, obtain regulatory status for and commercialize bempedoic acid and the bempedoic acid / ezetimibe combination tablet.***

There is a high failure rate for drugs proceeding through clinical studies. Even if we are able to complete our ongoing CLEAR Outcomes CVOT, the positive results from our completed Phase 1, Phase 2 and Phase 3 clinical studies of bempedoic acid and our Phase 3 1002FDC-053 clinical study of the bempedoic acid / ezetimibe combination tablet, may not be replicated in our ongoing CLEAR Outcomes CVOT or any future studies of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, nor do they guarantee approval of bempedoic acid and the bempedoic acid / ezetimibe combination tablet by the FDA for additional indications such as a CVD risk reduction indication, the EMA or any other regulatory authorities in a timely manner or at all. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical studies after achieving positive results earlier in development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical studies were underway or safety or efficacy observations made in clinical studies, including previously unreported adverse events. In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development. If we fail to obtain positive results in the CLEAR Outcomes CVOT or any future clinical studies, the regulatory status of our product candidates or future product candidates, and correspondingly, our business and financial prospects, may be materially adversely affected.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt non-clinical studies and clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities.

Clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our product candidates receive marketing approval and we or others identify undesirable side effects caused by such products (or any other similar products) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such products;
- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contraindication;
- we may be required to change the way such products are distributed or administered, conduct additional clinical trials or change the labeling of the products;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to recall or remove such products from the marketplace; or
- we could be sued and held liable for injury caused to individuals exposed to or taking our products and product candidates; and our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected products, and could substantially increase the costs of commercializing our products and significantly impact our ability to successfully commercialize our products and generate revenues.

***Changes in regulatory requirements, FDA or EMA guidance or unanticipated events, including in our CVOT of bempedoic acid, may occur, which may result in changes to clinical study protocols or additional clinical study requirements, which could result in increased costs to us and could delay our development timeline.***

Changes in regulatory requirements, FDA or EMA guidance or unanticipated events during our clinical studies may force us to amend clinical study protocols or the FDA or EMA may impose additional clinical study requirements. Significant amendments to our clinical study protocols may require resubmission to the FDA and/or IRBs for review and approval, which may adversely impact the cost, timing and/or successful completion of these studies. If we experience substantial delays completing—or if we terminate our CVOT, or if we are required to conduct additional clinical studies, the commercial prospects for bempedoic acid and the bempedoic acid / ezetimibe combination tablet may be harmed and our ability to generate product revenue will be impaired. Even though we have completed enrollment for our CVOT, we may not ultimately be able to

demonstrate sufficient clinical benefits from bempedoic acid or the bempedoic acid / ezetimibe combination tablet, and our failure to do so may delay or hinder our ability to obtain FDA or EMA approval for a CVD risk reduction indication.

***Our future product development programs for candidates other than bempedoic acid or the bempedoic acid / ezetimibe combination tablet may require substantial financial resources and may ultimately be unsuccessful.***

In addition to the development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, we may pursue the development of other early-stage development programs. If we conduct any clinical studies for our future product candidates, there will be a number of FDA requirements that we must satisfy before we can commence such clinical studies. Satisfaction of these requirements will entail substantial time, effort and financial resources. We may never satisfy these requirements. Any time, effort and financial resources we expend on any early-stage development programs that we may pursue may adversely affect our ability to continue development and commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, and we may never commence clinical studies of such development programs despite expending significant resources in pursuit of their development. If we do commence clinical studies of our other potential product candidates, such product candidates may never be approved by the FDA.

### **Risks Related to Litigation**

***We face potential product liability exposure, and, if claims are brought against us, we may incur substantial liability.***

The use of bempedoic acid and the bempedoic acid / ezetimibe combination tablet in clinical studies and the sale of bempedoic acid and the bempedoic acid / ezetimibe combination tablet exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with bempedoic acid or the bempedoic acid / ezetimibe combination tablet. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, including as a result of interactions with alcohol or other drugs, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we become subject to product liability claims and cannot successfully defend ourselves against them, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in, among other things:

- withdrawal of patients from our clinical studies;
- substantial monetary awards to patients or other claimants;
- decreased demand for bempedoic acid or the bempedoic acid / ezetimibe combination tablet or any future product candidates following marketing approval, if obtained;
- damage to our reputation and exposure to adverse publicity;
- increased FDA warnings on product labels;
- litigation costs;
- distraction of management's attention from our primary business;
- loss of revenue; and
- the inability to successfully commercialize bempedoic acid or the bempedoic acid / ezetimibe combination tablet or any future product candidates, if approved.

We maintain product liability insurance coverage for our clinical studies with a \$10.0 million annual aggregate coverage limit, in addition to insurance coverage in specific local jurisdictions. Nevertheless, our insurance coverage may be insufficient to reimburse us for any expenses or losses we may suffer. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses, including if insurance coverage becomes increasingly expensive. We expanded our insurance coverage to include the sale of commercial products. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial, particularly in light of the size of our business and financial resources. A product liability claim or series of claims brought against us could cause our stock price to decline

and, if we are unsuccessful in defending such a claim or claims and the resulting judgments exceed our insurance coverage, our financial condition, business and prospects could be materially adversely affected.

***We may be at an increased risk of securities class action litigation.***

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. For example, a purported securities class action lawsuit was filed in January 2016 naming us and certain of our officers as defendants. In December 2016, the federal district court granted our motion to dismiss with prejudice and entered judgment in our favor. In May 2017, the court denied plaintiffs' motion to alter or amend that judgment. On June 19, 2017, plaintiffs filed a notice of appeal to the Sixth Circuit Court of Appeals and on September 14, 2017, they filed their opening brief in support of the appeal. The appeal was fully briefed on December 7, 2017, and it was argued before the Sixth Circuit on March 15, 2018. On September 27, 2018, the Sixth Circuit issued an opinion in which it reversed the district court's dismissal and remanded for further proceedings. On October 11, 2018, we filed a petition for rehearing en banc and, on October 23, 2018, the Sixth Circuit Court of Appeals directed plaintiffs to respond to that petition. On December 3, 2018, the Sixth Circuit Court of Appeals denied our petition for en banc rehearing, and on December 11, 2018, the case was returned to the federal district court by mandate from the Sixth Circuit. On December 26, 2018, we filed our answer to the amended complaint, and on March 28, 2019, we filed our amended answer to the amended complaint. On September 15, 2020, we filed a motion for summary judgment, and the plaintiffs filed a motion for partial summary judgment, and on October 23, 2020, the parties filed oppositions to both motions for summary judgment. On November 20, 2020, we and plaintiffs filed replies in support of our respective motions.

Additionally, in December 2016, a purported stockholder of our company filed a derivative lawsuit in the Court of Chancery of the State of Delaware against Tim Mayleben, Roger Newton, Mary McGowan, Nicole Vitullo, Dov Goldstein, Daniel Janney, Antonio Gotto Jr., Mark McGovern, Gilbert Omenn, Scott Braunstein, and Patrick Enright. Our company is named as a nominal defendant. The lawsuit alleges that the defendants breached their fiduciary duties to the company when they made or approved improper statements on August 17, 2015, regarding our lead product candidate's path to FDA approval, and failed to ensure that reliable systems of internal controls were in place at our company. On February 8, 2019, we and the defendants filed a motion to dismiss the derivative lawsuit. On April 23, 2019, the plaintiff filed an opposition to the motion to dismiss the derivative lawsuit, and we filed a reply brief on May 15, 2019. On November 6, 2019, the court held a hearing on the motion to dismiss. On February 13, 2020, the court granted our motion to dismiss with prejudice and entered judgment in our favor. On March 16, 2020, the plaintiff filed a notice of appeal to the Supreme Court of Delaware. On June 1, 2020, the plaintiff filed his opening brief on appeal to the Supreme Court of Delaware. On July 1, 2020, the Company and the defendants filed an answering brief, and on July 16, 2020, the plaintiff filed a reply brief. On October 14, 2020, the Supreme Court of Delaware held oral arguments on the appeal. On October 29, 2020, the Supreme Court of Delaware issued an order affirming the judgment of the Court of Chancery.

Any lawsuit to which we or our directors or officers are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our offerings or business practices. Any of these results could adversely affect our business. In addition, defending claims is costly and can impose a significant burden on our management. Any proceeding in which we are or may become involved could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

***We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing bempedoic acid and the bempedoic acid / ezetimibe combination tablet.***

Our success will depend in part on our ability to operate without infringing the intellectual property and proprietary rights of third parties. We cannot assure you that our business, products and methods do not or will not infringe the patents or other intellectual property rights of third parties.

The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may allege that bempedoic acid or the bempedoic acid / ezetimibe combination tablet or the use of our technologies infringe patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. For example, we are aware of U.S. patents relating to compositions containing ezetimibe. Although we believe that our bempedoic acid / ezetimibe combination tablet would not infringe a claim of such patents, the owner of such patents may disagree and initiate a patent infringement action against us. Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. Any claim relating to

intellectual property infringement that is successfully asserted against us may require us to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing another party's patents, for past use of the asserted intellectual property and royalties and other consideration going forward if we are forced to take a license. In addition, if any such claim were successfully asserted against us and we could not obtain such a license, we may be forced to stop or delay developing, manufacturing, selling or otherwise commercializing bempedoic acid or the bempedoic acid / ezetimibe combination tablet.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign our products. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease developing, selling or otherwise commercializing bempedoic acid or the bempedoic acid / ezetimibe combination tablet;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all; and
- redesign, or rename in the case of trademark claims, bempedoic acid or the bempedoic acid / ezetimibe combination tablet to avoid infringing the intellectual property rights of third parties, which may not be possible and, even if possible, could be costly and time-consuming.

Any of these risks coming to fruition could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

Our employees have been previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we are not aware of any claims currently pending against us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of the former employers of our employees. 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 be a distraction to management. 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 personnel or their work product could hamper or prevent our ability to commercialize bempedoic acid or the bempedoic acid / ezetimibe combination tablet, which would materially adversely affect our commercial development efforts.

## **Risks Related to Our Financial Position, Capital Needs and Ownership of Our Stock**

### **Risks Related to Our Financial Position**

***We have incurred significant operating losses since our inception, and anticipate that we will incur continued losses for the foreseeable future.***

Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We were incorporated in January 2008. Our operations to date have been limited primarily to organizing and staffing our company and conducting research and development activities for bempedoic acid and the bempedoic acid / ezetimibe combination tablet, as well as preparing for the commercial launch and the initial commercial launch of these products. We have generated \$13.0 million in revenue from product sales in the U.S. We have obtained regulatory approval for both products from the FDA in the U.S., the EC in Europe and Swissmedic in Switzerland, but have not received approval for bempedoic acid and the bempedoic acid / ezetimibe combination tablet from any other regulatory agency. As such, we are subject to all the risks incident to the development, regulatory approval and commercialization of new pharmaceutical products and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors.

Since our inception, we have focused substantially all of our efforts and financial resources on developing bempedoic acid. We have funded our operations to date primarily through proceeds from sales of preferred stock, public offerings of common stock, convertible promissory notes and warrants, the incurrence of indebtedness, milestone payments from collaboration agreements and revenue interest purchase agreements, and we have incurred losses in each year since our inception. Our net losses were \$143.6 million, \$97.2 million and \$201.8 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of \$838.8 million. Substantially all of our operating losses resulted from costs incurred in connection with our development program and from selling, general and administrative costs associated with our operations. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future related to the CLEAR Outcomes CVOT and to commercialization activities, as well as other related personnel and activities. Our research and development expenses are expected to continue in the foreseeable future as they relate to our ongoing CLEAR Outcomes CVOT and any other early-stage development programs or additional indications we choose to pursue. We also expect to incur significant sales, marketing and outsourced manufacturing expenses and expect further significant increases in our general and administration expenses in connection with the commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, respectively. Even though bempedoic acid and the bempedoic acid / ezetimibe combination tablet are approved in the U.S. and Europe for commercial sale, and despite expending these costs, bempedoic acid or the bempedoic acid / ezetimibe combination tablet may not be commercially successful drugs. As a public company, we have incurred and will continue to incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

### **Risks Related to our Capital Needs**

***We may need substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations.***

In February 2020 we announced that the FDA approved NEXLETOL and NEXLIZET. In April 2020, we announced that the EC approved NILEMDO and NUSTENDI.

We expect that our commercialization efforts and any additional clinical studies that we undertake for the clinical development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any other product candidate we pursue will consume substantial additional financial resources. We expect that our existing cash and cash equivalents and proceeds to be received in the future for product sales, under the DSE and Otsuka collaboration agreements and the Revenue Interest Purchase Agreement, or RIPA, with Eiger II SA LLC, or Oberland, an affiliate of Oberland Capital LLC, are sufficient to fund operations for the foreseeable future. We may, however, need to secure additional cash resources to continue to fund the commercialization and further clinical development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet. Our future capital requirements may be substantial and will depend on many factors including:

- the scope, size, rate of progress, results and costs of completing our CLEAR Outcomes CVOT of bempedoic acid;
- our commercial sales, and our ability to secure and maintain reimbursement coverage, in the United States, and in Europe;
- the costs associated with commercializing bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any future product candidates if we receive marketing approval, including the cost and timing of developing sales and marketing capabilities or entering into strategic collaborations to market and sell bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any future product candidates;
- DSE and Otsuka's ability to successfully commercialize bempedoic acid and the bempedoic acid / ezetimibe combination tablet in their respective territories;
- the number and characteristics of any additional product candidates we develop or acquire;
- the cost of manufacturing bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any future product candidates and any products we successfully commercialize; and



- the costs associated with general corporate activities, such as the cost of filing, prosecuting and enforcing patent claims.

Changing circumstances may cause us to consume capital significantly faster than we currently anticipate. Because the outcome of any clinical study is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval and commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablet and any future product candidates. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If adequate funds are unavailable to us on a timely basis, or at all, we may not be able to continue the development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any future product candidate, or to commercialize bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any future product candidate, if approved.

***If we do not establish successful collaborations, we may have to alter our development and commercialization plans for bempedoic acid and the bempedoic acid / ezetimibe combination tablet.***

Our drug development programs and commercialization plans for bempedoic acid and the bempedoic acid / ezetimibe combination tablet will require substantial additional cash to fund expenses. We developed and commercialized bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the United States without a partner. However, in order to pursue the broader cholesterol modifying market in the United States, we may also enter into a partnership or co-promotion arrangement with an established pharmaceutical company that has a larger sales force. We are continuing to establish our commercialization and distribution capabilities to support the sales, marketing and distribution of our pharmaceutical products, including through our arrangements with DSE and Otsuka. In order to market bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the U.S. and, if approved by any other regulatory body, we must continue to build our sales, marketing, managerial, and other non-technical capabilities or make arrangements with third parties to perform these services.

We will face significant competition in seeking appropriate collaborators and these collaboration agreements are complex and time-consuming to negotiate. We may not be able to negotiate collaborations on acceptable terms, or at all. If that were to occur, we may have to curtail the development or delay commercialization of bempedoic acid or the bempedoic acid / ezetimibe combination tablet in certain geographies, reduce the scope of our sales or marketing activities, reduce the scope of our commercialization plans, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities outside of the United States, the DSE Territory and Japan on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all.

***Our payment obligations under the Revenue Interest Purchase Agreement with Oberland may adversely affect our financial position or results of operations and our ability to raise additional capital which in turn may increase our vulnerability to adverse regulatory developments or economic or business downturns.***

On June 26, 2019, we entered into the RIPA with Oberland and the Purchasers named therein. Pursuant to the RIPA, Oberland paid us \$125.0 million on closing, less certain transaction expenses, and, Oberland paid us an additional \$25.0 million in March 2020 upon receiving regulatory approval of NEXLETOL. Subject to the terms and conditions in the RIPA, we are eligible for an additional \$50.0 million at our option upon reaching certain sales thresholds. As consideration for the payments, Oberland has the right to receive certain revenue interests from us based on the net sales of certain products, once approved, which will be tiered payments initially ranging from 2.5% to 7.5% of our net sales in the covered territory. See Note 11 to our financial statements included elsewhere in this Annual Report on Form 10-K for a further discussion on the RIPA.

The RIPA and the revenue interest stream payable to Oberland could have important negative consequences to the holders of our securities. For example, a portion of our cash flow from operations will be needed to pay certain revenue interests to Oberland and will not be available to fund future operations. Additionally, we may have increased vulnerability to adverse general economic and industry conditions.

Payment requirements under the RIPA will increase our cash outflows. Our future operating performance is subject to market conditions and business factors that are beyond our control. If our cash inflows and capital resources are insufficient to allow us to make required payments, we may have to reduce or delay capital expenditures, sell assets or seek additional capital. If we raise funds by selling additional equity, such sale would result in dilution to our stockholders. There is no assurance that if we are required to secure funding we can do so on terms acceptable to us, or at all. Failure to pay certain amounts to Oberland when due would result in a default under the RIPA and result in foreclosure on certain of our assets which would have a material adverse effect.

The RIPA contains customary affirmative and negative non-financial covenants and events of default, including, covenants and restrictions that among other things, grant a senior security interest in our assets and restrict our ability to incur liens, incur additional indebtedness, make loans and investments, engage in mergers and acquisitions, and engage in asset sales. Additionally, the Purchasers under the RIPA have an option (the “Put Option”) to terminate the RIPA and to require the Company to repurchase future Revenue Interests upon enumerated events such as a bankruptcy event, an uncured material breach, a material adverse effect (which can include adverse developments related to the regulatory approval of our product candidates) or a change of control. The triggering of the Put Option, including by our failure to comply with these covenants, could permit the Purchasers to declare certain amounts to be immediately due and payable. If we default under the terms of the RIPA, including by failure to make such accelerated payments, the Purchasers take control of our pledged assets. Further, if we are liquidated, the Purchasers’ right to repayment would be senior to the rights of the holders of our common stock. Any triggering of the Put Option or other declaration by the Purchasers of an event of default under the RIPA could significantly harm our financial condition, business and prospects and could cause the price of our common stock to decline.

### **Risks Related to our Convertible Notes**

***Servicing our debt may require a significant amount of cash. We may not have sufficient cash flow from our business to pay our indebtedness.***

In November 2020, we completed a private offering of Notes, issuing an aggregate principal amount of \$280.0 million of 4.00% convertible senior subordinated notes due 2025. The interest rate is fixed at 4.00% per annum and is payable semi-annually in arrears on May 15 and November 15 of each year, beginning on May 15, 2021. Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional debt financing or equity capital on terms that may be onerous or highly dilutive. Our ability to refinance any future indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations. In addition, any of our future debt agreements may contain restrictive covenants that may prohibit us from adopting any of these alternatives. Our failure to comply with these covenants could result in an event of default which, if not cured or waived, could result in the acceleration of our debt.

***We may not have the ability to raise the funds necessary for cash settlement upon conversion of the Notes or to repurchase the Notes for cash upon a fundamental change, and our future debt may contain limitations on our ability to pay cash upon conversion of the Notes or to repurchase the Notes.***

Holders of the Notes have the right to require us to repurchase their Notes upon the occurrence of a fundamental change (as defined in the indenture governing the Notes) at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any. Upon conversion of the Notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the Notes being converted. We may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Notes surrendered or Notes being converted. In addition, our ability to repurchase the Notes or to pay cash upon conversions of the Notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase Notes at a time when the repurchase is required by the indenture governing such notes or to pay any cash payable on future conversions of the Notes as required by such indenture would constitute a default under such indenture. A default under the indenture governing the Notes or the fundamental change itself could also lead to a default under agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes or make cash payments upon conversions.

In addition, our indebtedness, combined with our other financial obligations and contractual commitments, could have other important consequences. For example, it could:

- make us more vulnerable to adverse changes in general U.S. and worldwide economic, industry and competitive conditions and adverse changes in government regulation;
- limit our flexibility in planning for, or reacting to, changes in our business and our industry;

- place us at a disadvantage compared to our competitors who have less debt;
- limit our ability to borrow additional amounts to fund acquisitions, for working capital and for other general corporate purposes; and
- make an acquisition of our company less attractive or more difficult.

Any of these factors could harm our business, results of operations and financial condition. In addition, if we incur additional indebtedness, the risks related to our business and our ability to service or repay our indebtedness would increase.

***The conditional conversion feature of the Notes, if triggered, may adversely affect our financial condition and results of operations.***

In the event the conditional conversion feature of the Notes is triggered, holders of the Notes will be entitled to convert the Notes at any time during specified periods at their option. If one or more holders elect to convert their Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

***Transactions relating to our Notes may affect the value of our common stock.***

The conversion of some or all of the Notes would dilute the ownership interests of existing stockholders to the extent we satisfy our conversion obligation by delivering shares of our common stock upon any conversion of such Notes. Our Notes may become in the future convertible at the option of their holders under certain circumstances. If holders of our Notes elect to convert their notes, we may settle our conversion obligation by delivering to them a significant number of shares of our common stock, which would cause dilution to our existing stockholders.

In addition, in connection with the issuance of the Notes, we entered into the Capped Calls with certain financial institutions, or the Option Counterparties. The Capped Calls are generally expected to reduce potential dilution to our common stock upon any conversion or settlement of the Notes and/or offset any cash payments we are required to make in excess of the principal amount of converted Notes, with such reduction and/or offset subject to a cap.

In connection with establishing their initial hedges of the Capped Calls, the Option Counterparties or their respective affiliates entered into various derivative transactions with respect to our common stock and/or purchased shares of our common stock concurrently with or shortly after the pricing of the Notes.

From time to time, the Option Counterparties or their respective affiliates may modify their hedge positions by entering into or unwinding various derivative transactions with respect to our common stock and/or purchasing or selling our common stock or other securities of ours in secondary market transactions prior to the maturity of the Notes (and are likely to do so following any conversion of the Notes, any repurchase of the Notes by us on any fundamental change repurchase date, any redemption date, or any other date on which the Notes are retired by us, in each case, if we exercise our option to terminate the relevant portion of the Capped Calls). This activity could cause a decrease and/or increased volatility in the market price of our common stock.

We do not make any representation or prediction as to the direction or magnitude of any potential effect that the transactions described above may have on the price of the Notes or our common stock. In addition, we do not make any representation that the Option Counterparties will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

***We are subject to counterparty risk with respect to the Capped Calls.***

The Option Counterparties are financial institutions, and we will be subject to the risk that any or all of them might default under the Capped Calls. Our exposure to the credit risk of the Option Counterparties will not be secured by any collateral. Past global economic conditions have resulted in the actual or perceived failure or financial difficulties of many financial institutions. If an Option Counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings with a claim equal to our exposure at that time under the Capped Calls with such Option Counterparty. Our

exposure will depend on many factors but, generally, an increase in our exposure will be correlated to an increase in the market price and in the volatility of our common stock. In addition, upon a default by an Option Counterparty, we may suffer adverse tax consequences and more dilution than we currently anticipate with respect to our common stock. We can provide no assurances as to the financial stability or viability of the Option Counterparties.

***The accounting method for convertible debt securities that may be settled in cash, such as the Notes, could have a material effect on our reported financial results.***

Under Financial Accounting Standards Board Accounting Standards Codification 470-20, Debt with Conversion and Other Options, which we refer to as ASC 470-20, an entity must separately account for the liability and equity components of convertible debt instruments (such as the Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. ASC 470-20 requires the value of the conversion options of the Notes, representing the equity component, to be recorded as additional paid-in capital within stockholders' equity in our balance sheets and as a discount to the Notes, which reduces their initial carrying value. The carrying value of the Notes, net of the applicable discount recorded, will be accreted up to the principal amount of the Notes, as the case may be, from the issuance date until maturity, which will result in non-cash charges to interest expense in our statement of operations. Accordingly, we will report lower net income or higher net loss in our financial results because ASC 470-20 requires interest to include both the current period's accretion of the debt discount and the instrument's coupon interest, which could adversely affect our reported or future financial results, the trading price of our common stock and the respective trading price of the Notes.

In addition, under certain circumstances, convertible debt instruments (such as the Notes) that may be settled entirely or partly in cash are currently permitted to be accounted for using the treasury stock method, the effect of which is that the shares issuable upon conversion of the Notes are not included in the calculation of diluted earnings per share except to the extent that the conversion value of the Notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued.

Accounting standards in the future will not permit the use of the treasury stock method. As disclosed in Note 2 to our financial statements, the Financial Accounting Standards Board recently issued an accounting standards update to amend these accounting standards to eliminate the treasury stock method for convertible instruments and instead require application of the "if-converted" method which would be effective for us beginning in fiscal 2023, but may be voluntarily adopted earlier. We intend to early adopt January 1, 2021. We currently already apply the "if-converted" method for calculating any potential dilutive effect of the conversion options embedded in the Notes on diluted net income per share, which assumes that all of the Notes were converted solely into shares of common stock at the beginning of the reporting period or the issuance date of the corresponding Notes, unless the result would be anti-dilutive. The standards update also eliminates the liability and equity component separation model for convertible debt instruments with a cash conversion feature, which is expected to reduce reported interest expense, increase reported net income, and result in a reclass of certain balance sheet amounts from stockholders' equity to liabilities as it relates to our Notes. See Note 2 to our financial statements included elsewhere in this Annual Report on Form 10-K for a further discussion on the financial statement impact of adoption of this standard.

### **Risks Related to Ownership of Our Common Stock**

***Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights.***

We may seek additional cash resources through a combination of collaborations with third parties, strategic alliances, licensing arrangements, permitted debt financings, permitted royalty-based financings, private and public equity offerings or through other sources. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest in our company will be diluted. In addition, the terms of any such securities may include liquidation or other preferences that materially adversely affect your rights as a stockholder. Debt financing, if available and permitted under the terms of our RIPA, would increase our fixed payment obligations. Debt or royalty-based financings may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic partnerships and licensing arrangements with third parties, such as the collaboration arrangements with DSE and Otsuka and the RIPA with Oberland, we may have to relinquish valuable rights to bempedoic acid or the bempedoic acid / ezetimibe combination tablet, our intellectual property, future revenue streams or grant licenses on terms that are not favorable to us. For instance, as part of the RIPA with Oberland, Oberland has the right to receive certain revenue interests from us based on the net sales of certain products and we have granted Oberland a senior security interest in certain of our assets. If our cash flows and capital resources are insufficient to allow us to make required payments, we may

have to reduce or delay capital expenditures, sell assets or seek additional capital. If we raise funds by selling additional equity, such sale would result in dilution to our stockholders. If we are unable to raise additional funds through equity or permitted debt financings or through collaborations, strategic alliances or licensing arrangements or permitted royalty-based financing arrangements when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market bempedoic acid and the bempedoic acid / ezetimibe combination tablet that we would otherwise prefer to develop and market ourselves.

***Our executive officers, directors, and principal stockholders, if they choose to act together, will continue to have the ability to exert significant influence over matters subject to stockholder approval.***

At December 31, 2020, our executive officers, directors, combined with our stockholders who own more than 5% of our outstanding capital stock, and entities affiliated with certain of our directors beneficially owned approximately 79.2% of our outstanding voting common stock. These stockholders have the ability to influence us through their ownership position. These stockholders may be able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

***Complying with public company reporting and other obligations may strain our financial and managerial resources. Additionally, we are obligated to maintain proper and effective internal control over financial reporting. If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our common stock.***

As a public company, we are required to comply with applicable provisions of the Sarbanes-Oxley Act of 2002, as well as other rules and regulations promulgated by the SEC and the NASDAQ Stock Market LLC, or NASDAQ, which results in significant continuing legal, accounting, administrative and other costs and expenses. The listing requirements of the NASDAQ Global Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel need to devote a substantial amount of time to ensure that we comply with all of these requirements.

We are subject to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, and the related rules of the SEC that generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Section 404 requires an annual management assessment, as well as an opinion from our independent registered public accounting firm, on the effectiveness of our internal control over financial reporting.

During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, we are required to timely file accurate quarterly and annual reports with the SEC under the Securities Exchange Act of 1934, or the Exchange Act, as amended. In order to report our results of operations and financial statements on an accurate and timely basis, we depend on CROs to provide timely and accurate notice of their costs to us. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the NASDAQ Global Market or other adverse consequences that would materially harm our business.

***If securities or industry analysts cease publishing research or reports or publish misleading, inaccurate or unfavorable research about us, our business or our market, our stock price and trading volume could decline.***

The trading market for our common stock is influenced by the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. We only recently started receiving research coverage by securities and industry analysts. If one or more of the industry analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, or provides more favorable relative recommendations about our competitors, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price or trading volume to decline.

***Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, even one that may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our certificate of incorporation and bylaws may delay or prevent an acquisition of us or a change in our management. These provisions include a classified board of directors, a prohibition on actions by written consent of our stockholders and the ability of our board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirors to negotiate with our board of directors, they would apply even if an offer rejected by our board were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

***We do not intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.***

We have never declared or paid any cash dividend on our common stock and do not currently intend to do so in the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which you purchased them.

#### **Risks Related to our Intellectual Property**

***If we are unable to adequately protect our proprietary technology or maintain issued patents which are sufficient to protect bempedoic acid and the bempedoic acid / ezetimibe combination tablet, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects.***

Our commercial success will depend in part on our success obtaining and maintaining issued patents and other intellectual property rights in the United States and elsewhere and protecting our proprietary technology. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

As of December 31, 2020, our patent estate, including patents we own, on a worldwide basis, included approximately 24 issued United States patents and seven pending United States patent applications and over 20 issued patents and over 75 pending patent applications in other foreign jurisdictions. Of our worldwide patent estate, only a subset of our patents and pending patent applications relates to our bempedoic acid program.

Bempedoic acid is claimed in U.S. Patent No. 7,335,799 that is scheduled to expire in December 2025, which includes 711 days of patent term adjustment, and may be eligible for a patent term extension period of up to five years. We have requested a five year patent term extension of U.S. Patent No. 7,335,799, and we believe that this patent could also be the subject of an additional six month pediatric exclusivity period. In addition, U.S. Patent Nos. 9,000,041, 8,497,301, 9,624,152 and 10,118,881, which are scheduled to expire in December 2023, claim methods of using bempedoic acid. There are currently seven issued patents in countries outside the United States, including, Brazil, Canada, Europe, Japan and Mexico, that relate to bempedoic acid and its use. Furthermore, of the seven granted patents, we have two granted European patents that have been validated in numerous European countries including France, Germany, Great Britain, Ireland, Italy, the Netherlands, Spain, Sweden and Switzerland. We are seeking five year patent term extensions via supplementary protection certificates for 23 national patents validated from one of the granted European patents, which, if approved, could extend our patent protection in those countries until 2028.

In addition, we have three patent families in which we are pursuing patent protection for our bempedoic acid and bempedoic acid / ezetimibe combination tablet in combination with one or more statins. We have two pending U.S. patent applications and 19 pending applications outside the U.S. with claims directed to methods of treatment using the bempedoic acid / ezetimibe combination. Additionally, we have one pending U.S. patent application and 23 pending applications outside the U.S. directed to the manufacturing of our bempedoic acid / ezetimibe combination tablet. We also have one pending U.S. patent application and 18 pending applications outside the U.S., with claims directed to methods of treatment using a fixed dose combination of bempedoic acid and one or more statins.

We may not have identified all patents, published applications or published literature that affect our business either by blocking our ability to commercialize our products and drug candidates, by preventing the patentability of one or more aspects of our products and drug candidates to us or our licensors or co-owners, or by covering the same or similar technologies that may affect our ability to market our products and drug candidates. For example, we (or the licensor of a drug candidate to us) may not have conducted a patent clearance search to identify potentially obstructing third party patents. Moreover, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office, or the USPTO, for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside of the United States are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. We cannot be certain that we or our licensors or co-owners were the first to invent, or the first to file, patent applications covering our products and drug candidates. We also may not know if our competitors filed patent applications for technology covered by our pending applications or if we were the first to invent the technology that is the subject of our patent applications. Competitors may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our patents.

Others may have filed patent applications or received patents that conflict with patents or patent applications that we own, have filed or have licensed, either by claiming the same methods, compounds or uses or by claiming methods, compounds or uses that could dominate those owned by or licensed to us. In addition, we may not be aware of all patents or patent applications that may affect our ability to make, use or sell any of our products or drug candidates. Any conflicts resulting from third-party patent applications and patents could affect our ability to obtain the necessary patent protection for our products or processes. If other companies or entities obtain patents with conflicting claims, we may be required to obtain licenses to these patents or to develop or obtain alternative technology. We may not be able to obtain any such licenses on acceptable terms or at all. Any failure to obtain such licenses could delay or prevent us from using discovery-related technology to pursue the development or commercialization of our products or drug candidates, which would adversely affect our business.

We cannot assure you that any of our patents have, or that any of our pending patent applications will mature into issued patents that will include, claims with a scope sufficient to protect bempedoic acid or the bempedoic acid / ezetimibe combination tablet or any other product candidates. Others have developed technologies that may be related or competitive to our approach, and may have filed or may file patent applications and may have received or may receive patents that may overlap or conflict with our patent applications, either by claiming the same methods or formulations or by claiming subject matter that could dominate our patent position. The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions, and, therefore, the issuance, scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated, or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, ex parte reexamination, inter partes review and post-grant review proceedings, supplemental examination and may be challenged in district court. Patents granted in certain other countries may be subjected to revocation, opposition or comparable proceedings lodged in various national and regional patent offices, and national courts. These proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, re-examination, post-grant review, inter partes review, supplemental examination, opposition, or revocation proceedings may be costly. Thus, any patents that we may own or exclusively license may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third-party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize bempedoic acid and the bempedoic acid / ezetimibe combination tablet.

Furthermore, the issuance of a patent, while presumed valid and enforceable, is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, vendors, former employees and current employees. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. If these developments were to occur, they could have a material adverse effect on our sales.

Furthermore, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We have submitted a request for a patent term extension in the United States for U.S. Patent No. 7,335,799 and have been seeking supplementary protection certificates for one of the granted, counterpart European patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, but the total patent term including the restoration period must not exceed 14 years following FDA

approval. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

Our ability to enforce our patent rights depends on our ability to detect infringement. It is difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. Any litigation to enforce or defend our patent rights, if any, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If, in any proceeding, a court invalidated or found unenforceable our patents covering bempedoic acid or the bempedoic acid / ezetimibe combination tablet, our financial position and results of operations would be materially and adversely impacted. In addition, if a court found that valid, enforceable patents held by third parties covered bempedoic acid or the bempedoic acid / ezetimibe combination tablet, our financial position and results of operations would also be materially and adversely impacted.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope and patent term sufficient to protect bempedoic acid or the bempedoic acid / ezetimibe combination tablet;
- any of our pending patent applications will result in issued patents;
- we will be able to successfully commercialize bempedoic acid or the bempedoic acid / ezetimibe combination tablet in all of the jurisdictions we intend to pursue before our relevant patents expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents;
- any of our patents will be valid and enforceable;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or product candidates that are separately patentable; or
- that our commercial activities or products, or those of our licensors, will not infringe upon the patents of others.

We rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors.

***If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished.***



We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, contract manufacturers, vendors and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, we cannot guarantee that we have executed these agreements with each party that may have or have had access to our trade secrets.

Moreover, because we acquired certain rights from Pfizer, we must rely on Pfizer's practices, and those of its predecessors, with regard to parties that may have had access to our trade secrets related thereto before our incorporation. Any party with whom we or they have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they disclose such trade secrets, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed, either intentionally or unintentionally, to or independently developed by a competitor or other third-party, our competitive position would be harmed.

***Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.***

The United States has enacted the America Invents Act of 2011, which is wide-ranging patent reform legislation. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

***We could become dependent on licensed intellectual property. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing bempedoic acid or the bempedoic acid / ezetimibe combination tablet or other product candidates, if approved.***

In the future, we may enter into license(s) to third-party intellectual property that are necessary or useful to our business. Such license agreement(s) will likely impose various obligations upon us, and our licensor(s) may have the right to terminate the license thereunder in the event of a material breach or, in some cases, at will. Future licensor(s) may allege that we have breached our license agreement with them and accordingly seek to terminate our license or decide to terminate our license at will. If successful, this could result in our loss of the right to use the licensed intellectual property, which could materially adversely affect our ability to develop and commercialize our products and product candidates as well as harm our competitive business position and our business prospects.

***We do not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.***

Filing, prosecuting and defending patents on our products and product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able

to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing with us.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to emerging pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and even if successful the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

### **Risks Related to our Dependence on Third Parties**

***If a collaborative partner terminates or fails to perform its obligations under an agreement with us, the commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablet could be delayed or terminated.***

In January 2019, we entered into a license and collaboration agreement with DSE, pursuant to which DSE will be responsible for the commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the DSE Territory. In April 2020, we entered into a license and collaboration agreement with Otsuka, pursuant to which Otsuka will be responsible for the commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablet in Japan. Otsuka will be responsible for all development and regulatory activities in Japan. In addition, Otsuka will fund all clinical development costs associated with the program in Japan, if approved. We may also enter into similar arrangements with other partners or collaborators to commercialize bempedoic acid and the bempedoic acid / ezetimibe combination tablet, outside of the United States, Europe and Japan, or to further commercialize bempedoic acid or the bempedoic acid / ezetimibe combination tablet in the broader cholesterol modifying market in the United States. If DSE or Otsuka or any of our future collaborative partners does not devote sufficient time and resources to the collaboration arrangement with us, we may not realize the potential commercial benefits of the arrangement, and our results of operations may be materially adversely affected. In addition, if DSE or Otsuka or any such future collaboration partner were to breach or terminate its arrangements with us, the commercialization of bempedoic acid or the bempedoic acid / ezetimibe combination tablet could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue commercialization of bempedoic acid or the bempedoic acid / ezetimibe combination tablet on our own in such locations.

Pursuant to the collaboration arrangement with DSE, we will receive significant commercial and regulatory milestone payments, as well as tiered fifteen percent (15%) to twenty-five percent (25%) royalties on certain net DSE Territory sales. Pursuant to the collaboration arrangement with Otsuka, we will receive significant commercial and regulatory milestone payments, as well as tiered fifteen percent (15%) to thirty percent (30%) royalties on certain net sales in Japan. Similar to these collaboration arrangements, much of the potential revenue from future collaborations may consist of contingent payments, such as payments for achieving regulatory milestones or royalties payable on sales of drugs. The milestone and royalty revenue that we may receive under these collaborations will depend upon our collaborators' ability to successfully introduce, market and sell new products. In addition, collaborators may decide to enter into arrangements with third parties to commercialize products developed under collaborations using our technologies, which could reduce the milestone and royalty revenue that we may receive, if any. DSE, Otsuka and our future collaboration partners may fail to develop or effectively commercialize products using our products or technologies because they:

- decide not to devote the necessary resources due to internal constraints, such as limited personnel with the requisite expertise, limited cash resources or specialized equipment limitations, or the belief that other drug development programs may have a higher likelihood of obtaining marketing approval or may potentially generate a greater return on investment;
- decide to pursue other technologies or develop other product candidates, either on their own or in collaboration with others, including our competitors, to treat the same diseases targeted by our own collaborative programs;

- do not have sufficient resources necessary to carry the product candidate through clinical development, marketing approval and commercialization; or
- cannot obtain the necessary marketing approvals.

Competition may negatively impact a partner's focus on and commitment to bempedoic acid or the bempedoic acid / ezetimibe combination tablet and, as a result, could delay or otherwise negatively affect the commercialization of bempedoic acid or the bempedoic acid / ezetimibe combination tablet outside of the United States or in the broader cholesterol modifying market in the United States. If DSE or Otsuka and our future collaboration partners fail to develop or effectively commercialize bempedoic acid or the bempedoic acid / ezetimibe combination tablet for any of these reasons, our sales of bempedoic acid or the bempedoic acid / ezetimibe combination tablet may be limited, which would have a material adverse effect on our operating results and financial condition.

***We will be unable to directly control all aspects of our clinical studies due to our reliance on CROs and other third parties that assist us in conducting clinical studies.***

We relied on CROs in our prior clinical studies, including our global pivotal Phase 3 clinical studies and our pivotal Phase 3 1002FDC-053 clinical study, and will continue to rely on CROs to conduct our CLEAR Outcomes CVOT, as well as any future clinical studies we may undertake. As a result, we will have less direct control over the conduct, timing and completion of these clinical studies and the management of data developed through the clinical studies than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical studies and may subject us to unexpected cost increases that are beyond our control.

Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording, and reporting the results of clinical studies to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical study participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements.

Problems with the timeliness or quality of the work of any CRO may lead us to seek to terminate our relationship with any such CRO and use an alternative service provider. Making this change may be costly and may delay our clinical studies, and contractual restrictions may make such a change difficult or impossible to effect. If we must replace any CRO that is conducting our clinical studies, our clinical studies may have to be suspended until we find another CRO that offers comparable services. The time that it takes us to find alternative organizations may cause a delay in the commercialization of bempedoic acid or the bempedoic acid / ezetimibe combination tablet or may cause us to incur significant expenses to replicate data that may be lost. Although we do not believe that any CRO on which we may rely will offer services that are not available elsewhere, it may be difficult to find a replacement organization that can conduct our clinical studies in an acceptable manner and at an acceptable cost. Any delay in or inability to complete our clinical studies could significantly compromise our ability to secure regulatory approval of bempedoic acid or the bempedoic acid / ezetimibe combination tablet for additional indications we may seek and preclude our ability to commercialize bempedoic acid or the bempedoic acid / ezetimibe combination tablet, thereby limiting or preventing our ability to generate revenue from its sales.

*We rely completely on third-party suppliers to manufacture our clinical drug supplies for bempedoic acid and the bempedoic acid / ezetimibe combination tablet and rely on third parties to produce commercial supplies of bempedoic acid and the bempedoic acid / ezetimibe combination tablet and preclinical, clinical and commercial supplies of any future product candidate.*

We do not currently have, nor do we plan to acquire, the infrastructure or capability to internally manufacture our commercial supply and clinical drug supply of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, or any future product candidates, for use in the commercialization and conduct of our preclinical studies and clinical studies, and we lack the internal resources and the capability to manufacture any product candidates on a commercial or clinical scale. In addition, we have no control over the production of ezetimibe for the bempedoic acid / ezetimibe combination tablet. The facilities used by our contract manufacturers to manufacture the active pharmaceutical ingredient and final drug for bempedoic acid, or any future product candidates, must be approved by the FDA and other comparable foreign regulatory agencies pursuant to inspections that would be conducted after submission of our NDA or relevant foreign regulatory submission to the applicable regulatory agency.

We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers to comply with current Good Manufacturing Practices for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or applicable foreign regulatory agencies, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, all of our contract manufacturers are engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes our manufacturers to regulatory risks for the production of such materials and products. As a result, failure to satisfy the regulatory requirements for the production of those materials and products may affect the regulatory clearance of our contract manufacturers' facilities generally. If the FDA or a comparable foreign regulatory agency does not approve these facilities for the manufacture of our products and product candidates or if it withdraws its approval in the future, we may need to find alternative manufacturing facilities, which would adversely impact our ability to commercialize, develop, obtain regulatory approval for or market our products and product candidates. If any contract manufacturer with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different contract manufacturer, which we may not be able to do on reasonable terms, if at all. In either scenario, our commercialization supply or clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original contract manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change contract manufacturers for any reason, we will be required to verify that the new contract manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our products and product candidates according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new contract manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a contract manufacturer may possess technology related to the manufacturing of our products and product candidates that such contract manufacturer owns independently. This would increase our reliance on such contract manufacturer or require us to obtain a license from such contract manufacturer in order to have another contract manufacturer manufacture our product and product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Throughout the COVID-19 outbreak, there has been public concern over the availability and accessibility of critical medical products, and the CARES Act enhances FDA's existing authority with respect to drug shortage measures. Under the CARES Act, we must have in place a risk management plan that identifies and evaluates the risks to the supply of approved drugs for certain serious diseases or conditions for each establishment where the drug or API is manufactured. The risk management plan will be subject to FDA review during an inspection. If we experience shortages in the supply of our marketed products, our results could be materially impacted.

#### **Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

Our corporate headquarters are located in Ann Arbor, Michigan where we lease and occupy approximately 19,400 square feet of office space. We believe our current facilities will be sufficient to meet our needs until expiration.

**Item 3. Legal Proceedings**

We are currently involved, as we are from time to time, in legal proceedings that arise in the ordinary course of our business. We believe that we have adequately accrued for these liabilities and that there is no other litigation pending that could materially harm our results of operations and financial condition. See "Commitments and Contingencies" under Note 6 to our financial statements included elsewhere in this Annual Report on Form 10-K for a further discussion of our current legal proceedings.

In the future, we may become party to legal matters and claims arising in the ordinary course of business, the resolution of which we do not anticipate would have a material adverse impact on our financial position, results of operations or cash flows.

**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

#### Market Information

Our common stock is listed on the NASDAQ Global Select Market under the symbol “ESPR”.

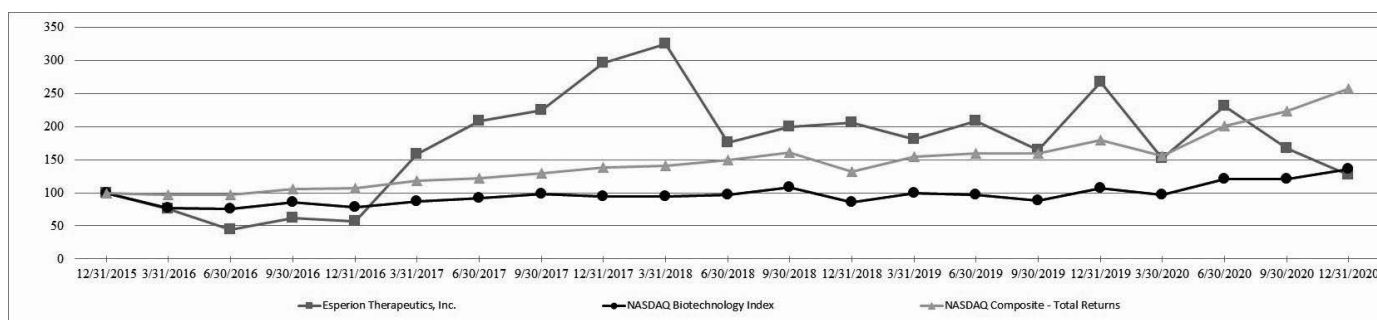
#### Stockholders

As of February 1, 2021, there were 5 stockholders of record, which excludes stockholders whose shares were held in nominee or street name by brokers.

#### Performance Graph

The following graph illustrates a comparison of the total cumulative stockholder return for our common stock since December 31, 2015, to two indices: the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph set forth below compares the cumulative total stockholder return on an initial investment of \$100 in our common stock from December 31, 2015 through December 31, 2020, with the comparative cumulative total return of such amount on (i) NASDAQ Composite Index, and (ii) the NASDAQ Biotechnology Index over the same period. Historical stockholder return is not necessarily indicative of the performance to be expected for any future periods.

**Comparison of 5 Year Cumulative Total Return\***  
**Among Esperion Therapeutics, Inc., the NASDAQ Composite Index and**  
**the NASDAQ Biotechnology Index**



\* \$100 invested on December 31, 2015 in stock or index.

The performance graph shall not be deemed to be incorporated by reference by means of any general statement incorporating by reference this Form 10-K into any filing under the Securities Act of 1933, as amended or the Exchange Act, except to the extent that we specifically incorporate such information by reference, and shall not otherwise be deemed filed under such acts.

#### Dividend Policy

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

#### Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 11 of Part III of this Annual Report.

## Unregistered Securities Sold Within Last 3 Years

On November 11, 2020, we agreed to sell to the several initial purchasers (the “Initial Purchasers”), and the Initial Purchasers agreed to purchase from us, \$250.0 million aggregate principal amount of our 4.00% Convertible Senior Subordinated Notes due 2025 (the “initial notes”), pursuant to a purchase agreement, or the Purchase Agreement between us and the Initial Purchasers. We also granted the Initial Purchasers an option to purchase from us up to an additional \$30.0 million aggregate principal amount of our 4.00% Convertible Senior Subordinated Notes due 2025 (the “additional notes” and, together with the initial notes, the “notes”) pursuant to the Purchase Agreement for settlement within a 13-day period beginning on, and including, the date the initial notes are issued. The issuance of the initial notes was consummated on November 16, 2020, or the Closing Date, and the issuance of the additional notes was consummated on November 18, 2020.

The net proceeds we received from the offering of the initial notes was approximately \$242.0 million, after deducting the Initial Purchasers’ discounts and commissions and offering expenses payable by us. On the Closing Date, we used approximately \$41.1 million of the net proceeds from the offering of the initial notes to pay the cost of the Base Capped Call Transactions (as defined below) and \$55.0 million of the net proceeds from the offering of the initial notes to finance the Forward Stock Purchase Transaction (as defined below). We intend to use the remaining net proceeds from the offering for general corporate purposes, including potential in-licensing opportunities. We used a portion of the net proceeds from the sale of the additional notes to enter into the Additional Capped Call Transactions (as defined below). We intend to use the remaining net proceeds for general corporate purposes as described above.

In connection with the pricing of the initial notes on November 11, 2020, we entered into privately negotiated capped call transactions (together, the “Base Capped Call Transactions”) with one of the initial purchasers of the notes or its affiliate and certain other financial institutions (together, the “Option Counterparties”). The Base Capped Call Transactions cover, subject to customary anti-dilution adjustments, the aggregate number of shares of our common stock that underlie the initial notes, and are expected generally to reduce potential dilution to our common stock upon any conversion of initial notes and/or offset any cash payments we are required to make in excess of the principal amount of converted initial notes, as the case may be, with such reduction and/or offset subject to a cap, based on the cap price of the Base Capped Call Transactions. The cap price of the Base Capped Call Transactions will initially be \$55.1600, which represents a premium of 100.0% over the last reported sale price of our common stock on November 11, 2020, and is subject to certain adjustments under the terms of the Base Capped Call Transactions. The cost of the Base Capped Call Transactions was approximately \$41.1 million. We used a portion of the net proceeds from the sale of the additional notes to enter into additional capped call transactions with the Option Counterparties (together, the “Additional Capped Call Transactions” and, together with the Base Capped Call Transactions, the “Capped Call Transactions”).

On November 11, 2020, in connection with the pricing of the initial notes, we entered into a forward stock purchase transaction (the “Forward Stock Purchase Transaction”) pursuant to a forward stock purchase confirmation (the “Forward Stock Purchase Confirmation”) with Morgan Stanley & Co. LLC, pursuant to which we agreed to purchase 1,994,198 shares of our common stock for settlement on or about November 15, 2025. The number of shares of common stock that we will ultimately repurchase in the Forward Stock Purchase Transaction is subject to customary anti-dilution adjustments. On November 16, 2020, we used \$55.0 million of the proceeds from the offering of the initial notes to finance the cost of the Forward Stock Purchase Transaction.

The Forward Stock Purchase Transaction is intended to allow investors in the notes to establish short positions that generally correspond to (but may be greater than) commercially reasonable initial hedges of their investment in the notes. The Forward Stock Purchase Transaction is subject to early settlement or settlement with alternative consideration in the event of certain corporate transactions.

The notes were issued pursuant to an indenture, dated as of the Closing Date, or the Indenture, between us and U.S. Bank National Association, as trustee. The notes were issued to the Initial Purchasers in reliance upon Section 4(a)(2) of the Securities Act in transactions not involving any public offering. The notes were resold by the Initial Purchasers to persons whom the Initial Purchasers reasonably believe are “qualified institutional buyers” in accordance with Rule 144A under the Securities Act. Any shares of our common stock that may be issued upon conversion of the notes will be issued in reliance upon Section 3(a)(9) of the Securities Act as involving an exchange by us exclusively with its security holders. We relied on this exemption from registration based in part on representations made by the Initial Purchasers in the Purchase Agreement.

The Base Capped Call Transactions and the Forward Stock Purchase Transaction were, and any Additional Capped Call Transactions will be, entered into by us in reliance upon Section 4(a)(2) of the Securities Act in transactions not involving any public offering. We relied on this exemption from registration based in part on representations made by the Option Counterparties party thereto.

## Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

## Item 6. Selected Financial Data

The selected financial data set forth below is derived from our audited financial statements and may not be indicative of future operating results. The following selected financial data should be read in conjunction with Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the financial statements and the notes thereto included elsewhere in this report. The selected financial data in this section are not intended to replace our financial statements and the related notes. Our historical results are not necessarily indicative of our future results.

	Year Ended December 31,				
	2020	2019	2018	2017	2016
	(in thousands, except share and per share data)				
<b>Revenues:</b>					
Product sales, net	\$ 12,965	\$ —	\$ —	\$ —	\$ —
Collaboration revenue	214,582	148,364	—	—	—
Total Revenues	227,547	148,364	—	—	—
<b>Operating expenses:</b>					
Cost of goods sold	2,392	—	—	—	—
Research and development	146,936	175,611	171,488	147,603	57,868
Selling, general and administrative	199,615	65,854	33,097	21,379	18,282
Total operating expenses	348,943	241,465	204,585	168,982	76,150
<b>Loss from operations</b>	(121,396)	(93,101)	(204,585)	(168,982)	(76,150)
Interest expense	(22,670)	(8,120)	(28)	(198)	(376)
Other income, net	515	4,056	2,803	2,192	1,548
<b>Net loss</b>	\$ (143,551)	\$ (97,165)	\$ (201,810)	\$ (166,988)	\$ (74,978)
Net loss per common share - basic and diluted	\$ (5.23)	\$ (3.59)	\$ (7.54)	\$ (6.98)	\$ (3.33)
Weighted average shares outstanding - basic and diluted	27,473,873	27,090,284	26,754,308	23,933,273	22,544,475

The table below presents a summary of our balance sheet data as of December 31, 2020, 2019, 2018, 2017 and 2016:

	As of December 31,				
	2020	2019	2018	2017	2016
	(in thousands)				
<b>Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 304,962	\$ 166,130	\$ 36,973	\$ 34,468	\$ 38,165
Working capital	251,827	145,634	78,299	170,780	197,988
Investments	—	34,651	99,293	239,151	204,324
Restricted cash	—	928	—	—	—
Total assets	353,258	214,447	143,451	277,835	245,213
Revenue interest liability	176,604	132,544	—	—	—
Convertible notes	179,367	—	—	—	—
Other long-term debt	—	—	—	—	1,022
Common stock	26	27	27	26	23
Accumulated deficit	(838,817)	(695,266)	(598,101)	(396,291)	(229,200)
Total stockholders' (deficit) equity	(96,134)	19,950	79,118	244,691	228,602



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

*You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this report, including those set forth under Item 1A. "Risk Factors" and under "Forward-Looking Statements" in this Annual Report on Form 10-K.*

### Overview

#### Corporate Overview

We are the Lipid Management Company, a pharmaceutical company singularly focused on developing and commercializing affordable, oral, once-daily, non-statin medicines for patients struggling with elevated low-density lipoprotein cholesterol, or LDL-C. Our team of lipid experts are dedicated to lowering bad cholesterol through the discovery, development and commercialization of innovative medicines and their combinations with established medicines. Our first two products were approved by the U.S. Food and Drug Administration, or FDA, European Medicines Agency, or EMA and Swiss Agency for Therapeutic Products, or Swissmedic, in 2020. Bempedoic acid and the bempedoic acid / ezetimibe combination tablets are oral, once-daily, non-statin, LDL-C lowering medicines for patients with atherosclerotic cardiovascular disease, or ASCVD, or heterozygous familial hypercholesterolemia, or HeFH.

On February 21, 2020, we announced that the U.S. Food and Drug Administration, or FDA, approved NEXLETOL as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or established ASCVD who require additional lowering of LDL-C. The effect of NEXLETOL on cardiovascular morbidity and mortality has not been determined. NEXLETOL is the first oral, once-daily, non-statin LDL-C lowering medicine approved since 2002 for indicated patients. NEXLETOL became commercially available in the U.S. on March 30, 2020.

On February 26, 2020, we announced that the FDA approved NEXLIZET as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or established ASCVD who require additional lowering of LDL-C. The effect of NEXLIZET on cardiovascular morbidity and mortality has not been determined. NEXLIZET is the first non-statin, LDL-C lowering fixed combination drug product ever approved. NEXLIZET became commercially available in the U.S. on June 4, 2020.

On April 6, 2020, we announced that the European Commission, or EC, approved NILEMDO (bempedoic acid) and NUSTENDI (bempedoic acid and ezetimibe) tablets for the treatment of hypercholesterolemia and mixed dyslipidemia. The decision is applicable to all 27 European Union member states plus the United Kingdom, Iceland, Norway and Liechtenstein. NILEMDO (bempedoic acid) and NUSTENDI (bempedoic acid and ezetimibe) are the branded product names for bempedoic acid and the bempedoic acid / ezetimibe combination tablets in Europe. NILEMDO is the first, oral, non-statin, LDL-C lowering medicine approved in Europe in almost two decades for indicated patients, and NUSTENDI is the first non-statin, LDL-C lowering combination medicine ever approved in Europe. In November 2020, we announced the commercial launch of NILEMDO and NUSTENDI in Germany. In December 2020, we announced the approval of NILEMDO and NUSTENDI in Switzerland. With respect to the United Kingdom, on January 1, 2021 all existing centralized marketing authorizations (which applied to our marketing authorizations for NILEMDO and NUSTENDI) were automatically converted to Great Britain marketing authorizations (under the Northern Ireland Protocol, centralized marketing authorizations remain valid for marketing products in Northern Ireland).

On April 17, 2020, we entered into a license and collaboration agreement, or the Otsuka Agreement, with Otsuka Pharmaceutical Co., Ltd., or Otsuka. Pursuant to the Otsuka Agreement, we granted Otsuka exclusive development and commercialization rights to NEXLETOL and NEXLIZET in Japan. Otsuka will be responsible for all development, regulatory, and commercialization activities in Japan. In addition, Otsuka will fund all clinical development costs associated with the program in Japan. We estimate this amount to total up to \$100 million over the next few years. We received an upfront cash payment of \$60 million in April 2020 and will receive up to an additional \$450 million in total development and sales milestones. We will also receive tiered royalties ranging from 15 percent to 30 percent on net sales in Japan.

In 2019 we entered into a license and collaboration agreement with Daiichi Sankyo Europe GmbH, or DSE. Pursuant to the agreement, we have granted DSE exclusive commercialization rights to bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the European Economic Area and Switzerland, or the DSE Territory. DSE will be responsible for

commercialization in the DSE Territory. We remain responsible for clinical development, regulatory and manufacturing activities for the licensed products globally, including in the DSE Territory. On June 18, 2020, we entered into an amendment to the license and collaboration agreement, or LCA Amendment, with DSE. In June 2020, we completed the transfer of the MAAs for NILEMDO and NUSTENDI. Pursuant to the terms of the amendment, DSE paid us the second \$150 million milestone based on completion of the NUSTENDI MAA transfer rather than the first product sale in the EU. Prior to the execution of the LCA Amendment, the milestone payment was due upon the first commercial sale in Europe. Additionally, we and DSE have agreed to expand the territory in which DSE has exclusive commercialization rights to NILEMDO and NUSTENDI to include Turkey. DSE's designated affiliate in Turkey will be solely responsible, at its sole cost and expense, for all regulatory matters relating to such products in Turkey, including obtaining regulatory approval for such product in Turkey.

On June 26, 2019, we entered into a Revenue Interest Purchase Agreement, or RIPA, with Eiger II SA LLC, or Oberland, an affiliate of Oberland Capital LLC, and the Purchasers named therein. Pursuant to the RIPA, Oberland paid us \$125.0 million on closing, less certain issuance costs and \$25.0 million in March 2020 upon receiving regulatory approval of NEXLETOL. Subject to the RIPA, we are eligible for an additional \$50.0 million at our option upon reaching certain sales thresholds. As consideration for the payments, Oberland has the right to receive certain revenue interests from us based on the net sales of certain products, once approved, which will be tiered payments initially ranging from 2.5% to 7.5% of our net sales in the covered territory. The initial mid-single digit repayment rate on U.S. revenue steps down to less than one percent rate upon certain revenue achievements. Esperion reacquires 100% revenue rights upon repayment completion. Refer to Note 11 to our audited financial statements appearing elsewhere in this Annual Report on Form 10-K.

On November 16, 2020, we issued \$250.0 million aggregate principal amount of 4.00% convertible senior subordinated notes due 2025 to certain financial institutions as the initial purchasers of the convertible notes. An additional \$30.0 million of additional convertible notes (collectively, the "Convertible Notes"), which were issued pursuant to the exercise of the initial purchasers' option to purchase such convertible notes, closed on November 16, 2020. In connection with the offering of the Convertible Notes, we entered into a prepaid forward stock repurchase transaction ("Prepaid Forward") with a financial institution and entered into privately-negotiated capped call transactions with one of the initial purchasers of the Convertible Notes or its affiliate and certain other financial institutions. Pursuant to the Prepaid Forward, the Company used approximately \$55.0 million and \$46.0 million of the net proceeds from the offering of the Convertible Notes to fund the Prepaid Forward and the Capped Call, respectively. Refer to Note 12 to our audited financial statements appearing elsewhere in this Annual Report on Form 10-K.

We are conducting a global cardiovascular outcomes trial, or CVOT, – known as Cholesterol Lowering via Bempedoic Acid, an ACL-inhibiting Regimen (CLEAR) Outcomes. The trial is designed to evaluate whether treatment with bempedoic acid reduces the risk of cardiovascular events in patients who are statin averse and who have CVD or are at high risk for CVD. We initiated the CLEAR Outcomes CVOT in December 2016 and fully enrolled the study with over 14,000 patients in August 2019. The primary endpoint of the study is the effect of bempedoic acid on four types of major adverse cardiovascular events, or MACE (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, or coronary revascularization; also referred to as "four-component MACE"). CLEAR Outcomes is an event-driven trial and will conclude once the predetermined number of MACE endpoints occur. Based on estimated cardiovascular event rates, we expect to meet the target number of events in the second half of 2022. We intend to use positive results from this CVOT to support submissions for a CV risk reduction indication in the U.S., Europe and other territories.

We were incorporated in Delaware in January 2008, and commenced our operations in April 2008. Since our inception, we have focused substantially all of our efforts and financial resources on developing bempedoic acid and the bempedoic acid / ezetimibe tablet. In February 2020, the FDA approved NEXLETOL and NEXLIZET. NEXLETOL was commercially available in the U.S. on March 30, 2020 and NEXLIZET was commercially available in the U.S. on June 4, 2020. We have funded our operations to date primarily through proceeds from sales of preferred stock, convertible promissory notes and warrants, public offerings of common stock, the incurrence of indebtedness, through collaborations with third parties and revenue interest purchase agreements. We have incurred losses in each year since our inception.

We have never been profitable and our net losses were \$143.6 million, \$97.2 million and \$201.8 million for the years ended December 31, 2020, 2019 and 2018, respectively. Substantially all of our net losses resulted from costs incurred in connection with research and development programs, selling, general and administrative costs associated with our operations. We expect to incur significant expenses and operating losses for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, including, among others:

- commercializing NEXLETOL and NEXLIZET tablets in the U.S; and
- completing the clinical development activities for the CLEAR Outcomes CVOT.

Accordingly, we may need additional financing to support our continuing operations and further the development of our products. We may seek to fund our operations and further development activities through collaborations with third parties, strategic alliances, licensing arrangements, permitted debt financings, permitted royalty-based financings, permitted public or private equity offerings or through other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a material adverse effect on our financial condition and our ability to pursue our business strategy or continue operations. We will need to generate significant revenues to achieve profitability, and we may never do so.

### ***Product Overview***

NEXLETOL is a first-in-class ATP Citrate Lyase, or ACL, inhibitor that lowers LDL-C by reducing cholesterol biosynthesis and up-regulating the LDL receptors. Completed Phase 3 studies conducted in more than 3,000 patients, with over 2,000 patients treated with NEXLETOL, demonstrated an average 18 percent placebo corrected LDL-C lowering when used in patients on moderate or high-intensity statins. NEXLETOL was approved by the FDA in February 2020 as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or established ASCVD who require additional lowering of LDL-C.

NEXLIZET contains bempedoic acid and ezetimibe and lowers elevated LDL-C through complementary mechanisms of action by inhibiting cholesterol synthesis in the liver and absorption in the intestine. Phase 3 data demonstrated NEXLIZET lowered LDL-C by a mean of 38 percent compared to placebo when added on to maximally tolerated statins. NEXLIZET was approved by the FDA in February 2020 as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or established ASCVD who require additional lowering of LDL-C.

NILEMDO is a first-in-class ACL inhibitor that lowers LDL-C by reducing cholesterol biosynthesis and up-regulating the LDL receptors. NILEMDO was approved by the EC in March 2020 for use in adults with primary hypercholesterolemia (heterozygous familial and non-familial) or mixed dyslipidemia, as an adjunct to diet in combination with a statin or statin with other lipid-lowering therapies in adult patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or alone or in combination with other lipid-lowering therapies as an adjunct to diet in adult patients who are statin-intolerant, or for whom a statin is contraindicated.

NUSTENDI contains bempedoic acid and ezetimibe and lowers elevated LDL-C through complementary mechanisms of action by inhibiting cholesterol synthesis in the liver and absorption in the intestine. NUSTENDI was approved by the EC in March 2020 for use in adults with primary hypercholesterolemia (heterozygous familial and non-familial) or mixed dyslipidemia, as an adjunct to diet in combination with a statin in adult patients unable to reach LDL-C goals with the maximum tolerated dose of a statin in addition to ezetimibe, alone in patients who are either statin-intolerant or for whom a statin is contraindicated, and are unable to reach LDL-C goals with ezetimibe alone, or as an adjunct to diet in adult patients already being treated with the combination of bempedoic acid and ezetimibe as separate tablets with or without statin.

During the year ended December 31, 2020, we incurred \$70.4 million in expenses related to our CLEAR Outcomes CVOT and other ongoing clinical studies.

During the year ended December 31, 2019, we incurred \$108.9 million in expenses related to our CLEAR Outcomes CVOT, our open-label extension study, and our 1002-FDC-058 study.

During the year ended December 31, 2018, we incurred \$121.7 million in expenses related to the four studies in our global pivotal Phase 3 LDL-C lowering program, our CLEAR Outcomes CVOT, our 1002FDC-053 study, our open-label extension study, our 1002-FDC-058 study and our Phase 2 (1002-39) clinical study of bempedoic acid when added-on to an injectable proprotein convertase subtilisin/kexin type 9 inhibitor, or PCSK9i, therapy in patients with hypercholesterolemia.

### ***The COVID-19 Pandemic***

The full extent to which the COVID-19 pandemic, or the future outbreak of any other highly infectious or contagious diseases, may impact our business, including our CVOT and commercialization efforts will depend on continuously changing circumstances, which are highly uncertain and cannot be predicted at this time, such as the duration of such pandemic including future waves of infection or the broad availability of an effective vaccine, the actions taken to contain the pandemic or mitigate its impact, and the direct and indirect economic effects of the pandemic and containment measures, among others. The ongoing fluidity of this situation precludes any prediction as to the full impact of the COVID-19 pandemic but it could have a material adverse effect on our business, financial condition, and results of operations. The COVID-19 pandemic may also have the effect of heightening the risks to which we are subject, including various aspects of our ongoing CVOT, the reliance on third parties

in our supply chain for materials and manufacturing of our drugs and drug candidates, disruptions in health regulatory agencies' operations globally, the volatility of our common stock, our ability to access capital markets, and our ability to successfully commercialize and generate revenue from our approved drugs.

We are continuing to assess the long-term impact of COVID-19 on our business operations in an effort to mitigate interruption to our commercialization of our approved drugs and other business activities and to ensure the safety and well-being of our employees, as well as the physicians and patients participating in our CVOT. Because COVID-19 infections have been reported throughout the U.S. and worldwide, certain national, state, and local governmental authorities have issued orders, proclamations, and/or directives aimed at minimizing the spread of COVID-19. Although some of these restrictions were eased or lifted, in response to local surges and new waves of infection, some countries, states, and local governments have reinstated these restrictions, and additional, more restrictive orders, proclamations, and/or directives may be issued in the future. In response to the COVID-19 pandemic, we have implemented precautionary measures to protect the health and safety of our employees, partners, and patients, including encouraging all employees to work-from-home if able to perform their duties remotely, and requiring adherence to onsite occupancy limits and appropriate safety measures designed to comply with federal, state, and local guidelines.

Our ability to successfully launch, commercialize, and generate revenue from NEXLETOL, NEXLIZET, NILEMDO and NUSTENDI may be adversely affected by the economic impact of the COVID-19 pandemic. Physicians' offices and other medical institutions continue to have limited access for non-patients, which includes our sales personnel. In addition, social distancing requirements and precautionary measures due to COVID-19 have impacted the ability of our sales personnel to interact in-person with customers. As a result, in many circumstances we have needed to limit our interactions with physicians and payors and adapt our launch strategies and tactics to a virtual model, including developing and deploying various technology-enabled platforms for virtual engagement such as remote detailing, digital and non-personal marketing channels, and social media. These circumstances may adversely affect the ability of our sales professionals to effectively market our approved drugs to physicians and the rates of uptakes for our approved drugs, which may have a negative impact on our sales and our market penetration. In addition, patient visits with physicians have decreased as a result of COVID-19, due to travel restrictions, social distancing requirements, prioritization of healthcare resources to address the pandemic, and/or fear of exposure to the virus, which could have a material adverse impact on new patient starts and overall patient treatment volume. Market disruption and rising unemployment caused by the COVID-19 pandemic may lead to delays in obtaining insurance coverage and reimbursement of newly approved products.

While it is not possible at this time to estimate the entirety of the impact that the COVID-19 pandemic will have on our business or operations, the continued spread or future waves of COVID-19, measures taken by governments, actions taken to protect employees, and the broad impact of the pandemic on all business activities may materially and adversely affect our preclinical activities, clinical development progress, data and timelines, commercialization efforts including any revenue from sales, supply chain continuity, and general business operations, and our business, prospects, financial condition, and results of operations could be materially harmed as a result.

To date, we have not experienced any interruption of our supply of drug products needed to support our ongoing clinical study and product sales. We remain focused on maintaining a strong balance sheet, liquidity and financial flexibility and continue to monitor developments as we deal with the disruptions and uncertainties from a business and financial perspective relating to COVID-19. We will continue to work diligently with our partners and stakeholders to continue supporting patient access to our approved medicines, advancing our product under regulatory review as well as in our clinical studies to the extent safe to do so for patients, caregivers and healthcare practitioners, and ensuring the continuity of our manufacturing and supply chain. For additional information related to the potential impact of COVID-19 on our business, please read Part I-Item 1A, "Risk Factors" of this Annual Report on Form 10-K.

## **Financial Operations Overview**

### ***Product sales, net***

Product sales, net is related to our sales of NEXLETOL and NEXLIZET. NEXLETOL was commercially available in the U.S. on March 30, 2020 and NEXLIZET was commercially available in the U.S. on June 4, 2020

### ***Collaboration revenue***

Collaboration revenue is related to our collaboration agreements with DSE and Otsuka. Collaboration revenue in the year ended December 31, 2020, was primarily related to the \$150.0 million milestone from the MAA transfer to DSE and the \$60.0 million from the upfront payment with Otsuka. During the year ended December 31, 2019, collaboration revenue was primarily

related to the initial recognition of the \$150.0 million upfront payment from our collaboration agreement with DSE. Under contracted supply agreements with ex-U.S. collaborators, we may manufacture and supply quantities of active pharmaceutical ingredient, or API, or bulk tablets reasonably required by ex-U.S. collaboration partners for the development or sale of licensed products in their respective territory. We recognize revenue when the collaboration partner has obtained control of the API or bulk tablets. We also receive royalties from the commercialization of such products, and records our share of the variable consideration, representing a percentage of net product sales, as collaboration revenue in the period in which such underlying sales occur and costs are incurred by the collaborators.

### ***Cost of Goods Sold***

Cost of goods sold is related to our net product sales of NEXLETOL and NEXLIZET and the cost of goods sold from our supply agreements with collaboration partners. Prior to the FDA approval of NEXLETOL and NEXLIZET, expenses associated with the manufacturing of our products were recorded as research and development expense.

### ***Research and Development Expenses***

Our research and development expenses consist primarily of costs incurred in connection with the development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, which include:

- expenses incurred under agreements with consultants, contract research organizations, or CROs, and investigative sites that conduct our preclinical and clinical studies;
- the cost of acquiring, developing and manufacturing clinical study materials and commercial product manufacturing supply prior to product approval, including the procurement of ezetimibe in our continued development of our bempedoic acid / ezetimibe combination tablet;
- employee-related expenses, including salaries, benefits, stock-based compensation and travel expenses;
- allocated expenses for rent and maintenance of facilities, insurance and other supplies; and
- costs related to compliance with regulatory requirements.

We expense research and development costs as incurred. To date, substantially all of our research and development work has been related to bempedoic acid and the bempedoic acid / ezetimibe combination tablets. Costs for certain development activities, such as clinical studies, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors. Our direct research and development expenses consist principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical studies. We do not allocate acquiring and manufacturing clinical study materials, salaries, stock-based compensation, employee benefits or other indirect costs related to our research and development function to specific programs.

We will continue to incur research and development expenses in the foreseeable future as they relate to our ongoing CLEAR Outcomes CVOT and any other development programs or additional indications we choose to pursue. We cannot determine with certainty the duration and completion costs associated with the ongoing or future clinical studies of bempedoic acid and the bempedoic acid / ezetimibe combination tablets. The duration, costs and timing associated with the development of bempedoic acid and the bempedoic acid / ezetimibe combination tablets will depend on a variety of factors, including uncertainties associated with the results of our clinical studies and our ability to obtain regulatory approval outside the U.S. and Europe. For example, if a regulatory authority were to require us to conduct clinical studies beyond those that we currently anticipate will be required for the completion of clinical development or post-commercialization clinical studies of bempedoic acid or the bempedoic acid / ezetimibe combination tablets, we could be required to expend significant additional financial resources and time on the completion of clinical development or post-commercialization clinical studies of bempedoic acid and the bempedoic acid / ezetimibe combination tablets.

In accordance with ASC 730-10-25-1, Research and Development, costs incurred in obtaining in-licenses are charged to research and development expense if the in-licensed technology has not reached commercial feasibility and has no alternative future use. Such licenses purchased by us require substantial completion of research and development, regulatory and marketing approval efforts in order to reach commercial feasibility and has no alternative future use.

## ***Selling, General and Administrative Expenses***

Selling, general and administrative expenses primarily consist of salaries and related costs for personnel, including stock-based compensation, associated with our sales, executive, accounting and finance, commercial, operational and other administrative functions. Other general and administrative expenses include selling expenses, facility-related costs, communication expenses and professional fees for legal, patent prosecution, protection and review, consulting and accounting services.

We anticipate that our selling, general and administrative expenses will increase in the future in connection with the commercialization of NEXLETOL and NEXLIZET, increases in our headcount, expansion of our information technology infrastructure, and increased expenses associated with being a public company and complying with exchange listing and Securities and Exchange Commission, or SEC, requirements. These increases will likely include higher legal, compliance, accounting and investor and public relations expenses.

## ***Interest Expense***

Interest expense for the year ended December 31, 2020 was related to our RIPA with Oberland and our Convertible Notes. Costs during the year ended December 31, 2019 related to our RIPA with Oberland.

## ***Other Income***

Other income, net, primarily relates to interest income and the accretion of premiums and discounts earned on our cash, cash equivalents and investment securities.

## **Critical Accounting Policies and Significant Judgments and Estimates**

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. We evaluate our estimates and judgments on an ongoing basis, including those related to our collaboration agreements and revenue interest liability. We base our estimates on historical experience, known trends and events, contractual milestones and other various factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in more detail in Note 2 to our audited financial statements appearing elsewhere in this Annual Report on Form 10-K. We believe the following accounting policies to be most critical to understanding our results and financial operations.

### ***Product Sales, Net***

We sell NEXLETOL and NEXLIZET to wholesalers in the U.S and, in accordance with ASC 606, recognizes revenue at the point in time when the customer is deemed to have obtained control of the product. The customer is deemed to have obtained control of the product at the time of physical receipt of the product at the customers' distribution facilities, or free on board ("FOB") destination, the terms of which are designated in the contract.

Product sales are recorded at the net selling price, which includes estimates of variable consideration for which reserves are established for (a) rebates and chargebacks, (b) co-pay assistance programs, (c) distribution fees, (d) product returns, and (e) other discounts and fees. Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as current contractual and statutory requirements, and forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the applicable contract. The amount of variable consideration may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Given the early stage of our commercial operations we have provided constraint of our variable consideration due to its potential consumption trends. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from estimates, we adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Liabilities for co-pay assistance, expected product returns, rebates, and distributor fees are classified as “Other accrued liabilities” in the balance sheets. Discounts, such as prompt pay discounts, and chargebacks are recorded as a reduction to trade accounts receivable, which is included in “Other prepaid and current assets” in the balance sheets.

#### *Forms of Variable Consideration*

*Rebates and Chargebacks:* We estimate reductions to product sales for Public Health Service Institutions, such as Medicaid, Medicare and Veterans' Administration ("VA") programs, as well as certain other qualifying federal and state government programs, and other group purchasing organizations. We estimate these reductions based upon our contracts with government agencies and other organizations, statutorily defined discounts and estimated payor mix. These organizations purchase directly from our wholesalers at a discount and the wholesalers charge us back the difference between the wholesaler price and the discounted price. Our liability for Medicaid rebates consists of estimates for claims that a state will make for a current quarter. We reserve for this discounted pricing based on expected sales to qualified healthcare providers and the chargebacks that customers have already claimed.

*Co-pay assistance:* Eligible patients who have commercial insurance may receive assistance from us to reduce the patient's out of pocket costs. We will buy down the difference between the amount of the eligible patient's co-pay when the drug is purchased at the pharmacy at a determined price. Liabilities for co-pay assistance are calculated by actual program participation from third-party administrators.

*Distribution Fees:* We have written contracts with our customers that include terms for distribution fees and costs for inventory management. We estimate and record distribution fees due to our customers based on gross sales.

*Product Returns:* We generally offer a right of return based on the product's expiration date and certain spoilage and damaged instances. We estimate the amount of product sales that may be returned and record the estimate as a reduction of product sales in the period the related product sales is recognized. We estimate for expected returns based primarily on an ongoing analysis of sales information and visibility into the inventory remaining in the distribution channel.

*Discounts:* We provide product discounts, such as prompt pay discounts, to our customers. We estimate cash discounts based on terms in negotiated contracts and our expectations regarding future payment patterns.

#### ***Revenue Interest Liability***

We have entered into a RIPA to support the commercialization and further development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet and provide for other working capital needs. The revenue interest liability related to the RIPA is presented net of deferred issuance costs on the balance sheets. The Company imputes interest expense associated with this liability using the effective interest rate method and is presented as interest expense on the statements of operations. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. The interest rate on the liability may vary during the term of the agreement depending on a number of factors, including the level of forecasted net sales. The Company evaluates the interest rate quarterly based on its current net sales forecasts utilizing the prospective method. A significant increase or decrease in net sales will materially impact the revenue interest liability, interest expense and the time period for repayment. Issuance costs in connection with the RIPA are amortized to interest expense over the estimated term of the RIPA.

#### ***Convertible Notes***

We account for convertible debt instruments that may be settled in cash or equity upon conversion by separating the liability and equity components of the instruments in a manner that reflects our nonconvertible debt borrowing rate. We determined the carrying amount of the liability component of the Convertible Notes by using estimates and assumptions that market participants would use in pricing a debt instrument. These estimates and assumptions are judgmental in nature and could have a significant impact on the determination of the debt component, and the associated non-cash interest expense.

The equity component is treated as a discount on the liability component of the Convertible Notes, which is amortized over the term of the Convertible Notes using the effective interest rate method. Debt issuance costs related to the Convertible Notes is allocated to the liability and equity components of the Convertible Notes based on their relative values. Debt issuance costs allocated to the liability component are amortized over the life of the Convertible Notes as additional non-cash interest expense. Transaction costs allocated to equity are netted with the equity component of the convertible debt instrument in stockholders' equity.

## Recent Accounting Pronouncements

For information on new accounting standards and the impact, if any, on our financial position or results of operations, see Note 2 to our audited financial statements found elsewhere in this Annual Report on Form 10-K.

## Results of Operations

### Comparison of the Years Ended December 31, 2020 and 2019

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019:

	Year Ended December 31,		
	2020	2019	Change
	(in thousands)		
<b>Revenues:</b>			
Product sales, net	\$ 12,965	\$ —	\$ 12,965
Collaboration revenue	214,582	148,364	66,218
<b>Operating Expenses:</b>			
Cost of goods sold	2,392	—	2,392
Research and development	146,936	175,611	(28,675)
Selling, general and administrative	199,615	65,854	133,761
<b>Loss from operations</b>	<b>(121,396)</b>	<b>(93,101)</b>	<b>(28,295)</b>
Interest expense	(22,670)	(8,120)	(14,550)
Other income, net	515	4,056	(3,541)
<b>Net loss</b>	<b>\$ (143,551)</b>	<b>\$ (97,165)</b>	<b>\$ (46,386)</b>

### Product sales, net

Product sales, net for the year ended December 31, 2020 was \$13.0 million relating to our sales of NEXLETOL and NEXLIZET. NEXLETOL was commercially available in the U.S. on March 30, 2020 and NEXLIZET was commercially available in the U.S. on June 4, 2020.

### Collaboration revenue

Collaboration revenue recognized from our collaboration agreements for the year ended December 31, 2020 was \$214.6 million compared to \$148.4 million for the year ended December 31, 2019, an increase of \$66.2 million. Revenue for the year ended December 31, 2020 was primarily attributable to \$150.0 million for the milestone payment from DSE and \$60.0 million for the upfront payment in the Otsuka collaboration agreement signed on April 17, 2020. Revenue for the year ended December 31, 2019 was attributable to the initial recognition of the upfront payment from our collaboration agreement signed with DSE on January 2, 2019 and the ongoing performance obligation from the ongoing regulatory efforts for the MAA in the DSE Territory.

### Cost of goods sold

Cost of goods sold for the year ended December 31, 2020 was \$2.4 million, primarily related to cost of goods sold from our supply agreements with collaboration partners and our net product sales of NEXLETOL and NEXLIZET. NEXLETOL and NEXLIZET became commercially available in the U.S. on March 30, 2020 and June 4, 2020, respectively. Prior to the FDA approval of NEXLETOL and NEXLIZET, expenses associated with the manufacturing of our products were recorded as research and development expense.

### Research and development expenses

Research and development expenses for the year ended December 31, 2020, were \$146.9 million compared to \$175.6 million for the year ended December 31, 2019, a decrease of \$28.7 million. The decrease in research and development expenses was primarily attributable to a decline in costs related to the completion of enrollment of our CLEAR CVOT, which was fully



enrolled during the third quarter of 2019, and a decline in costs related to our regulatory submission activities completed in 2019, partially offset by \$12.5 million in 2020 from the definitive agreement with Serometrix to in-license its oral, small molecule PCSK9 inhibitor program.

### ***Selling, general and administrative expenses***

Selling, general and administrative expenses for the year ended December 31, 2020, were \$199.6 million compared to \$65.9 million for the year ended December 31, 2019, an increase of approximately \$133.8 million. The increase in selling, general and administrative expenses was primarily attributable to salaries and benefits, including stock based compensation, from the build out of our customer-facing team and other costs to support the commercialization of NEXLETOL and NEXLIZET in the U.S.

### ***Interest expense***

Interest expense for the year ended December 31, 2020, was \$22.7 million, compared to \$8.1 million for the year ended December 31, 2019. Interest expense for the year ended December 31, 2020 was related to our RIPA with Oberland and our Convertible Notes, which we entered into in November 2020. Interest expense for the year ended December 31, 2019 was related to our RIPA with Oberland, which was entered into on June 26, 2019.

### ***Other income, net***

Other income, net for the year ended December 31, 2020, was \$0.5 million compared to \$4.1 million for the year ended December 31, 2019. This decrease was primarily related to lower interest income on our cash, cash equivalents, and investments due to lower interest rates.

## **Results of Operations**

### ***Comparison of the Years Ended December 31, 2019 and 2018***

Management's discussion and analysis of our results of operations for the year ended December 31, 2019 compared to the year ended December 31, 2018 may be found in the "Management's Discussion and Analysis of Financial Condition and Results of Operations – Comparison of the Years Ended December 31, 2019 and 2018" section of our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on February 27, 2020.

## **Liquidity and Capital Resources**

We have funded our operations to date primarily through proceeds from sales of preferred stock, convertible promissory notes and warrants, public offerings of common stock, the incurrence of indebtedness, milestone payments from collaboration agreements and revenue interest purchase agreement. Pursuant to the license and collaboration agreement with DSE signed on January 2, 2019, we received an upfront cash payment of \$150.0 million from DSE and a cash payment of \$150.0 million upon the MAA transfer in June 2020 and are eligible for substantial additional sales and regulatory milestone payments and royalties. Pursuant to the RIPA with Oberland, we received an upfront cash payment of \$124.4 million, net of issuance costs, in 2019, received an additional \$25.0 million upon regulatory approval of NEXLETOL in 2020 and are eligible to receive \$50.0 million at our option upon reaching certain net product sales thresholds. In return, Oberland will have a right to receive revenue interests based on net sales of our products. Pursuant to the license and collaboration agreement with Otsuka signed on April 17, 2020, we received an upfront cash payment of \$60.0 million in April 2020 and are eligible for substantial additional development and sales milestone payments and royalties. In November 2020, we received net proceeds of \$170.1 million, net of issuance costs, forward stock re-purchase and capped call transactions in connections with the issuance of our Convertible Notes. We anticipate that we will continue to incur losses for the foreseeable future.

As of December 31, 2020, our primary sources of liquidity were our cash and cash equivalents which totaled \$305.0 million. We invest our cash equivalents and investments in highly liquid, interest-bearing investment-grade securities and government securities to preserve principal.

The following table summarizes the primary sources and uses of cash for the periods presented below:

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Net cash used in operating activities	\$ (85,177)	\$ (70,341)
Net cash provided by investing activities	21,356	64,231
Net cash provided by financing activities	201,725	136,195
<b>Net increase in cash, cash equivalents and restricted cash</b>	<b>\$ 137,904</b>	<b>\$ 130,085</b>

### *Operating Activities*

We have incurred and expect to continue to incur, significant costs related to the commercialization of NEXLETOL and NEXLIZET and related to ongoing research and development, regulatory and other clinical study costs associated with the development of bempedoic acid and the bempedoic acid / ezetimibe combination tablets.

Net cash used in operating activities totaled \$85.2 million for the year ended December 31, 2020, consisting of the \$150.0 million milestone payment from our collaboration agreement with DSE, \$60.0 million from the Otsuka collaboration agreement and net product sales of NEXLETOL and NEXLIZET offset by cash used to fund the commercialization activities of NEXLETOL and NEXLIZET and the research and development costs related to bempedoic acid and the bempedoic acid / ezetimibe combination tablets, adjusted for non-cash expenses such as stock-based compensation expense, amortization of debt issuance costs, interest expense related to our RIPA with Oberland and Convertible Notes, depreciation and amortization and changes in working capital. Net cash used in operating activities totaled \$70.3 million for the year ended December 31, 2019, consisting of the \$150.0 million upfront payment from the DSE collaboration offset by cash used to fund the development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, adjusted for non-cash expenses such as stock-based compensation expense, interest expense related to our RIPA with Oberland, depreciation and amortization and changes in working capital.

### *Investing Activities*

Net cash provided by investing activities of \$21.4 million for the year ended December 31, 2020 consisted primarily of proceeds from the sale and maturities of highly liquid, interest bearing investment grade and government securities partially offset by \$12.5 million for the purchase of in-process research and development to in-license intellectual property for our PCSK9 inhibitor program. Net cash provided by investing activities of \$64.2 million for the year ended December 31, 2019 consisted primarily of proceeds from the sale and maturities of highly liquid, interest bearing investment grade and government securities.

### *Financing Activities*

Net cash provided by financing activities of \$201.7 million for the year ended December 31, 2020, related primarily to the \$280.0 million in cash received from the Convertible Notes, \$25.0 million in cash received from the RIPA with Oberland upon regulatory approval of NEXLETOL and \$6.6 million in cash received from stock option exercises, offset by the prepayment of a forward stock repurchase of \$55.0 million, \$46.0 million from the purchase of capped call options related to the Convertible Notes and \$8.4 million in debt issuance costs as described in Item 8, Note 11, Convertible Notes. Net cash provided by financing activities of \$136.2 million for the year ended December 31, 2019, related primarily to the upfront cash received from the RIPA with Oberland.

### *Plan of Operations and Funding Requirements*

We expect to continue to incur significant expenses and operating losses for the foreseeable future in connection with our ongoing CLEAR Outcomes CVOT and commercial launch activities associated with NEXLETOL and NEXLIZET in the U.S. Pursuant to the license and collaboration agreement with DSE, we received an upfront cash payment of \$150.0 million from DSE in the first quarter of 2019, \$150.0 million in June 2020 upon transfer to DSE of MMA of NUSTENDI and are eligible for substantial additional sales and regulatory milestone payments and royalties. Pursuant to the RIPA with Oberland, we received an upfront cash payment of \$125.0 million and received \$25.0 million upon regulatory approval of NEXLETOL. We are eligible for an additional \$50.0 million at our option upon reaching certain sales thresholds. In return, Oberland will have a right to receive revenue interest payments from us based on net sales of certain of our products. Pursuant to the license and

collaboration agreement with Otsuka, we received an upfront cash payment of \$60.0 million from Otsuka in April 2020 and are eligible for substantial additional development and sales milestone payments and royalties. In November 2020, we received net proceeds of \$170.1 million, net of issuance cost, forward stock re-purchase and capped call transactions in connections with our Convertible Notes. We estimate that current cash resources and proceeds to be received in the future for product sales, proceeds received under the DSE and Otsuka collaboration agreements and the RIPA with Oberland are sufficient to fund operations for the foreseeable future. We have based these estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. We may need to secure additional cash resources to continue to fund the commercialization and further development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet. Because of the numerous risks and uncertainties associated with the development and ongoing commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, and the extent to which we entered and may enter into collaborations with pharmaceutical partners regarding the development and commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development and commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablets. Our future funding requirements will depend on many factors, including, but not limited to:

- our ability to successfully develop and commercialize NEXLETOL and NEXLIZET or other product candidates;
- the costs, timing and outcomes of our CLEAR Outcomes CVOT and other ongoing clinical studies of bempedoic acid and the bempedoic acid / ezetimibe combination tablet;
- the time and cost necessary to obtain regulatory approvals for bempedoic acid and the bempedoic acid / ezetimibe combination tablet outside the U.S. and Europe;
- our ability to establish any future collaboration or commercialization arrangements on favorable terms, if at all;
- our ability to realize the intended benefits of our existing and future collaboration and partnerships;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the implementation of operational and financial information technology.

Until such time, if ever, as we can generate U.S. substantial product revenues, we expect to finance our cash needs through a combination of collaborations with third parties, strategic alliances, licensing arrangements, permitted debt financings, permitted royalty-based financings and equity offerings or other sources. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available and permitted under the terms of our RIPA, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners or royalty-based financing arrangements, such as the collaboration arrangement with DSE and Otsuka, and the RIPA with Oberland, we may have to relinquish valuable rights to our technologies, future revenue streams or grant licenses on terms that may not be favorable to us. For instance, as part of the RIPA with Oberland, Oberland has the right to receive certain revenue interests from us based on the net sales of certain products, and we have granted Oberland a senior security interest in certain of our assets. If our cash flows and capital resources are insufficient to allow us to make required payments, we may have to reduce or delay capital expenditures, sell assets or seek additional capital. If we raise funds by selling additional equity, such sale would result in dilution to our stockholders. If we are unable to raise additional funds through equity or permitted debt financings or through collaborations, strategic alliances or licensing arrangements or permitted royalty-based financing arrangements when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market bempedoic acid and the bempedoic acid / ezetimibe combination tablet that we would otherwise prefer to develop and market ourselves.

### **Contractual Obligations and Commitments**

In 2019, we entered into a RIPA with Oberland. Pursuant to the RIPA, Oberland paid us \$125.0 million at closing, less certain issuance costs, and, subject to the terms and conditions of the RIPA, we received an additional \$25.0 million upon regulatory approval of NEXLETOL in 2020 and our eligible to receive an additional \$50.0 million at our option upon reaching certain sales thresholds. As consideration for the payments, Oberland has the right to receive certain revenue interests from us based on the net sales of certain products which will be tiered payments initially ranging from 2.5% to 7.5% of our net sales in

the covered territory (as detailed in the RIPA). The initial mid-single digit repayment rate on U.S. revenue steps down to less than one percent rate upon certain revenue achievements. Esperion reacquires 100% revenue rights upon repayment completion. We recorded the proceeds from the RIPA as a liability on the balance sheets and are accounting for the RIPA under the effective-interest method over the estimated life of the RIPA. Future payments under the RIPA may range from \$5.4 million in the next year to a maximum total payment of \$286.6 million beyond one year. Per the terms of the agreement, every \$100 million of net sales generated, less than or equal to \$250 million in an annual aggregate, would result in a repayment obligation of approximately \$7.5 million at the stated repayment rate in the first year. In the future, as net sales thresholds set forth in the agreement are met and the repayment percentage rate changes, the amount of the obligation and timing of payment is likely to change. A significant increase or decrease in net sales will materially impact the revenue interest liability, interest expense and the time period for repayment. Refer to Note 11 to our audited financial statements appearing elsewhere in this Annual Report on Form 10-K for further information.

We have entered into a contract manufacturing agreement with a third-party commercial manufacturing organization for the production of certain inventory supplies of NEXLETOL and NEXLIZET. The agreement has an initial term of three years and will renew automatically for successive periods of one year each unless terminated by either party. Under the agreement we are obligated to purchase minimum order commitments on a rolling twelve-month period for the batches of inventory supplies produced.

On November 16, 2020, we issued \$250.0 million aggregate principal amount of 4.00% convertible senior subordinated notes due 2025 to certain financial institutions as the initial purchasers of the convertible notes. An additional \$30.0 million of additional convertible notes (collectively, the "Convertible Notes"), which were issued pursuant to the exercise of the initial purchasers' option to purchase such convertible notes, closed on November 18, 2020. Refer to Note 12 to our audited financial statements appearing elsewhere in this Annual Report on Form 10-K.

On July 6, 2018, we signed the first amendment of the lease for our principal executive office in Ann Arbor, Michigan. The amended lease is to increase the current 7,941 rentable square feet of office space by 11,471 rentable square feet. The lease has a term of 60 months and provides for fixed monthly rent of \$19,412 until the end of the 12th month, with scheduled increases on an annual basis and/or as provided in the lease agreement, and also provides for certain rent adjustments to be paid as determined by the landlord. In addition, we have also entered into various operating leases related to vehicle leases and other IT equipment.

The following table summarizes our future estimated minimum contractual obligations as of December 31, 2020:

	Total	Less than 1 Year	1 -3 Years	3 -5 Years	More than 5 Years
	(in thousands)				
Revenue interest liability	\$ 292,000	\$ 5,392	\$ —	\$ —	\$ 286,608
Convertible Notes	\$ 336,000	11,200	22,400	302,400	—
Operating leases	\$ 6,287	2,746	3,541	—	—
Minimum inventory purchase commitments	\$ 19,091	\$ 19,091	\$ —	\$ —	\$ —
<b>Total</b>	<b>\$ 653,378</b>	<b>\$ 38,429</b>	<b>\$ 25,941</b>	<b>\$ 302,400</b>	<b>\$ 286,608</b>

There have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed above.

### Off-Balance Sheet Arrangements

We do not currently have, nor did we have during the periods presented, any off-balance sheet arrangements as defined by Securities and Exchange Commission rules.

### Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We had cash and cash equivalents of approximately \$305.0 million at December 31, 2020. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. Our primary exposure to market risk relates to fluctuations in interest rates which are affected by changes in the general level of U.S. interest rates. Given the short-term nature of our cash equivalents, we believe that a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operation. We do not have any foreign currency or other derivative financial instruments.

We maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits. We do not believe that our cash and cash equivalents have significant risk of default or illiquidity.

We contract with CROs and investigational sites globally. We are therefore subject to fluctuations in foreign currency rates in connection with these agreements. We do not hedge our foreign currency exchange rate risk.

Inflation generally affects us by increasing our cost of labor and clinical study costs. We do not believe that inflation has had a material effect on our results of operations during the year ended December 31, 2020.

We have entered into a revenue interest purchase agreement. Our primary exposure to market risk is that the interest rate on the liability may vary during the term of the agreement depending on a number of factors, including the level of forecasted net sales. A significant increase or decrease in net sales will materially impact the revenue interest liability, interest expense and the time period for repayment. Our Convertible Notes, which were issued in September 2020, carry a fixed interest rate of 4.0% per year. Since the Convertible Notes bear interest at a fixed rate, we have no direct financial statement risk associated with changes in interest rates. We do not believe a change in interest rate has had a material effect on our results of operations during the year ended December 31, 2020.

## **Item 8. Financial Statements and Supplementary Data**

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found in Item 15.

## **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**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities and Exchange Act of 1934 is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our President and Chief Executive Officer, who is our principal executive officer, and our Chief Financial Officer, who is our principal financial officer, to allow timely decisions regarding required disclosure.

As of December 31, 2020, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of December 31, 2020, our disclosure controls and procedures were effective at the reasonable assurance level.

### **Management's Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for our company. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the company's principal executive officer and principal financial officer and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) 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 our company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our company's assets that could have a material effect on the financial statements.

Internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements prepared for external purposes in accordance with generally accepted

accounting principles. 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.

Our management, with the participation of our principal executive officer and principal financial officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2020, based on criteria for effective internal control over financial reporting established in Internal Control — Integrated Framework (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on its assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2020, based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2020, has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included herein.

#### **Changes in Internal Control over Financial Reporting**

During the quarter ended December 31, 2020, we implemented new procedures and controls around our convertible notes, net product sales and inventory processes.

## **Report of Independent Registered Public Accounting Firm**

**To the Stockholders and the Board of Directors of Esperion Therapeutics, Inc.**

### **Opinion on Internal Control over Financial Reporting**

We have audited Esperion Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2020, 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, Esperion Therapeutics, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, 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 balance sheets of Esperion Therapeutics, Inc. as of December 31, 2020 and 2019, and the related statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2020, and the related notes and our report dated February 23, 2021 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

Detroit, Michigan

February 23, 2021

**Item 9B. Other Information**

None.



## **PART III**

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

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2021 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

### **Item 11. Executive Compensation**

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2021 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

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

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2021 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

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

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2021 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

### **Item 14. Principal Accounting Fees and Services**

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2021 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

## PART IV

### Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this report:

(1) Financial Statements:

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(2) Financial Statement Schedules:

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

(3) Exhibits. The exhibits filed as part of this Annual Report on Form 10-K are set forth on the Exhibit Index included herein. The Exhibit Index is incorporated herein by reference.

### Item 16. Form 10-K Summary.

None.

## Exhibit Index

Exhibit No.	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Amendment No. 2 to the Registration Statement on Form S-1, File No. 333-188595, filed on June 12, 2013)
3.2	Amended and Restated By-laws of the Registrant (incorporated by reference to Exhibit 3.4 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-1, File No. 333-188595, filed on June 7, 2013)
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Amendment No. 2 to the Registration Statement on Form S-1, File No. 333-188595, filed on June 12, 2013)
4.2	Investor Rights Agreement by and between the Registrant and certain of its stockholders dated April 28, 2008 (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-1, File No. 333-188595, filed on May 14, 2013)
4.3	Amendment No. 1 to Investor Rights Agreement by and between the Registrant and certain of its stockholders dated April 11, 2013 (incorporated by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form S-1, File No. 333-188595, filed on May 14, 2013)
4.4	Description of Registrant's Securities (incorporated by reference to Exhibit 4.4 to the Registrant's Annual Report on Form 10-K, File No. 001-35986, filed on February 27, 2020)
4.5	Indenture, dated as of November 16, 2020, between Esperion Therapeutics, Inc. and U.S. Bank National Association (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on November 16, 2020)
4.6	Form of 4.00% Convertible Senior Subordinated Note due 2025 (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on November 16, 2020)
10.1*	License Agreement between Pfizer Inc. and the Registrant dated April 28, 2008 and amended on November 17, 2010 (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1, File No. 333-188595, filed on May 14, 2013)
10.2	Termination Agreement, dated December 2, 2015, by and between the Registrant and Michigan Land Bank Fast Track Authority (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on December 3, 2015)
10.3	Valley Ranch Business Park Lease by and between the Registrant and McMullen SPE, LLC, dated February 4, 2014 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on February 7, 2014)
10.4	Form of Officer Indemnification Agreement entered into between the Registrant and its officers (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1, File No. 333-188595, filed on May 14, 2013)
10.5	Form of Director Indemnification Agreement entered into between the Registrant and its directors (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1, File No. 333-188595, filed on May 14, 2013)
10.6#	2008 Incentive Stock Option and Restricted Stock Plan and forms of agreements thereunder (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, File No. 333-188595, filed on May 14, 2013)
10.7#	Amended and Restated 2013 Stock Option and Incentive Plan and forms of agreements thereunder (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q, File No. 001-35986, filed on November 3, 2016).
10.8#	Senior Executive Cash Bonus Plan (incorporated by reference to Exhibit 10.11 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-1, File No. 333-188595, filed on June 7, 2013)
10.9#	Employment Agreement, dated May 14, 2015, between the Registrant and Tim M. Mayleben (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on May 20, 2015)
10.10#	Employment Agreement by and between the Registrant and Richard B. Bartram dated May 14, 2015 (incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K, File No. 001-35986 filed on February 28, 2019)
10.11#	Employment Agreement by and between the Registrant and Mark Glickman dated March 14, 2018 (incorporated by reference to Exhibit 10.13 to the Registrant's Annual Report on Form 10-K, File No. 001-35986 filed on February 28, 2019)
10.12#	2017 Inducement Equity Plan and form of award agreement thereunder (incorporated by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form S-8, File No. 333-218084, filed on May 18, 2017).

Exhibit No.	Description of Exhibit
10.13	First Amendment to Valley Ranch Business Park Lease, dated July 6, 2018, between the Registrant and Blackbird Ann Arbor, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, File No. 001-35986, filed on August 2, 2018)
10.14*	License and Collaboration Agreement by and between Daiichi Sankyo Europe GmbH and the Company, dated as of January 2, 2019 (incorporated by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K, File No. 001-35986 filed on February 28, 2019)
10.15	Revenue Interest Purchase Agreement by and between the Company, Eiger III SA LLC, and the Purchasers named therein, dated June 26, 2019 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on June 26, 2019)
10.16	First Amendment to 2017 Inducement Equity Plan (incorporated by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K, File No. 001-35986, filed on February 27, 2020)
10.17#	Esperion Therapeutics, Inc. 2020 Employee Stock Purchase Plan, as amended (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q, File No. 001-35986, filed on August 10, 2020)
10.18*	License and Collaboration Agreement by and between the Company and Otsuka Pharmaceutical Co., Ltd. dated April 17, 2020 (incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q, File No. 001-35986, filed on August 10, 2020)
10.19*	1st Amendment to the License and Collaboration Agreement by and between the Registrant and Daiichi Sankyo Europe GMBH dated June 18, 2020 (incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q, File No. 001-35986, filed on August 10, 2020)
10.20	Form of Capped Call Confirmation (incorporated by reference to Exhibit 1.10 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on November 16, 2020)
10.21	Forward Stock Purchase Confirmation, dated November 11, 2020, by and between the Company and Morgan Stanley & Co. LLC (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on November 16, 2020)
10.22**	Amendment No. 1 to the Revenue Interest Purchase Agreement, dated November 11, 2020, by and among the Company, the purchasers from time to time party thereto and Eiger III SA LLC, as the purchaser agent, dated effective as of June 26, 2019
10.23#**	Employment Agreement by and between the Registrant and Sheldon Koenig effective December 15, 2020.
10.24#**	Employment Agreement by and between the Registrant and Ashley Hall effective August 28, 2015.
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Registration Statement on Form S-1, File No. 333-188595, filed on May 14, 2013)
23.1**	Consent of Ernst & Young LLP
31.1**	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2**	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1***	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.SCH**	Inline XBRL Taxonomy Extension Schema Document
101.CAL**	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB**	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF**	Inline XBRL Taxonomy Extension Definition Linkbase Document
104**	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*)

(#) Management contract or compensatory plan or arrangement.

(\*) Portions of this exhibit (indicated by asterisks) have been omitted in accordance with the rules of the Securities and Exchange Commission.

(\*\*) Filed herewith.

(\*\*\*) The certifications furnished in Exhibit 32.1 hereto are deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

## SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

### ESPERION THERAPEUTICS, INC.

Date: February 23, 2021

By:                           /s/ TIM M. MAYLEBEN                            
                          Tim M. Mayleben  
                          *President and Chief Executive Officer*  
                          *(Principal Executive Officer)*

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed by the following persons in the capacities indicated below and on the dates indicated:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>                          /s/ TIM M. MAYLEBEN                          </u> Tim M. Mayleben	President, Chief Executive Officer and Director (Principal Executive Officer)	February 23, 2021
<u>                          /s/ RICHARD B. BARTRAM                          </u> Richard B. Bartram	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 23, 2021
<u>                          /s/ JEFFREY BERKOWITZ, J.D.                          </u> Jeffrey Berkowitz, J.D.	Director	February 23, 2021
<u>                          /s/ ALAN FUHRMAN                          </u> Alan Fuhrman	Director	February 23, 2021
<u>                          /s/ ANTONIO M. GOTTO, M.D., D. PHIL                          </u> Antonio M. Gotto, M.D., D. Phil	Director	February 23, 2021
<u>                          /s/ DANIEL JANNEY                          </u> Daniel Janney	Director	February 23, 2021
<u>                          /s/ MARK E. MCGOVERN, M.D.                          </u> Mark E. McGovern, M.D.	Director	February 23, 2021
<u>                          /s/ JAY SHEPARD                          </u> Jay Shepard	Director	February 23, 2021
<u>                          /s/ NICOLE VITULLO                          </u> Nicole Vitullo	Director	February 23, 2021
<u>                          /s/ TRACY M. WOODY                          </u> Tracy M. Woody	Director	February 23, 2021

**Esperion Therapeutics, Inc.**  
**Index to the Financial Statements**

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## Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Esperion Therapeutics, Inc.

### Opinion on the Financial Statements

We have audited the accompanying balance sheets of Esperion Therapeutics, Inc. (the Company) as of December 31, 2020 and 2019, and the related statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. 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, 2020, 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 February 23, 2021 expressed an unqualified opinion thereon.

### 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 U.S. 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 included 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.

### Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

#### *Valuation of convertible notes*

##### *Description of the Matter*

In November 2020, the Company issued an aggregate principal \$280.0 million of 4.0% senior subordinated convertible senior notes due November 15, 2025. As discussed in Notes 2 and 12 of the financial statements the Company measured the separate liability and equity components of the notes based on the estimated fair value of a similar liability without an associated conversion feature. The resulting liability was recorded at its estimated fair value on the date of issuance. The carrying amount of the liability component of the convertible debt instrument as of December 31, 2020 was \$179.4 million.

Auditing the Company's fair value determination of the liability component was especially judgmental because it was calculated based on an interest rate of similar liability that does not have an associated convertible feature.

*How we Addressed the Matter in Our Audit* We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company’s valuation of the conversion option, including controls over management’s review of the valuation model and the significant assumptions used in the calculation.

To test the interest rates used to calculate the fair value of debt, our audit procedures included testing the Company’s valuation methodology, evaluating the significant assumptions used by the Company, and evaluating the completeness and accuracy of the underlying data supporting the significant assumptions and estimates. In addition, we involved our valuation specialists to assist in our evaluation of the methodology used by the Company and significant assumptions. We also tested the completeness and accuracy of the calculation used to estimate the fair value of the liability component.

***Valuation of revenue interest liability***

*Description of the Matter* As described in Notes 2 and 11 to the financial statements, the Company entered into a Revenue Interest Purchase Agreement (“RIPA”) in June 2019 with Eiger III SA LLC. Pursuant to the RIPA, the Company received net proceeds of \$125.0 million in 2019 and \$25.0 million in 2020. The Company will also be entitled to receive up to approximately \$50.0 million in a subsequent installment, subject to the terms and conditions set forth in the RIPA. The carrying amount of the RIPA as of December 31, 2020 was \$176.6 million.

In connection with the RIPA, the Company evaluated the accounting and determined it should be treated as a debt instrument. The Company imputes interest expense associated with this liability using the effective interest rate method. The effective interest rate is calculated based on the rate that would enable the liability to be repaid in full over the anticipated life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of forecasted sales which impacts the repayment timing. The Company evaluates the interest rate quarterly based on its current sales forecasts utilizing the prospective method.

Auditing the revenue interest liability was complex and highly judgmental due to the estimation uncertainty in determining the effective interest rate. The Company’s effective interest rate model includes revenue projections which are affected by expectations about future economic and market conditions.

*How we Addressed the Matter in Our Audit* We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company’s processes to account for the revenue interest liability, including controls over management’s review of the revenue projections within the model.

To test the RIPA, we performed audit procedures that included, among others, assessing the methodologies and the underlying data used by the Company in its effective interest rate model. We compared the significant assumptions within the revenue projections, primarily population, penetration and sales price, to current industry, market and economic trends and performed sensitivity analyses to evaluate the changes in the effective interest rate, and associated interest expense, that would result from changes in the assumptions.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2008.  
Detroit, Michigan  
February 23, 2021



**Esperion Therapeutics, Inc.**

**Balance Sheets**

(in thousands, except share data)

	December 31, 2020	December 31, 2019
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 304,962	\$ 166,130
Restricted cash	—	928
Short-term investments	—	34,651
Prepaid clinical development costs	844	6,081
Inventories	16,136	—
Other prepaid and current assets	23,954	3,924
Total current assets	<u>345,896</u>	<u>211,714</u>
Property and equipment, net	1,276	1,145
Intangible assets	56	56
Right of use operating lease assets	6,030	1,532
Total assets	<u>\$ 353,258</u>	<u>\$ 214,447</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 51,975	\$ 28,856
Accrued clinical development costs	7,663	17,511
Other accrued liabilities	24,790	11,871
Revenue interest liability	5,392	5,236
Deferred revenue from collaborations	1,662	2,152
Operating lease liabilities	2,587	454
Total current liabilities	<u>94,069</u>	<u>66,080</u>
Convertible notes, net of issuance costs	179,367	—
Revenue interest liability	171,212	127,308
Operating lease liabilities	3,454	1,109
Other long-term liabilities	1,290	—
Total liabilities	<u>\$ 449,392</u>	<u>\$ 194,497</u>
Commitments and contingencies (Note 6)		
<b>Stockholders' (deficit) equity:</b>		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized and no shares issued or outstanding as of December 31, 2020 and December 31, 2019	—	—
Common stock, \$0.001 par value; 120,000,000 shares authorized as of December 31, 2020 and December 31, 2019; 27,910,366 shares issued at December 31, 2020 and 27,497,911 shares issued and outstanding at December 31, 2019	26	27
Additional paid-in capital	797,655	715,166
Treasury stock, at cost; 1,994,198 shares at December 31, 2020	(54,998)	—
Accumulated other comprehensive gain	—	23
Accumulated deficit	(838,817)	(695,266)
Total stockholders' (deficit) equity	<u>(96,134)</u>	<u>19,950</u>
Total liabilities and stockholders' (deficit) equity	<u>\$ 353,258</u>	<u>\$ 214,447</u>

See accompanying notes to the financial statements.

**Esperion Therapeutics, Inc.**

**Statements of Operations and Comprehensive Loss**

(in thousands, except share and per share data)

	Year Ended December 31,		
	2020	2019	2018
<b>Revenues:</b>			
Product sales, net	\$ 12,965	\$ —	\$ —
Collaboration revenue	214,582	148,364	—
Total Revenues	<u>227,547</u>	<u>148,364</u>	<u>—</u>
<b>Operating expenses:</b>			
Cost of goods sold	\$ 2,392	\$ —	\$ —
Research and development	146,936	\$ 175,611	\$ 171,488
Selling, general and administrative	199,615	65,854	33,097
Total operating expenses	<u>348,943</u>	<u>241,465</u>	<u>204,585</u>
<b>Loss from operations</b>	<b>\$ (121,396)</b>	<b>\$ (93,101)</b>	<b>\$ (204,585)</b>
Interest expense	(22,670)	(8,120)	(28)
Other income, net	515	4,056	2,803
<b>Net loss</b>	<b>\$ (143,551)</b>	<b>\$ (97,165)</b>	<b>\$ (201,810)</b>
Net loss per common share (basic and diluted)	<u>\$ (5.23)</u>	<u>\$ (3.59)</u>	<u>\$ (7.54)</u>
Weighted-average shares outstanding (basic and diluted)	<u>27,473,873</u>	<u>27,090,284</u>	<u>26,754,308</u>
<b>Other comprehensive (loss) gain:</b>			
Unrealized (loss) gain on investments	\$ (23)	\$ 342	\$ 526
<b>Total comprehensive loss</b>	<b>\$ (143,574)</b>	<b>\$ (96,823)</b>	<b>\$ (201,284)</b>

See accompanying notes to the financial statements.

**Esperion Therapeutics, Inc.**

**Statements of Stockholders' Equity (Deficit)**

(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Treasury Stock	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
	Shares	Amount					
Balance December 31, 2017	26,304,669	\$ 26	\$ 641,801	\$ (396,291)	\$ —	\$ (845)	\$ 244,691
Exercise of stock options	356,809	1	11,742	—	—	—	11,743
Exercise of warrants	159,944	—	—	—	—	—	—
Vesting of restricted stock units	3,437	—	—	—	—	—	—
Stock-based compensation	—	—	23,968	—	—	—	23,968
Other comprehensive gain	—	—	—	—	—	526	526
Net loss	—	—	—	(201,810)	—	—	(201,810)
Balance December 31, 2018	26,824,859	\$ 27	\$ 677,511	\$ (598,101)	\$ —	\$ (319)	\$ 79,118
Exercise of stock options	649,529	—	11,771	—	—	—	11,771
Exercise of warrants	5,813	—	—	—	—	—	—
Vesting of restricted stock units	17,710	—	—	—	—	—	—
Stock-based compensation	—	—	25,884	—	—	—	25,884
Other comprehensive gain	—	—	—	—	—	342	342
Net loss	—	—	—	(97,165)	—	—	(97,165)
Balance December 31, 2019	27,497,911	\$ 27	\$ 715,166	\$ (695,266)	\$ —	\$ 23	\$ 19,950
Exercise of stock options	299,435	1	6,633	—	—	—	6,634
Vesting of restricted stock units	113,020	—	—	—	—	—	—
Stock-based compensation	—	—	28,385	—	—	—	28,385
Other comprehensive loss	—	—	—	—	—	(23)	(23)
Equity component of convertible notes	—	—	93,475	—	—	—	93,475
Repurchase of common stock under prepaid forward contract	(1,994,198)	(2)	—	—	(54,998)	—	(55,000)
Capped call options associated with convertible notes	—	—	(46,004)	—	—	—	(46,004)
Net loss	—	—	—	(143,551)	—	—	(143,551)
Balance December 31, 2020	25,916,168	\$ 26	\$ 797,655	\$ (838,817)	\$ (54,998)	\$ —	\$ (96,134)

See accompanying notes to the financial statements.

**Esperion Therapeutics, Inc.**

**Statements of Cash Flows**

(in thousands)

	Year Ended December 31,		
	2020	2019	2018
<b>Operating activities</b>			
Net loss	\$ (143,551)	\$ (97,165)	\$ (201,810)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation expense	547	319	265
Accretion of premiums and discounts on investments	(97)	(200)	(217)
Amortization of discount and issuance costs on convertible notes	1,741	—	—
Acquired in-process research and development (Note 3)	12,500	—	—
Non-cash interest expense related to the revenue interest liability	19,560	8,120	—
Stock-based compensation expense	28,385	25,884	23,968
Changes in assets and liabilities:			
Prepays and other assets	(14,793)	(3,396)	(2,884)
Deferred revenue	(490)	2,152	—
Inventories	(16,136)	—	—
Other long-term liabilities	1,290	—	—
Accounts payable	23,106	(16,055)	24,446
Other accrued liabilities	2,761	10,000	7,594
Net cash used in operating activities	(85,177)	(70,341)	(148,638)
<b>Investing activities</b>			
Purchases of investments	(4,420)	(34,326)	(25,481)
Purchases of in-process research and development	(12,500)	—	—
Proceeds from sales/maturities of investments	39,145	99,510	166,081
Purchase of property and equipment	(869)	(953)	(151)
Net cash provided by investing activities	21,356	64,231	140,449
<b>Financing activities</b>			
Proceeds from issuance of convertible notes	280,000	—	—
Payment for debt issuance costs	(8,405)	—	—
Prepayment of forward stock repurchase transaction	(55,000)	—	—
Purchase of capped call options associated with convertible notes	(46,004)	—	—
Proceeds from revenue interest liability, net of issuance costs	25,000	124,424	—
Payments on revenue interest liability	(500)	—	—
Proceeds from exercise of common stock options	6,634	11,771	11,743
Payments on long-term debt	—	—	(1,049)
Net cash provided by financing activities	201,725	136,195	10,694
Net increase in cash, cash equivalents and restricted cash	137,904	130,085	2,505
Cash and cash equivalents at beginning of period	167,058	36,973	34,468
Cash, cash equivalents and restricted cash at end of period	\$ 304,962	\$ 167,058	\$ 36,973
<b>Supplemental disclosure of cash flow information:</b>			
Purchase of property and equipment not yet paid	\$ —	\$ 190	\$ 199
Non cash right of use asset	\$ 20	\$ 31	\$ —
Offering costs not yet paid	\$ 495	\$ —	\$ —

See accompanying notes to the financial statements.

## Esperion Therapeutics, Inc.

### Notes to Financial Statements

#### 1. The Company and Basis of Presentation

Esperion Therapeutics, Inc. ("the Company") is the Lipid Management Company, a pharmaceutical company singularly focused on developing and commercializing affordable, oral, once-daily, non-statin medicines for the treatment of patients struggling with elevated low density lipoprotein cholesterol ("LDL-C"). The Esperion team of lipid experts are dedicated to lowering bad cholesterol through the discovery, development and commercialization of innovative medicines and their combinations with established medicines. The Company's first two products were approved by the U.S. Food and Drug Administration ("FDA"), European Medicines Agency ("EMA") and Swiss Agency for Therapeutic Products ("Swissmedic") in 2020. Bempedoic acid and the bempedoic acid / ezetimibe combination tablets are oral, once-daily, non-statin, LDL-C lowering medicines for patients with atherosclerotic cardiovascular disease ("ASCVD") or heterozygous familial hypercholesterolemia ("HeFH").

On February 21, 2020, the Company announced that the FDA approved NEXLETOL® as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or established ASCVD who require additional lowering of LDL-C. The effect of NEXLETOL on cardiovascular morbidity and mortality has not been determined. NEXLETOL is the first oral, once-daily, non-statin LDL-C lowering medicine approved since 2002 for indicated patients. NEXLETOL became commercially available in the U.S. on March 30, 2020.

On February 26, 2020, the Company announced that the FDA approved NEXLIZET® as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or established ASCVD who require additional lowering of LDL-C. The effect of NEXLIZET on cardiovascular morbidity and mortality has not been determined. NEXLIZET is the first non-statin, LDL-C lowering fixed combination drug product ever approved. NEXLIZET became commercially available in the U.S. on June 4, 2020.

On April 6, 2020, the Company announced that the European Commission ("EC") approved the NILEMDO™ (bempedoic acid) and NUSTENDI™ (bempedoic acid and ezetimibe) tablets for the treatment of hypercholesterolemia and mixed dyslipidemia. The decision is applicable to all 27 European Union member states plus the United Kingdom (until December 31, 2020), Iceland, Norway and Liechtenstein. NILEMDO (bempedoic acid) and NUSTENDI (bempedoic acid and ezetimibe) are the branded products names for bempedoic acid and the bempedoic acid / ezetimibe combination tablets in Europe. NILEMDO is the first, oral, non-statin, LDL-C lowering medicine approved in Europe in almost two decades for indicated patients, and NUSTENDI is the first non-statin, LDL-C lowering combination medicine ever approved in Europe. In November 2020, the Company announced the commercial launch of NILEMDO and NUSTENDI in Germany. In December 2020, the Company announced the approval of NILEMDO and NUSTENDI in Switzerland. With respect to the United Kingdom, on January 1, 2021 all existing centralized marketing authorizations (which applied to our marketing authorizations for NILEMDO and NUSTENDI) were automatically converted to Great Britain marketing authorizations (under the Northern Ireland Protocol, centralized marketing authorizations remain valid for marketing products in Northern Ireland).

On April 17, 2020, the Company entered into a license and collaboration agreement (the "Otsuka Agreement") with Otsuka Pharmaceutical Co., Ltd. ("Otsuka"). Pursuant to the Otsuka Agreement, the Company granted Otsuka exclusive development and commercialization rights to NEXLETOL and NEXLIZET in Japan. Otsuka will be responsible for all development, regulatory, and commercialization activities in Japan (the "Otsuka Territory"). In addition, Otsuka will fund all clinical development costs associated with the program in Japan. The Company received an upfront cash payment of \$60 million in April 2020 and will receive up to an additional \$450 million in total development and sales milestones. The Company will also receive tiered royalties ranging from 15 percent to 30 percent on net sales in Japan.

In 2019 the Company entered into a license and collaboration agreement ("LCA Agreement") with Daiichi Sankyo Europe GmbH ("DSE"). Pursuant to the agreement, the Company granted DSE exclusive commercialization rights to bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the European Economic Area and Switzerland (the "DSE Territory"). DSE will be responsible for commercialization in the DSE Territory. The Company remains responsible for clinical development, regulatory and manufacturing activities for the licensed products globally, including in the DSE Territory. On June 18, 2020, the Company entered into an amendment to the license and collaboration agreement ("LCA Amendment") with DSE dated as of January 2, 2019. In June 2020, the Company completed the transfer of the Marketing Authorisation Applications ("MAAs") for NILEMDO and NUSTENDI. Pursuant to the terms of the amendment, DSE paid the Company the

## Esperion Therapeutics, Inc.

### Notes to Financial Statements (Continued)

#### 1. The Company and Basis of Presentation (Continued)

second \$150 million milestone based on completion of the NUSTENDI MAA transfer rather than the first product sale in the EU. Prior to the execution of the LCA Amendment, the milestone payment was due upon the first commercial sale in Europe. Additionally, the Company and DSE have agreed to expand the territory in which DSE has exclusive commercialization rights to NILEMDO and NUSTENDI to include Turkey. DSE's designated affiliate in Turkey will be solely responsible, at its sole cost and expense, for all regulatory matters relating to such products in Turkey, including obtaining Regulatory Approval for such product in Turkey.

The Company's primary activities since incorporation have been conducting research and development activities, including nonclinical, preclinical and clinical testing, performing business and financial planning, recruiting personnel, and raising capital. The Company received approval by the FDA in February 2020 to commercialize NEXLETOL and NEXLIZET in the U.S., and accordingly commenced principal operations on March 30, 2020 with the commercialization of NEXLETOL. The Company is subject to risks and uncertainties which include the need to successfully commercialize its products, research, develop, and clinically test therapeutic products; obtain regulatory approvals for its products; expand its management, commercial and scientific staff; and finance its operations with an ultimate goal of achieving profitable operations.

The Company has sustained annual operating losses since inception and expects such losses to continue over the foreseeable future. While management believes current cash resources and future cash received from the Company's net product sales, collaboration agreements with DSE and Otsuka, entered into on January 2, 2019 and April 17, 2020, respectively, and from the Revenue Interest Purchase Agreement ("RIPA") with Eiger III SA LLC ("Oberland"), an affiliate of Oberland Capital LLC, and the Purchasers named therein, entered into on June 26, 2019, will fund operations for the foreseeable future, management may continue to fund operations and advance the development of the Company's products and product candidates through a combination of collaborations with third parties, strategic alliances, licensing arrangements, permitted debt financings, permitted royalty-based financings, and permitted private and public equity offerings or through other sources. The impact of COVID-19 and the uncertainty around the global pandemic could further impact the commercial launch of NEXLETOL and NEXLIZET and the Company's research and development programs and could result in lower cash flows or higher costs that could further impact the Company's overall operations and cash needs in the future.

If adequate funds are not available, the Company may not be able to continue the development of its current products or future product candidates, or to commercialize its current or future product candidates, if approved.

#### *Basis of Presentation*

The accompanying financial statements have been prepared by the Company in accordance with generally accepted accounting principles in the United States of America ("GAAP").

#### 2. Summary of Significant Accounting Policies

##### **Use of Estimates**

The preparation of financial statements in accordance with generally accepted accounting principles in the United States requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, net revenues, expenses and related disclosures. Actual results could differ from those estimates.

##### **Cash and Cash Equivalents**

The Company invests its excess cash in bank deposits, money market accounts, and short-term investments. The Company considers all highly liquid investments with an original maturity of 90 days or less at the time of purchase to be cash equivalents. Cash equivalents are reported at fair value.

##### **Restricted Cash**

Restricted cash consists of legally restricted amounts held by financial institutions pursuant to contractual arrangements.

## Esperion Therapeutics, Inc.

### Notes to Financial Statements (Continued)

#### 2. Summary of Significant Accounting Policies (Continued)

##### Investments

Investments are considered to be available-for-sale and are carried at fair value. Unrealized gains and losses, if any, are reported as a separate component of stockholders' equity. The cost of investments classified as available-for-sale are adjusted for the amortization of premiums and accretion of discounts to maturity and recorded in other income, net. Realized gains and losses, if any, are determined using the specific identification method and recorded in other income, net. Investments with original maturities beyond 90 days at the date of purchase and which mature at, or less than twelve months from, the balance sheet date are classified as current. Investments with a maturity beyond twelve months from the balance sheet date are classified as long-term.

##### Selling, General and Administrative Expenses

Selling, general and administrative expenses primarily consist of salaries and benefits, stock-based compensation, and costs of programs necessary for the general conduct of the Company's business, including costs associated with the commercialization of NEXLETOL and NEXLIZET in the U.S. Selling, general and administrative expenses are expensed as costs are incurred, services are performed, or goods are delivered. The Company incurred advertising costs of \$19.3 million for the year ended December 31, 2020.

##### Concentration of Credit Risk

Cash, cash equivalents, and marketable securities consist of financial instruments that potentially subject the Company to concentrations of credit risk. The Company has established guidelines for investment of its excess cash and believes the guidelines maintain safety and liquidity through diversification of counterparties and maturities. The Company enters into a limited number of distribution agreements with distributors and specialty pharmacies. The Company's net product sales are with these customers. As of December 31, 2020, eight customers accounted for all of the Company's net trade receivables.

##### Inventories

Inventories are stated at the lower of cost or net realizable value and recognized on a first-in, first-out ("FIFO") method. The Company uses standard cost to determine the cost basis for inventory. Inventory is capitalized based on when future economic benefit is expected to be realized. The Company began capitalizing inventory upon receiving FDA approval for NEXLETOL and NEXLIZET on February 21, 2020 and February 26, 2020, respectively. Prior to the FDA approval of NEXLETOL and NEXLIZET, expenses associated with the manufacturing of the Company's products were recorded as research and development expense.

The Company analyzes its inventory levels on a periodic basis to determine if any inventory is at risk for expiration prior to sale or has a cost basis that is greater than its estimated future net realizable value. Any adjustments are recognized through cost of goods sold in the period in which they are incurred.

##### Segment Information

The Company views its operations and manages its business in one operating segment, which is the business of researching, developing and commercializing therapies for the treatment of patients with elevated LDL-C.

##### Fair Value of Financial Instruments

The Company's cash, cash equivalents, restricted cash and investments are carried at fair value. Financial instruments, including other prepaid and current assets, accounts payable and accrued liabilities are carried at cost, which approximates fair value. Debt is carried at amortized cost, which approximates fair value.

## Esperion Therapeutics, Inc.

### Notes to Financial Statements (Continued)

#### 2. Summary of Significant Accounting Policies (Continued)

##### Property and Equipment, Net

Property and equipment are recorded at cost, less accumulated depreciation. Depreciation is provided using the straight-line method over the estimated useful lives of the respective assets, generally three to ten years. Leasehold improvements are amortized over the lesser of the lease term or the estimated useful lives of the related assets.

##### Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value. No impairment losses have been recorded through December 31, 2020.

##### Leases

The Company reviews all arrangements to determine if the contract contains a lease or an embedded lease using the criteria in Accounting Standards Codification ("ASC") 842 *Leases* ("ASC 842"). If a lease is identified, the Company reviews the consideration in the contract and separates the lease components from the nonlease components. In addition, the Company reviews the classification of the lease between operating and finance leases. According to ASC 842, lessees should discount lease payments at the lease commencement date using the rate implicit in the lease. If the rate implicit in the lease is not readily determinable, a lessee must use its incremental borrowing rate for purposes of classifying the lease and measuring the right-of-use asset and liability. To the extent the rate is not implicit in the lease, the Company uses the incremental borrowing rate it would have to pay to borrow on a collateralized basis over a similar term in an amount equal to the lease payments in a similar economic environment.

##### Convertible Notes

The Company accounts for convertible debt instruments that may be settled in cash or equity upon conversion by separating the liability and equity components of the instruments in a manner that reflects the nonconvertible debt borrowing rate. The Company determined the carrying amount of the liability component of the Convertible Notes by using estimates and assumptions that market participants would use in pricing a debt instrument. These estimates and assumptions are judgmental in nature and could have a significant impact on the determination of the debt component, and the associated non-cash interest expense.

The equity component is treated as a discount on the liability component of the Convertible Notes, which is amortized over the term of the Convertible Notes using the effective interest rate method. Debt issuance costs related to the Convertible Notes are allocated to the liability and equity components of the Convertible Notes based on their relative values. Debt issuance costs allocated to the liability component are amortized over the life of the Convertible Notes as additional non-cash interest expense. Transaction costs allocated to equity are netted with the equity component of the convertible debt instrument in stockholders' equity (deficit).

##### Revenue Interest Liability

The revenue interest liability is presented net of deferred issuance costs on the balance sheets. The Company imputes interest expense associated with this liability using the effective interest rate method. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. The interest rate on the liability may vary during the term of the agreement depending on a number of factors, including the level of forecasted net sales. The Company evaluates the interest rate quarterly based on its current net sales forecasts utilizing the prospective method.

##### Revenue Recognition

In accordance with ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), the Company recognizes revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration the Company



Notes to Financial Statements (Continued)

**2. Summary of Significant Accounting Policies (Continued)**

expects to receive in exchange for the goods or services provided. To determine revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps: identify the contracts with a customer; identify the performance obligations in the contract; determine the transaction price; allocate the transaction price to the performance obligations in the contract; and recognize revenue when or as the entity satisfies a performance obligation. 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 derives revenue through two primary sources: collaboration revenue and product sales. Collaboration revenue consists of the collaboration payments to the Company for collaboration arrangements outside of the United States for the development, manufacturing and commercialization of the Company's product candidates by the Company's partners and product sales consists of sales of NEXLETOL and NEXLIZET in the United States.

**a. Collaboration Revenue**

The Company has entered into agreements related to its activities to develop, manufacture, and commercialize its product candidates. The Company earns collaboration revenue in connection with a collaboration agreement to develop and/or commercialize product candidates where the Company deems the collaborator to be the customer. In accordance with ASC 606, revenue is measured as the amount of consideration expected to be entitled to in exchange for transferring promised goods or providing services to a customer. Revenue is recognized when (or as) the Company satisfies performance obligations under the terms of a contract. Depending on the terms of the arrangement, the Company may defer the recognition of all or a portion of the consideration received as the performance obligations are satisfied.

The collaboration agreements may require the Company to deliver various rights, services, and/or goods across the entire life cycle of a product or product candidate. In an agreement involving multiple goods or services promised to be transferred to a customer, the Company must assess, at the inception of the contract, whether each promise represents a separate performance obligation (i.e., is "distinct"), or whether such promises should be combined as a single performance obligation.

The terms of the agreements typically include consideration to be provided to the Company in the form of non-refundable up-front payments, development milestones, sales milestones, and royalties on sales of products within a respective territory. The Company recognizes regulatory and approval milestones consideration when it is probable that a future reversal is unlikely to occur. For sales based milestones and royalties based on sales of product in a territory, the Company applies the sales-based royalty exception in ASC 606 to all of these milestones and royalties.

At the inception of a contract, the transaction price reflects the amount of consideration the Company expects to be entitled to in exchange for transferring promised goods or services to its customer. In the arrangement where the Company satisfies performance obligation(s) during the regulatory phase over time, the Company recognizes collaboration revenue typically using an input method on the basis of regulatory costs incurred relative to the total expected cost which determines the extent of progress toward completion. The Company reviews the estimate of the transaction price and the total expected cost each period, and makes revisions to such estimates as necessary. Under contracted supply agreements with collaborators, the Company may manufacture and supply quantities of active pharmaceutical ingredient ("API") or bulk tablets reasonably required by collaboration partners for the development or sale of licensed products in their respective territory. The Company recognizes revenue when the collaboration partner has obtained control of the API or bulk tablets. The Company records the costs related to the supply agreement in cost of goods sold on the statements of operations and comprehensive income (loss).

Under the Company's collaboration agreements, product sales and cost of sales may be recorded by the Company's collaborators as they are deemed to be the principal in the transaction. The Company receives royalties from the commercialization of such products, and records its share of the variable consideration, representing a percentage of net product sales, as collaboration revenue in the period in which such underlying sales occur and costs are incurred by the collaborators. The collaborators will provide the Company with estimates of its royalties for such quarter; these estimates are reconciled to actual results in the subsequent quarter, and the royalty is adjusted accordingly, as necessary.

Please refer to the discussion in Note 3 "Collaborations with Third Parties" for further discussion of the accounting related to the collaboration agreements.

Notes to Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

b. Product Sales, Net

On March 30, 2020, NEXLETOL was commercially available in the U.S. through prescription and on June 4, 2020, NEXLIZET was commercially available in the U.S. through prescription. Net product sales totaled \$13.0 million for the year ended December 31, 2020.

The Company sells NEXLETOL and NEXLIZET to wholesalers in the U.S and recognizes revenue at the point in time when the customer is deemed to have obtained control of the product. The customer is deemed to have obtained control of the product at the time of physical receipt of the product at the customers' distribution facilities, or free on board ("FOB") destination, the terms of which are designated in the contract.

Product sales are recorded at the net selling price, which includes estimates of variable consideration for which reserves are established for (a) rebates and chargebacks, (b) co-pay assistance programs, (c) distribution fees, (d) product returns, and (e) other discounts and fees. Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as current contractual and statutory requirements, and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the applicable contract. The amount of variable consideration may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Given the early stage of the Company's commercial operations it has provided constraint of its variable consideration due to its potential consumption trends. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from estimates, the Company adjusts these estimates, which would affect net product revenue and earnings in the period such variances become known.

Liabilities for co-pay assistance, expected product returns, rebates, and distributor fees are classified as "Other accrued liabilities" in the balance sheets. Discounts, such as prompt pay discounts, and chargebacks are recorded as a reduction to trade accounts receivable, which is included in "Other prepaid and current assets" in the balance sheets.

*Forms of Variable Consideration*

*Rebates and Chargebacks:* The Company estimates reductions to product sales for Public Health Service Institutions, such as Medicaid, Medicare and Veterans' Administration ("VA") programs, as well as certain other qualifying federal and state government programs, and other group purchasing organizations. The Company estimates these reductions based upon the Company's contracts with government agencies and other organizations, statutorily defined discounts and estimated payor mix. These organizations purchase directly from the Company's wholesalers at a discount and the wholesalers charge the Company back the difference between the wholesaler price and the discounted price. The Company's liability for Medicare and Medicaid rebates consists of estimates for claims that a state will make for a current quarter. The Company's reserve for this discounted pricing is based on expected sales to qualified healthcare providers and the chargebacks that customers have already claimed.

*Co-pay assistance:* Eligible patients who have commercial insurance may receive assistance from the Company to reduce the patient's out of pocket costs. The Company will buy down the difference between the amount of the eligible patient's co-pay when the drug is purchased at the pharmacy at a determined price. Liabilities for co-pay assistance are calculated by actual program participation from third-party administrators.

*Distribution Fees:* The Company has written contracts with its customers that include terms for distribution fees and costs for inventory management. The Company estimates and records distribution fees due to its customers based on gross sales.

*Product Returns:* The Company generally offers a right of return based on the product's expiration date and certain spoilage and damaged instances. The Company estimates the amount of product sales that may be returned and records the estimate as a reduction of product sales in the period the related product sales is recognized. The Company's estimates for expected returns are based primarily on an ongoing analysis of sales information and visibility into the inventory remaining in the distribution channel.

## Esperion Therapeutics, Inc.

### Notes to Financial Statements (Continued)

#### 2. Summary of Significant Accounting Policies (Continued)

*Discounts:* The Company provides product discounts, such as prompt pay discounts, to its customers. The Company estimates cash discounts based on terms in negotiated contracts and the Company's expectations regarding future payment patterns.

#### Cost of Goods Sold

Cost of goods sold is related to the Company's net product sales of NEXLETOL and NEXLIZET and the cost of the API supplied to collaboration partners from supply agreements. Cost of goods sold includes the actual product costs, including inbound freight charges and certain outbound freight charges, purchasing, sourcing, inspection and receiving costs.

#### Research and Development

Research and development expenses consist of costs incurred to further the Company's research and development activities and include salaries and related benefits, costs associated with clinical activities, nonclinical activities, regulatory activities, manufacturing activities to support clinical activities and commercial product manufacturing supply prior to the Company's regulatory approval, research-related overhead expenses, in-licensing agreements and fees paid to external service providers that conduct certain research and development, clinical, and manufacturing activities on behalf of the Company. Research and development costs are expensed as incurred.

In accordance with ASC 730, *Research and Development*, costs incurred in obtaining in-licenses are charged to research and development expense if the in-licensed technology has not reached commercial feasibility and has no alternative future use. Such licenses purchased by the Company require substantial completion of research and development, regulatory and marketing approval efforts in order to reach commercial feasibility and has no alternative future use.

#### Accrued Clinical Development Costs

Outside research costs are a component of research and development expense. These expenses include fees paid to clinical research organizations and other service providers that conduct certain clinical and product development activities on behalf of the Company. Depending upon the timing of payments to the service providers, the Company recognizes prepaid expenses or accrued expenses related to these costs. These accrued or prepaid expenses are based on management's estimates of the work performed under service agreements, milestones achieved and experience with similar contracts. The Company monitors each of these factors and adjusts estimates accordingly.

#### Income Taxes

Deferred tax assets and liabilities are determined based on differences between financial reporting and the tax basis of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company has incurred annual operating losses since inception. Accordingly, it is not more likely than not that the Company will realize a tax benefit from its deferred tax assets and as such, it has recorded a full valuation allowance.

#### Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with the provisions of ASC 718, *Compensation—Stock Compensation*. Accordingly, compensation costs related to equity instruments granted are recognized over the requisite service periods of the awards on a straight-line basis at the grant-date fair value calculated using a Black-Scholes option-pricing model. The Company accounts for forfeitures as they occur. Expense is recognized during the period the related services are rendered.

#### Recent Accounting Pronouncements

In June 2016, the FASB issued Accounting Standard Update ("ASU") 2016-13, *Financial Instruments—Credit Losses (Topic 326)*, which requires financial instruments to be recognized at an estimate of current expected credit losses. As part of the ASU, financial assets measured at amortized cost will be presented at the net amount expected to be collected. In addition, companies will recognize an allowance for credit losses on available-for-sale investments rather than reducing the amortized

Notes to Financial Statements (Continued)

**2. Summary of Significant Accounting Policies (Continued)**

cost in an other-than-temporary impairment. The standard is effective for public companies for fiscal years beginning after December 15, 2019, and interim periods within those years. The Company has chosen the practical expedient to exclude accrued interest from both the fair value and the amortized cost basis of available-for-sale debt securities in identifying and measuring an impairment. The Company adopted the standard effective January 1, 2020. The adoption of this standard did not have a material impact on the Company's balance sheets, statements of operations or statements of cash flows.

In August 2018, the FASB issued ASU 2018-15, *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, which includes provisions to clarify customer's accounting for implementation costs incurred in a cloud computing arrangement. Under the updated guidance, a customer in a cloud computing arrangement that is a service contract should follow the internal-use software guidance to determine how to account for costs incurred in implementation. The updated guidance also requires certain classification on the balance sheets, statements of operations and statements of cash flows as well as additional quantitative and qualitative disclosures. The standard is effective for public companies for fiscal years beginning after December 15, 2019, and interim periods within those years. Entities can choose to adopt the new guidance prospectively or retrospectively. The Company adopted the standard effective January 1, 2020, and has chosen to adopt the standard prospectively. Implementation costs for cloud computing arrangements are capitalized in "Other prepaid and current assets" on the Company's balance sheets. The adoption of this standard did not have a material impact to the Company's balance sheets, statements of operations or statements of cash flows.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, as part of its initiative to reduce complexity in accounting standards. The amendments in this update simplify the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments also improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The amendments within ASU 2019-12 are effective for financial statements issued for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, and early adoption is permitted. The Company early adopted this standard for the year ended December 31, 2020, which amended the existing standards for income tax accounting, eliminating the legacy exception on how to allocate income tax expense or benefit for the year to continuing operations, discontinued operations, other comprehensive income, and other charges or credits recorded directly to shareholder's equity. We did not adjust comparative periods in our financial statements prior to that period. Adoption of the new standard on January 1, 2020 resulted in determining the tax effect of income or loss from continuing operations using a computation that does not consider the tax effects of items that are not included in continuing operations. As such, the Company did not record a tax expense or benefit related to amounts credited directly to shareholder equity. Refer to Note 16 for additional information.

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)* ("ASU 2020-06"). This ASU simplifies the accounting for convertible instruments by removing the separation models for convertible debt with cash conversion features and convertible instruments with a beneficial conversion feature, which requires the fair value of the embedded conversion feature of convertible instruments be allocated to equity. Under ASU 2020-06, a convertible debt instrument with those features will generally be reported as a single liability at its amortized cost with no separate accounting for the embedded conversion features in equity. The adoption of this ASU will result in the reclassification of the portion of the Company's convertible notes from equity to debt, which will also reduce reported interest expense and increase reported net income. ASU 2020-06 requires the application of the if-converted method when calculating diluted earnings per share, eliminating the Company's ability to use the treasury stock method when certain conditions are met. The ASU is effective for annual reporting periods beginning after December 15, 2021, with early adoption permitted no earlier than fiscal years beginning after December 15, 2020. The Company plans to early adopt this standard as of January 1, 2021 which will result in a net increase in the Convertible notes of approximately \$92.0 million, an adjustment to accumulated deficit of approximately \$1.5 million, and a reduction to additional paid-in capital of \$93.5 million. The Company does not expect any tax impact of the adoption to be material.

**3. Collaborations with Third Parties**

**DSE Agreement Terms**

On January 2, 2019, the Company entered into a license and collaboration agreement with DSE. Pursuant to the agreement, the Company granted DSE exclusive commercialization rights to bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the European Economic Area and Switzerland ("DSE Territory"). DSE will be responsible for

Notes to Financial Statements (Continued)

**3. Collaborations with Third Parties (Continued)**

commercialization in the DSE Territory. The Company remains responsible for clinical development, regulatory and manufacturing activities for the licensed products globally, including in the DSE Territory.

Pursuant to the agreement, the consideration consists of a \$150.0 million upfront cash payment as well as \$150.0 million cash payment to the Company upon first commercial sales in the DSE Territory. The Company also is responsible for supplying DSE with certain manufacturing supply of the API or bulk tablets. The Company is also eligible to receive a substantial additional regulatory milestone payment upon the grant of the marketing authorisation in the European Union for the CV risk reduction label, depending on the range of relative risk reduction in the CLEAR Outcomes study. In addition, the Company is eligible to receive additional sales milestone payments related to total net sales achievements for DSE in the DSE Territory. Finally, the Company will receive tiered fifteen percent (15%) to twenty-five percent (25%) royalties on net DSE Territory sales.

The agreement calls for both parties to participate in a Joint Collaboration Committee (the “DSE JCC”). The DSE JCC is comprised of executive management from each company and the Company will lead in all aspects related to development and DSE will lead in all aspects related to commercialization in the DSE Territory.

*Agreement Terms Amendment*

On June 18, 2020, the Company entered into an amendment to the license and collaboration agreement with DSE, dated as of January 2, 2019. In June, the Company completed the transfer of the MAAs for NILEMDO and NUSTENDI. Pursuant to the terms of the amendment, DSE paid the Company the second \$150.0 million milestone based on completion of the NUSTENDI MAA transfer rather than the first product sale in the EU, as previously agreed. Additionally, the Company and DSE have agreed to expand the DSE Territory, or the territory in which DSE has exclusive commercialization rights to NILEMDO and NUSTENDI to include Turkey. DSE's designated affiliate in Turkey will be solely responsible, at its sole cost and expense, for all regulatory matters relating to such products in Turkey, including obtaining regulatory approval for such products in Turkey.

*Collaboration Revenue*

The Company considered the guidance under ASC 606 and concluded that the agreement was in the scope of ASC 606. The Company concluded that the upfront payment of \$150.0 million should be included in the transaction price and related to the following performance obligations under the agreement: 1) the license to the Company's intellectual property and 2) the obligation to provide ongoing regulatory and development activities. The Company used the adjusted market assessment approach in determining the standalone selling price of the Company's intellectual property and the expected cost plus margin approach in determining the standalone selling price of the Company's obligation to provide ongoing regulatory and development activities. Accordingly, during the year ended December 31, 2019, the Company recognized \$148.4 million of collaboration revenue related to the \$150.0 million upfront payment, respectively. The \$148.4 million related to the performance obligations for the license to the Company's intellectual property and a portion of ongoing regulatory and development activities conducted during the period ended December 31, 2019, in the amounts of \$144.4 million and \$4.0 million, respectively. The remaining \$1.6 million of the upfront payment was deferred as of December 31, 2019 due to an on-going performance obligation related to the ongoing regulatory efforts related to the MAA in the DSE Territory. During the year ended December 31, 2020, the Company recognized \$1.6 million related to the on-going performance obligation for the ongoing regulatory efforts related to the MAA in the DSE Territory, which was transferred to DSE in June 2020.

In addition, in the year ended December 31, 2020, the Company recognized the \$150.0 million milestone as collaboration revenue based on the successful transfer of the NUSTENDI MAA. During the year ended December 31, 2020, the Company recognized collaboration revenue of \$2.8 million related to royalty revenue and the sales of bulk tablets of NILEMDO and NUSTENDI to DSE pursuant to the Supply Agreement that was executed with DSE.

All remaining future potential milestone amounts were not included in the transaction price, as they were all determined to be fully constrained following the concepts of ASC 606 due to the fact that such amounts hinge on development activities, regulatory approvals and sales-based milestones. Additionally, the Company expects that any consideration related to sales-based milestones will be recognized when the subsequent sales-based milestones are achieved.

## Esperion Therapeutics, Inc.

### Notes to Financial Statements (Continued)

#### 3. Collaborations with Third Parties (Continued)

##### Otsuka Agreement Terms

On April 17, 2020, the Company entered into the Otsuka Agreement. Pursuant to the Otsuka Agreement, the Company granted Otsuka exclusive development and commercialization rights to NEXLETOL and NEXLIZET in Japan. Otsuka will be responsible for all development, regulatory, and commercialization activities in Japan. In addition, Otsuka will fund all clinical development costs associated with the program in Japan.

Pursuant to the agreement, the consideration consists of a \$60.0 million upfront cash payment and the Company will be eligible to receive additional payments of up to \$450.0 million if certain regulatory and commercial milestones are achieved by Otsuka. The potential future milestone payments include up to \$20.0 million upon first JNDA submissions in the Otsuka Territory, up to \$70.0 million upon the first NHI Price Listing for NEXLETOL in the Otsuka Territory, and up to \$50.0 million upon the achievement of the primary major adverse cardiovascular events ("MACE") in the CLEAR Outcomes study and the CV risk reduction rate on the U.S. label, depending on the range of relative risk reduction in the CLEAR Outcomes study. In addition, the Company is eligible to receive additional sales milestone payments up to \$310.0 million related to total net sales achievements for Otsuka in Japan. Finally, the Company will receive tiered fifteen percent (15%) to thirty percent (30%) royalties on net sales in Japan.

The agreement calls for both parties to participate in a Joint Collaboration Committee (the "Otsuka JCC"). The Otsuka JCC is comprised of executive management from each company and Otsuka will lead in all aspects related to development and commercialization in the Otsuka Territory.

##### *Collaboration Revenue*

The Company considered the guidance under ASC 606 and concluded that the agreement was in the scope of ASC 606. The Company concluded that the upfront payment of \$60.0 million should be included in the transaction price and related to the performance obligation under the agreement to the license to the Company's intellectual property. During the year ended December 31, 2020, the Company recognized \$60.0 million of collaboration revenue related to the \$60.0 million upfront payment.

All future potential milestone amounts were not included in the transaction price, as they were all determined to be fully constrained following the concepts of ASC 606 due to the fact that such amounts hinge on development activities, regulatory approvals and sales-based milestones. Additionally, the Company expects that any consideration related to royalties and sales-based milestones will be recognized when the subsequent sales occur.

The Company has not yet recognized any revenue for milestone payments as the related regulatory and commercial milestones have not yet been achieved.

##### Other Agreements

During December 2020, the Company entered into a licensing agreement with Serometrix to in-license a series of early stage compounds known as scaffolds related to its oral, small molecule PCSK9 inhibitor program. PCSK9 is an enzyme responsible for regulating LDL receptors. PCSK9 inhibitors stop LDL receptors from being broken down, increasing the number of LDL receptors present to remove cholesterol from the blood. The agreement allows the Company use of the PCSK9 compounds, which were patented by Serometrix prior to the licensing agreement, to perform further research and development with the goal of developing a small molecule oral PCSK9 inhibitor that can be taken as a tablet.

In exchange for these rights, the Company agreed to pay Serometrix an upfront payment, milestone payments and royalties on net sales of licensed products under the agreement. The Company is obligated to make milestone payments to Serometrix upon the achievement of specified development, regulatory and commercialization milestones. The development milestone payments due under the agreement depend on the licensed product being developed. As part of the agreement, the Company made an upfront cash payment of \$12.5 million in December 2020, which was recorded to research and development expense, to Serometrix, with payments in future years tied to specific milestones. The Company has also agreed to pay tiered royalties based on net sales of all products licensed under the agreement of mid-single-digit to low double-digit percentages.

## Notes to Financial Statements (Continued)

## 4. Inventories

Inventories consist of the following:

	December 31,	
	2020	2019
	(in thousands)	
Raw materials	\$ 13,788	—
Work in process	2,028	—
Finished goods	320	—
	<u>\$ 16,136</u>	<u>\$ —</u>

## 5. Warrants

In June 2014, the Company entered into a loan and security agreement (the "Credit Facility") with Oxford Finance LLC which provided for borrowings of \$5.0 million under the term loan (the "Term A Loan"). On June 30, 2014, the Company received proceeds of \$5.0 million from the issuance of secured promissory notes under the Term A Loan, which were collateralized by substantially all of the Company's personal property, other than its intellectual property. The Term A Loan was fully repaid in July 2018. In connection with the Credit Facility entered into in June 2014, the Company issued a warrant to purchase 8,230 shares of common stock at an exercise price of \$15.19. The warrant was recorded at fair value of \$0.1 million to additional-paid-in-capital.

During the year ended December 31, 2019, 8,230 warrants were net exercised for 5,813 shares of the Company's common stock. During the year ended December 31, 2018, 177,123 warrants were net exercised for 159,944 shares of the Company's common stock.

As of December 31, 2020 and December 31, 2019, the Company had no warrants outstanding.

## 6. Commitments and Contingencies

The Company has entered into a contract manufacturing agreement with a third party commercial manufacturing organization for the production of certain inventory supplies of NEXLETOL and NEXLIZET. The agreement has an initial term of three years and will renew automatically for successive periods of one year each unless terminated by either party. Under the agreement, the Company is obligated to purchase minimum order commitments on a rolling twelve-month period for the batches of inventory supplies produced. The Company estimates future minimum inventory purchase commitments of \$19.1 million for 2021.

## Legal Proceedings

On January 12, 2016, a purported stockholder of the Company filed a putative class action lawsuit in the United States District Court for the Eastern District of Michigan, against the Company and Tim Mayleben, captioned *Kevin L. Dougherty v. Esperion Therapeutics, Inc., et al.* (No. 16-cv-10089). The lawsuit alleges that the Company and Mr. Mayleben violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 by allegedly failing to disclose in an August 17, 2015, public statement that the FDA would require a cardiovascular outcomes trial before approving the Company's lead product candidate. The lawsuit seeks, among other things, compensatory damages in connection with an allegedly inflated stock price between August 18, 2015, and September 28, 2015, as well as attorneys' fees and costs. On May 20, 2016, an amended complaint was filed in the lawsuit and on July 5, 2016, the Company filed a motion to dismiss the amended complaint. On December 27, 2016, the court granted the Company's motion to dismiss with prejudice and entered judgment in the Company's favor. On January 24, 2017, the plaintiffs in this lawsuit filed a motion to alter or amend the judgment. In May 2017, the court denied the plaintiff's motion to alter or amend the judgment. In May 2017, the court denied the plaintiff's motion to alter or amend the judgment. On June 19, 2017, the plaintiffs filed a notice of appeal to the Sixth Circuit Court of Appeals and on September 14, 2017, they filed their opening brief in support of the appeal. The appeal was fully briefed on December 7, 2017, and it was argued before the Sixth Circuit on March 15, 2018. On September 27, 2018, the Sixth Circuit issued an opinion in which it reversed the district court's dismissal and remanded for further proceedings. On October 11, 2018, the Company filed a petition for rehearing en banc and, on October 23, 2018, the Sixth Circuit Court of Appeals directed

## Esperion Therapeutics, Inc.

### Notes to Financial Statements (Continued)

#### 6. Commitments and Contingencies (Continued)

plaintiffs to respond to that petition. On December 3, 2018, the Sixth Circuit denied the Company's petition for en banc rehearing, and on December 11, 2018, the case was returned to the federal district court by mandate from the Sixth Circuit. On December 26, 2018, the Company filed an answer to the amended complaint, and on March 28, 2019, the Company filed its amended answer to the amended complaint. On September 15, 2020, the Company filed a motion for summary judgment, and the plaintiffs filed a motion for partial summary judgment, and on October 23, 2020, the parties filed oppositions to both motions for summary judgment. On November 20, 2020, the Company and plaintiffs filed replies in support of their respective motions. The Company is unable to predict the outcome of this matter and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from an unfavorable outcome.

On December 15, 2016, a purported stockholder of the Company filed a derivative lawsuit in the Court of Chancery of the State of Delaware against Tim Mayleben, Roger Newton, Mary McGowan, Nicole Vitullo, Dov Goldstein, Daniel Janney, Antonio Gotto Jr., Mark McGovern, Gilbert Omenn, Scott Braunstein, and Patrick Enright. The Company is named as a nominal defendant. The lawsuit alleges that the defendants breached their fiduciary duties to the Company when they made or approved improper statements on August 17, 2015, regarding the Company's lead product candidate's path to FDA approval, and failed to ensure that reliable systems of internal controls were in place at the Company. On February 8, 2019, the Company and defendants filed a motion to dismiss the derivative lawsuit. On April 23, 2019, the plaintiff filed an opposition to the motion to dismiss the derivative lawsuit, and the Company filed a reply brief on May 15, 2019. On November 6, 2019, the court held a hearing on the motion to dismiss. On February 13, 2020, the court granted the motion to dismiss with prejudice and entered judgment in the Company's favor. On March 16, 2020, the plaintiff filed a notice of appeal to the Supreme Court of Delaware. On June 1, 2020, the plaintiff filed his opening brief on appeal to the Supreme Court of Delaware. On July 1, 2020, the Company and the defendants filed an answering brief, and on July 16, 2020, the plaintiff filed a reply brief. On October 14, 2020, the Supreme Court of Delaware held oral arguments on the appeal. On October 29, 2020, the Supreme Court of Delaware issued an order affirming the judgment of the Court of Chancery.

#### 7. Property and Equipment

Property and equipment consist of the following:

	December 31,	
	2020	2019
	(in thousands)	
Computer equipment	\$ 278	\$ 256
Software	1,100	615
Furniture, fixtures and other	1,170	908
Leasehold improvements	299	298
Assets in Progress	—	99
Subtotal	2,847	2,176
Less accumulated depreciation and amortization	1,571	1,031
Property and equipment, net	\$ 1,276	\$ 1,145

Depreciation expense was \$0.5 million, \$0.3 million, and \$0.3 million for the years ended December 31, 2020, 2019 and 2018, respectively.



**Esperion Therapeutics, Inc.**

**Notes to Financial Statements (Continued)**

**8. Other Accrued Liabilities**

Other accrued liabilities consist of the following:

	December 31,	
	2020	2019
(in thousands)		
Accrued compensation	\$ 15,161	\$ 7,818
Accrued professional fees	3,183	3,842
Accrued other	6,446	211
Total other accrued liabilities	\$ 24,790	\$ 11,871

**9. Investments**

The following table summarizes the Company's cash equivalents and investments:

	December 31, 2020			
	Amortized	Gross	Gross	Estimated
	Cost	Unrealized	Unrealized	Fair
(in thousands)				
<b>Cash equivalents:</b>				
Money market funds	\$ 281,783	\$ —	\$ —	\$ 281,783
Total	\$ 281,783	\$ —	\$ —	\$ 281,783

	December 31, 2019			
	Amortized	Gross	Gross	Estimated
	Cost	Unrealized	Unrealized	Fair
(in thousands)				
<b>Cash equivalents:</b>				
Money market funds	\$ 20,970	\$ —	\$ —	\$ 20,970
U.S. treasury notes	2,497	—	—	2,497
Commercial paper	4,494	—	—	4,494
<b>Short-term investments:</b>				
Certificates of deposit	245	—	—	245
U.S. treasury notes	29,155	23	—	29,178
Commercial paper	5,228	—	—	5,228
Total	\$ 62,589	\$ 23	\$ —	\$ 62,612

At December 31, 2019, remaining contractual maturities of available-for-sale investments classified as current on the balance sheet were less than 12 months. The company does not intend to sell the investments before maturity.

During the years ended December 31, 2020, 2019 and 2018, other income, net in the statements of operations includes interest income on available-for-sale investments of \$0.5 million, \$3.7 million and \$2.6 million, respectively. Other income, net in the statements of operations includes income for the accretion of premiums and discounts on investments of \$0.1 million, \$0.3 million and \$0.2 million during the years ended December 31, 2020, 2019 and 2018, respectively.

**Esperion Therapeutics, Inc.**

**Notes to Financial Statements (Continued)**

**9. Investments (Continued)**

There were no unrealized gains or losses on investments reclassified from accumulated other comprehensive loss to other income, net in the statements of operations during the year ended December 31, 2020.

**10. Fair Value Measurements**

The Company follows accounting guidance that emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Fair value is defined as “the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.” Fair value measurements are defined on a three level hierarchy:

- Level 1 inputs: Quoted prices for identical assets or liabilities in active markets;
- Level 2 inputs: Observable inputs other than Level 1 prices, such as quoted market prices for similar assets or liabilities or other inputs that are observable or can be corroborated by market data; and
- Level 3 inputs: Unobservable inputs that are supported by little or no market activity and require the reporting entity to develop assumptions that market participants would use when pricing the asset or liability.

The following table presents the Company’s financial assets that have been measured at fair value on a recurring basis:

Description	Total	Level 1	Level 2	Level 3
<b>December 31, 2020</b>				
Money market funds	\$ 281,783	\$ 281,783	\$ —	\$ —
Total assets at fair value	<u>\$ 281,783</u>	<u>\$ 281,783</u>	<u>\$ —</u>	<u>\$ —</u>
<b>December 31, 2019</b>				
Money market funds	\$ 20,970	\$ 20,970	\$ —	\$ —
Investments:				
Certificates of deposit	245	245	—	—
U.S. treasury notes	31,675	31,675	—	—
Commercial paper	9,722	—	9,722	—
Total assets at fair value	<u>\$ 62,612</u>	<u>\$ 52,890</u>	<u>\$ 9,722</u>	<u>\$ —</u>

There were no transfers between Levels 1, 2 or 3 during the years ended December 31, 2020 or December 31, 2019.

**11. Liability Related to the Revenue Interest Purchase Agreement**

On June 26, 2019, the Company entered into a RIPA with Oberland, as agent for purchasers party thereto (the “Purchasers”), and the Purchasers named therein, to obtain financing in respect to the commercialization and further development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet and other working capital needs. Pursuant to the RIPA, the Company received \$125.0 million at closing, less certain issuance costs. The Company will also be entitled to receive up to approximately \$75.0 million in subsequent installments subject to the terms and conditions set forth in the RIPA: (i) \$25.0 million upon certain regulatory approval of its product candidates and (ii) \$50.0 million, at the Company’s option, upon reaching \$100.0 million trailing worldwide six-month net sales any time prior to December 31, 2021 (the “Third Payment”).

As consideration for such payments, the Purchasers will have a right to receive certain revenue interests (the “Revenue Interests”) from the Company based upon net sales of the Company’s certain products, once approved, which will be tiered payments initially ranging from 2.5% to 7.5% of the Company’s net sales in the covered territory (the “Covered Territory”); provided that (a) if annual net sales equal or exceed \$350.0 million by December 31, 2021 (the “Sales Threshold”), the initially tiered revenue interest rate will be decreased to a single rate of 2.5% of the Company’s net sales in the Covered Territory, beginning on January 1, 2022, and (b) if annual net sales equal or exceed the Sales Threshold and if the Purchasers receive

Notes to Financial Statements (Continued)

**11. Liability Related to the Revenue Interest Purchase Agreement (Continued)**

100% of their invested capital by December 31, 2024, the revenue interest rate will be decreased to a single rate of 0.4% of the Company's net sales in the Covered Territory beginning on January 1, 2025. If the Third Payment is drawn down by the Company, the applicable royalty rates will increase by one-third. The Covered Territory is the United States, but is subject to expand to include the world-wide net sales if the Company's annual U.S. net sales are less than \$350.0 million for the year ended December 31, 2021. The U.S. net sales milestone thresholds are not to be taken as financial guidance. The Purchasers' rights to receive the Revenue Interests shall terminate on the date on which the Purchasers have received Revenue Interests payments of 195% of the then aggregate purchase price (the "Cumulative Purchaser Payments") paid to the Company, unless the RIPA is terminated earlier.

Under the RIPA, the Company has an option (the "Call Option") to terminate the RIPA and repurchase future Revenue Interests at any time upon advance written notice. Additionally, the Purchasers have an option (the "Put Option") to terminate the RIPA and to require the Company to repurchase future Revenue Interests upon enumerated events such as a bankruptcy event, an uncured material breach, a material adverse effect or a change of control. If the Put Option is exercised prior to the first anniversary of the closing date by the Purchasers (except pursuant to a change of control), the required repurchase price will be 120% of the Cumulative Purchaser Payments (minus all payments Company has made to the Purchasers in connection with the Revenue Interests). In all other cases, if the Put Option or the Call Option are exercised, the required repurchase price will be 175% of the Cumulative Purchaser Payments (minus all payments Company has made to the Purchasers in connection with the Revenue Interests), if such option is exercised prior to the third anniversary of the closing date, and 195% of the Cumulative Purchaser Payments (minus all payments Company has made to the Purchasers in connection with the Revenue Interests), if such option is exercised thereafter.

In addition, the RIPA contains various representations and warranties, information rights, non-financial covenants, indemnification obligations and other provisions that are customary for a transaction of this nature.

In connection with the arrangement, as of December 31, 2020, the Company has recorded a liability, referred to as the "Revenue interest liability" on the balance sheets, of \$176.6 million, net of \$0.5 million of capitalized issuance costs in connection with the RIPA, which will be amortized to interest expense over the estimated term of the RIPA. The Company imputes interest expense associated with this liability using the effective interest rate method. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of forecasted net sales. The Company evaluates the interest rate quarterly based on its current net sales forecasts utilizing the prospective method.

A significant increase or decrease in net sales will materially impact the revenue interest liability, interest expense and the time period for repayment. The Company recorded approximately \$19.6 million and \$8.1 million in interest expense related to this arrangement for the years ended December 31, 2020 and 2019, respectively.

The repayment of the RIPA to Oberland does not have a fixed repayment schedule, rather it will be completely repaid and extinguished when the Company has repaid 195% of the aggregate purchase price unless the RIPA is terminated earlier. Since there is not a fixed repayment schedule, the Company does not project its future repayments by year. Each period, the Company estimates the future expected sales of its products in the covered territory and determines the effective annual imputed interest rate, which updates and changes the timing of the Company's payments. Under the terms of the agreement, every \$100 million of net sales generated, less than or equal to \$250 million in an annual aggregate year, would result in a repayment obligation of approximately \$7.5 million or 7.5% at the stated repayment rate in the first year. Annual Net Sales for a calendar year exceeding \$250 million would result in a repayment obligation of approximately \$2.5 million or 2.5% for every \$100 million of sales above the threshold. If the Company equals or exceeds \$350 million of sales in the U.S. in 2021, then the repayment amount would drop to \$2.5 million for every \$100 million of net sales starting in 2022. If the U.S. net sales are less than \$350 million for the year ended December 31, 2021, then the Covered Territory is expanded to include worldwide sales beginning in 2022. The Company's repayments of the RIPA are directly tied to the growth of its net sales, and as the Company's net sales grow, the Company expects the related repayments of the RIPA to grow as well. The Company currently expects to repay \$5.4 million in the next twelve months.

The Company received \$125.0 million in exchange for entering into the RIPA during June 2019 and \$25.0 million in March 2020 upon receiving regulatory approval of NEXLETOL. The effective annual imputed interest rate was 10.6% as of

## Esperion Therapeutics, Inc.

### Notes to Financial Statements (Continued)

#### 11. Liability Related to the Revenue Interest Purchase Agreement (Continued)

December 31, 2020. The Company incurred \$0.6 million of issuance costs in connection with the RIPA, which will be amortized to interest expense over the estimated term of the RIPA. Payments made to Oberland as a result of the Company's net sales will reduce the revenue interest liability.

The following table summarizes the revenue interest liability activity during the year ended December 31, 2020:

	(in thousands)
Revenue interest liability at December 31, 2019	\$ 132,544
Oberland funding for regulatory approval of NEXLETOL	25,000
Interest expense recognized	19,560
Revenue interest payments	(500)
Revenue interest liability at December 31, 2020	<u>\$ 176,604</u>

#### 12. Convertible Notes

On November 16, 2020, the Company issued \$250.0 million aggregate principal amount of 4.0% senior subordinated convertible notes due November 15, 2025. The net proceeds the Company received from the offering of the initial notes was approximately \$242.0 million, after deducting the initial purchasers' discounts and commissions and offering expenses payable by the Company. In connection with the offering of the senior subordinated convertible notes, the Company granted the initial purchasers of the senior subordinated convertible notes a 30-day option to purchase up to an additional \$30.0 million aggregate principal amount of the senior subordinated convertible notes on the same terms and conditions. On November 18, 2020 the option was exercised, which resulted in approximately \$29.1 million of additional proceeds, for total aggregate principal of \$280.0 million and net proceeds of \$271.1 million (the additional notes and, together with the initial notes, collectively called the "Convertible Notes"). The Company used approximately \$46.0 million of the net proceeds from the offering of the notes to pay the cost of the Capped Call (as defined below) and \$55.0 million of the net proceeds from the offering of the initial notes to finance the Prepaid Forward (as defined below). The Convertible Notes are the Company's senior unsecured obligations and mature on November 15, 2025 (the "Maturity Date"), unless earlier repurchased or converted into shares of common stock under certain circumstances described below. The Convertible Notes are convertible into shares of the Company's common stock, can be repurchased for cash, or a combination thereof, at the Company's election, at an initial conversion rate of 30.2151 shares of common stock per \$1,000 principal amount of the Convertible Notes, which is equivalent to an initial conversion price of approximately \$33.096 per share of common stock, subject to adjustment. The Company will pay interest on the Convertible Notes semi-annually in arrears on May 15 and November 15 of each year.

The \$271.1 million of proceeds received from the issuance of the Convertible Notes were allocated between long-term debt (the "liability component") of \$177.6 million and additional paid-in capital (the "equity component") of \$93.5 million. The fair value of the liability component was measured using rates determined for similar debt instruments without a conversion feature. The carrying amount of the equity component, representing the conversion option, was determined by deducting the fair value of the liability component from the aggregate face value of the Convertible Notes and is included in additional paid-in capital in the consolidated balance sheets and is not remeasured as long as it continues to meet the conditions for equity classification. The liability component will be accreted up to the face value of the Convertible Notes of \$280.0 million, which will result in additional non-cash interest expense being recognized through the Maturity Date.

The Company incurred approximately \$8.9 million of issuance costs related to the issuance of the Convertible Notes, of which \$5.8 million and \$3.1 million were allocated and recorded to long-term debt and additional paid-in capital, respectively. The \$5.8 million of issuance costs recorded as long-term debt on the consolidated balance sheet are being amortized over the five-year contractual term of the Convertible Notes using the effective interest method. The effective interest rate on the Convertible Notes, including accretion of the Convertible Notes fair value to par and debt issuance cost amortization, is 14.55%.

The Convertible Notes are general unsecured obligations of the Company that are subordinated in right of payment to indebtedness, obligations and other liabilities under the Company's RIPA, the revenue interests issued pursuant to such agreement, and any refinancing of the foregoing.

## Esperion Therapeutics, Inc.

### Notes to Financial Statements (Continued)

#### 12. Convertible Notes (Continued)

Holders may convert their Convertible Notes at their option at any time prior to the close of business on the business day immediately preceding August 15, 2025 in the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ending on March 31, 2021 (and only during such calendar quarter), if the last reported sale price per share of the Company's common stock, par value \$0.001 per share ("common stock"), is greater than or equal to 130% of the conversion price for each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter; (2) during the five business days after any five consecutive trading day period (such five consecutive trading day period, the "measurement period") in which the trading price per \$1,000 principal amount of notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price per share of the Company's common stock and the conversion rate for the notes on each such trading day; (3) if the Company calls such notes for redemption, any such notes that have been called for redemption may be converted at any time prior to the close of business on the second scheduled trading day immediately preceding the redemption date, but only with respect to the notes called for redemption; and (4) upon the occurrence of specified corporate events, as provided in the Indenture.

On or after August 15, 2025, to the close of business on the second scheduled trading day immediately before the maturity date, holders may convert all or any portion of their notes at the applicable conversion rate at any time at the option of the holder regardless of the foregoing conditions.

In addition, following certain corporate events or following issuance of a notice of redemption, the Company will, in certain circumstances, increase the conversion rate for a holder who elects to convert its notes in connection with such a corporate event or to convert its notes called (or deemed called) for redemption during the related redemption period, as the case may be.

The Convertible Notes will be redeemable, in whole or in part, at the Company's option at any time, and from time to time, on or after November 20, 2023 and before the 41st scheduled trading day immediately before the maturity date, at a cash redemption price equal to 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest, if any, but only if the last reported sale price per share of the Company's common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive), including the trading day immediately preceding the date the Company sends the related redemption notice, during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which the Company sends such redemption notice. No sinking fund is provided for the notes. If the Company redeems less than all the outstanding notes, at least \$125.0 million aggregate principal amount of notes must be outstanding and not subject to redemption as of the relevant redemption notice date.

If the Company undergoes a "fundamental change" (as defined in the Indenture), holders may require the Company to repurchase their notes for cash all or any portion of their notes at a fundamental change repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest, to, but excluding, the fundamental change repurchase date. The Indenture includes customary terms and covenants, including certain events of default.

The Convertible Notes consist of the following at December 31, 2020 (in thousands):

Principal amounts:		
Principal	\$	280,000
Unamortized debt discount		(94,900)
Unamortized debt issuance cost		(5,733)
Net carrying amount of the debt component	\$	<u>179,367</u>

The Company recorded \$3.1 million of interest expense during the year ended December 31, 2020, relating to the cash interest on the convertible notes due semi-annually, amortization of the debt discount and amortization of the debt issuance costs.

As of December 31, 2020, no Convertible Notes were convertible pursuant to their terms. The estimated fair value of the Convertible Notes was \$283.4 million as of December 31, 2020. The estimated fair value of the Convertible Notes was determined through consideration of quoted market prices. As of December 31, 2020, the if-converted value of the Convertible Notes did not exceed the principal value of those notes.

**Notes to Financial Statements (Continued)**

**12. Convertible Notes (Continued)**

*Capped Call Transactions*

In connection with the offering of the Convertible Notes, the Company entered into privately-negotiated capped call transactions with one of the initial purchasers of the convertible notes or its affiliate and certain other financial institutions. The Company used approximately \$46.0 million of the net proceeds from the offering of the Convertible Notes to pay the cost of the capped call transactions. The capped call transactions are expected generally to reduce potential dilution to the Company's common stock upon any conversion of the Convertible Notes and/or offset any cash payments the Company is required to make in excess of the principal amount of converted notes, as the case may be, in the event that the market value per share of the Company's common stock, as measured under the terms of the capped call transactions at the time of exercise, is greater than the strike price of the capped call transactions (which initially corresponds to the initial conversion price of the Convertible Notes, and is subject to certain adjustments), with such reduction and/or offset subject to a cap initially equal to approximately \$55.16 (which represents a premium of approximately 100% over the last reported sale price of the Company's common stock on November 11, 2020), subject to certain adjustments. The capped call transactions are separate transactions, entered into by the Company and are not part of the terms of the Convertible Notes.

Given that the transactions meet certain accounting criteria, the convertible note capped call transactions are recorded in stockholders' equity, and they are not accounted for as derivatives and are not remeasured each reporting period. As of December 31, 2020, the Company had not purchased any shares under the convertible note capped call transactions.

*Prepaid Forward*

In connection with the offering of the Convertible Notes, the Company entered into a prepaid forward stock repurchase transaction ("Prepaid Forward") with a financial institution ("Forward Counterparty"). Pursuant to the Prepaid Forward, the Company used approximately \$55.0 million of the net proceeds from the offering of the Convertible Notes to fund the Prepaid Forward. The aggregate number of shares of the Company's common stock underlying the Prepaid Forward was approximately 1,994,198. The expiration date for the Prepaid Forward is November 15, 2025, although it may be settled earlier in whole or in part. Upon settlement of the Prepaid Forward, at expiration or upon any early settlement, the Forward Counterparty will deliver to the Company the number of shares of common stock underlying the Prepaid Forward or the portion thereof being settled early. The shares purchased under the Prepaid Forward are treated as treasury stock and not outstanding for purposes of the calculation of basic and diluted earnings per share, but will remain outstanding for corporate law purposes, including for purposes of any future stockholders' votes, until the Forward Counterparty delivers the shares underlying the Prepaid Forward to the Company. The Company's Prepaid Forward hedge transaction exposes the Company to credit risk to the extent that its counterparty may be unable to meet the terms of the transaction. The Company mitigates this risk by limiting its counterparty to a major financial institution.

**13. Stock Compensation**

**2017 Inducement Equity Plan**

In May 2017, the Company's board of directors approved the 2017 Inducement Equity Plan (the "2017 Plan"). The number of shares of common stock available for awards under the 2017 Plan was set to 750,000, with any shares of common stock that are forfeited, cancelled, held back upon the exercise or settlement of an award to cover the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of common stock, or otherwise terminated (other than by exercise) under the 2017 Plan added back to the shares of common stock available for issuance under the 2017 Plan. The 2017 Plan provides for the granting of stock options, stock appreciation rights, restricted stock awards, restricted stock units ("RSUs"), unrestricted stock awards and dividend equivalent rights.

In November 2019, the Company's board of directors approved an amendment to the 2017 Plan to increase the number of shares of common stock available for issuance under the 2017 Plan by 400,000 shares.

**2013 Stock Option and Incentive Plan**

In May 2015, the Company's stockholders approved the amended and restated 2013 Stock Option and Incentive Plan (as amended, the "2013 Plan") which, among other things, increased the number of shares of common stock reserved for issuance

**Esperion Therapeutics, Inc.**

**Notes to Financial Statements (Continued)**

**13. Stock Compensation (Continued)**

thereunder. The number of shares of common stock available for awards under the 2013 Plan was increased by 923,622 shares from 2,051,378 shares to 2,975,000 shares, plus (i) shares of common stock that are forfeited, cancelled, held back upon the exercise or settlement of an award to cover the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of common stock or otherwise terminated (other than by exercise) under the 2013 Plan and the Company's 2008 Incentive Stock Option and Restricted Stock Plan are added back to the shares of common stock available for issuance under the 2013 Plan, and (ii) on January 1, 2016, and each January 1, thereafter, the number of shares of common stock reserved and available for issuance under the 2013 Plan will be cumulatively increased by 2.5% of the number of shares of common stock outstanding on the immediately preceding December 31, or such lesser number of shares of common stock determined by the compensation committee. The 2013 Plan provides for the granting of stock options, stock appreciation rights, restricted stock awards, RSUs, unrestricted stock awards, cash-based awards, performance share awards and dividend equivalent rights.

**2008 Stock Option and Restricted Stock Plan**

In April 2008, the Company adopted the 2008 Plan, administered by the Board of Directors or a committee appointed by the Board of Directors. The 2008 Plan provides for the granting of stock options and restricted stock to employees and nonemployees of the Company. Options granted under the 2008 Plan may either be incentive stock options, restricted stock awards or nonqualified stock options. Stock options and restricted stock grants may be granted to employees, directors and consultants. Stock awards under the 2008 Plan may be granted for up to ten years from the adoption of the 2008 Plan at prices no less than 100 percent of the fair value of the shares on the date of the grant as determined by (i) the closing price of the Company's common stock on any national exchange, (ii) the National Association of Securities Dealers Inc. Automated Quotation System ("NASDAQ"), if so authorized for quotation as a NASDAQ security, or (iii) by reasonable application of a reasonable valuation method. The valuation methods utilized by the Company are consistent with the AICPA Technical Practice Aid.

The Company incurs stock-based compensation expense related to stock options and RSUs. The fair value of RSUs is determined by the closing market price of the Company's common stock on the date of grant. The fair value of stock options is calculated using a Black-Scholes option-pricing model. Compensation costs related to equity instruments granted are recognized over the requisite service periods of the awards on a straight-line basis at the grant-date fair value. The Company accounts for forfeitures as they occur.

Under the 2017 Plan, 2013 Plan and the 2008 Plan the vesting of options granted or restricted awards given will be determined individually with each option grant. Generally, 25 percent of the granted amount will vest upon the first anniversary of the option grant with the remainder vesting ratably on the first day of each calendar quarter for the following three years. Stock options have a 10-year life and expire if not exercised within that period, or if not exercised within 90 days of cessation of providing service to the Company.

*Stock Options*

The following table summarizes the activity relating to the Company's options to purchase common stock for the year ended December 31, 2020:

	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2019	4,677,929	\$ 39.31	6.82	\$ 109,054
Granted	234,940	\$ 61.14		
Forfeited or cancelled (vested and unvested)	(436,916)	\$ 53.95		
Exercised	(299,435)	\$ 22.15		
Outstanding at December 31, 2020	<u>4,176,518</u>	\$ 40.24	5.28	\$ 18,415

**Esperion Therapeutics, Inc.**

**Notes to Financial Statements (Continued)**

**13. Stock Compensation (Continued)**

The following table summarizes information about the Company's stock option plan as of December 31, 2020:

	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Vested and expected to vest at December 31, 2020	4,176,518	\$ 40.24	5.28	\$ 18,415
Exercisable at December 31, 2020	<u>3,356,739</u>	\$ 36.96	4.62	\$ 18,154

The total pre-tax intrinsic value of stock options exercised during the years ended December 31, 2020, 2019 and 2018, was \$6.3 million, \$17.7 million and \$12.1 million, respectively.

The following table shows the weighted-average assumptions used to compute the stock-based compensation costs for the stock options granted to employees during each of the three years ending December 31, 2020, using the Black-Scholes option-pricing model:

	Year ended December 31,		
	2020	2019	2018
Risk-free interest rate	1.70%	2.10%	2.75%
Dividend yield	—	—	—
Weighted-average expected life of options (years)	6.25	6.25	6.21
Volatility	81%	73%	72%

The risk-free interest rate assumption was based on the United States Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. The weighted-average expected life of the options was calculated using the simplified method as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin No. 107 ("SAB No. 107"). This decision was based on the lack of relevant historical data due to the Company's limited historical experience. In addition, due to the Company's limited historical and predictive data, the estimated volatility incorporates the historical volatility of comparable companies whose share prices are publicly available.

The weighted-average grant-date fair values of stock options granted during the years ended December 31, 2020, 2019 and 2018, were \$43.22, \$31.18, and \$37.56, respectively. During the year ended December 31, 2020, the Company recognized stock-based compensation expense related to stock options of \$20.9 million, including \$0.6 million that was capitalized into inventory. During the years ended December 31, 2019 and 2018, the Company recognized stock-based compensation expense related to stock options of \$23.5 million and \$23.4 million, respectively.

As of December 31, 2020, there was approximately \$26.8 million of unrecognized compensation cost related to unvested options, which will be recognized over a weighted-average period of approximately 2.0 years.



**Esperion Therapeutics, Inc.**

**Notes to Financial Statements (Continued)**

**13. Stock Compensation (Continued)**

*Restricted Stock Units*

The following table summarizes the activity relating to the Company's RSUs for the year ended December 31, 2020:

	<u>Number of RSUs</u>	<u>Weighted-Average Fair Value Per Share</u>
Outstanding and unvested at December 31, 2019	245,966	\$ 44.45
Granted	381,396	\$ 49.14
Forfeited or expired	(113,108)	\$ 47.15
Vested	(113,020)	\$ 48.80
Outstanding and unvested at December 31, 2020	<u>401,234</u>	<u>\$ 46.92</u>

During the year ended December 31, 2020, the Company recognized stock-based compensation expense related to RSUs of \$7.0 million, including \$0.2 million that was capitalized into inventory. During the years ended December 31, 2019 and 2018, the Company recognized approximately \$2.4 million and \$0.6 million, respectively, of stock-based compensation expense recognized related to RSUs. As of December 31, 2020, there was approximately \$15.6 million of unrecognized stock-based compensation expense related to unvested RSUs, which will be recognized over a weighted-average period of approximately 2.9 years.

*Employee Stock Purchase Plan*

In April 2020, the board of directors approved the Esperion Therapeutics, Inc. 2020 Employee Stock Purchase Plan (the "ESPP") which was approved by the Company's shareholders on May 28, 2020. The ESPP allows eligible employees to authorize payroll deductions of up to 10% of their base salary or wages up to \$25,000 annually to be applied toward the purchase of shares of the Company's common stock on the last trading day of the offering period. Participating employees will purchase shares of the Company's common stock at a discount of up to 15% on the lesser of the closing price of the Company's common stock on the NASDAQ Global Select Market (i) on the first trading day of the offering period or (ii) the last day of any offering period. Offering periods under the ESPP will generally be in six months increments, commencing on September 1 and March 1 of each calendar year with the administrator having the right to establish different offering periods. During the year ended December 31, 2020, the Company recognized \$0.5 million of stock compensation expense related to the ESPP. As of December 31, 2020, there have been no shares issued and 825,000 shares reserved for future issuance under the ESPP.

**14. Employee Benefit Plan**

During 2008, the Company adopted the Esperion Therapeutics, Inc. 401(k) Plan (the "401(k) Plan"), which qualifies as a deferred salary arrangement under Section 401(k) of the Internal Revenue Code. Under the 401(k) Plan, participating employees may defer a portion of their pretax earnings. The Company may, at its sole discretion, contribute for the benefit of eligible employees. Company contributions to the 401(k) Plan during the years ended December 31, 2020, 2019 and 2018, were \$2.7 million, \$0.7 million and \$0.3 million, respectively.

**15. Leases**

The Company has operating leases primarily related to the Company's principal executive office, automobile leases and other IT related equipment. The lease for the principal executive office has a lease term of 5 years and the automobile leases and IT equipment leases primarily have a term of 3 years. During year ended December 31, 2020, the right of use operating lease assets and operating lease liabilities recognized on the balance sheet increased by \$4.5 million and \$4.5 million from December 31, 2019, respectively, due to the addition of automobile leases and IT equipment associated with the onboarding of the Company's commercial sales force to support the commercialization of NEXLETOL and NEXLIZET. During the years ended December 31, 2020 and December 31, 2019, the Company recognized \$2.2 million and \$0.3 million, respectively, of operating lease costs, recognized on the statements of operations, and paid cash for the amounts included in the measurement of lease liabilities of \$2.2 million and \$0.3 million, respectively, which were included in operating cash flows on the statements of

**Esperion Therapeutics, Inc.**

**Notes to Financial Statements (Continued)**

**15. Leases (Continued)**

cash flows. At December 31, 2020 and December 31, 2019, the weighted-average remaining lease term of operating leases was 2.3 years and 3.3 years, respectively, and the weighted average discount rate was 3.5% and 6.5%, respectively. There were no right-of-use assets obtained in exchange for lease obligations in the twelve months ended December 31, 2020 and December 31, 2019. The Company had no additional operating and finance leases that have not yet commenced as of December 31, 2020.

The total rent expense for the year ended December 31, 2018, recognized prior to the adoption of ASU 2016-2, was approximately \$0.3 million.

The following table summarizes the Company's future maturities of operating lease liabilities as of December 31, 2020:

	(in thousands)
2021	\$ 2,746
2022	2,711
2023	830
Total lease payments	6,287
Less imputed interest	246
Total	<u>\$ 6,041</u>

The following table summarizes supplemental balance sheet information related to leases as of December 31, 2020:

<b>Operating Leases</b>	(in thousands)
<b>Total right of use operating lease assets</b>	<u>\$ 6,030</u>
Operating lease liabilities (short-term)	\$ 2,587
Operating lease liabilities (long-term)	3,454
<b>Total lease obligations under operating leases</b>	<u>\$ 6,041</u>

**16. Income Taxes**

There was no provision for income taxes for the years ended December 31, 2020, 2019 and 2018, because the Company has incurred operating losses since inception. At December 31, 2020, the Company concluded that it is not more likely than not that the Company will realize the benefit of its deferred tax assets due to its history of losses. Accordingly, a full valuation allowance has been applied against the net deferred tax assets.

On March 27, 2020 the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was signed into law. In addition to some permanent technical corrections to the Tax Cuts and Jobs Act (TCJA), the law made temporary changes to provide taxpayers with tax relief and incentives due to the Coronavirus. The Act delayed certain changes to NOLs under the TCJA and allow additional NOL carryback periods, allowed for the deferral of payroll tax payments, made changes to the interest expense limitation rules to allow additional expensing amount other changes. The Act did not have a material effect on the Company's tax provision.

As of December 31, 2020, 2019 and 2018, the Company had net deferred tax assets, before valuation allowance, of approximately \$202.8 million, \$174.2 million and \$152.2 million, respectively. Realization of the deferred assets is dependent upon future taxable income, if any, the amount and timing of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. As of December 31, 2020, 2019 and 2018, the Company had federal net operating loss ("NOL") carryforwards of approximately \$700.7 million, \$618.1 million and \$539.2 million, respectively. Of the total federal NOL carryforwards, \$347.4 million will expire at various dates beginning in 2028, if not utilized; the remaining federal NOLs do not expire. As of December 31, 2020, 2019 and 2018, the Company had state NOL carryforwards of approximately \$530.3 million, \$527.1 million and \$526.6 million, respectively. The state NOL carryforwards will expire at various dates beginning in 2022, if not utilized.

**Esperion Therapeutics, Inc.**

**Notes to Financial Statements (Continued)**

**16. Income Taxes (Continued)**

The Company has research and developmental tax credits of \$26.1 million. The tax credit carryforwards will expire beginning in 2031, if not utilized.

The Company files income tax returns in the U.S. federal jurisdiction, and various states. With few exceptions, the Company is no longer subject to U.S. federal or state and local income tax examinations by tax authorities for years before 2016.

A reconciliation of the U.S. statutory income tax rate to the Company's effective tax rate is as follows:

	December 31,		
	2020	2019	2018
Federal income tax (benefit) at statutory rate	(21.0)%	(21.0)%	(21.0)%
Change in state tax rate	— %	(0.2)%	— %
Permanent items	0.6 %	(1.0)%	(0.5)%
R&D tax credits, net of reserves	(16.3)%	— %	— %
Other	0.8 %	0.7 %	0.5 %
Change in valuation allowance	35.9 %	21.5 %	21.0 %
Effective income tax rate	<u>0.0 %</u>	<u>0.0 %</u>	<u>0.0 %</u>

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. If the Company experiences a greater than 50 percentage point aggregate change in ownership of certain significant stockholders over a three-year period, a Section 382 ownership change could be deemed to have occurred. If a Section 382 change occurs, the Company's future utilization of the net operating loss carryforwards and credits as of the ownership change will be subject to an annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended, and similar state provisions. Such an annual limitation may result in the expiration of net operating losses before utilization.

The Company's reserves related to taxes are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized following resolution of any potential contingencies present related to the tax benefit. The Company recognized \$2.6 million for unrecognized income tax benefits for the year ended December 31, 2020. There were no unrecognized income tax benefits for the years ended December 31, 2019. The Company does not expect this amount to change in the next twelve months. At December 31, 2020, all of the amount of unrecognized tax benefits, if recognized, would result in a deferred tax asset and corresponding increase in the entity's valuation allowance. Such unrecognized tax benefit would not affect the effective rate if recognized.

**Esperion Therapeutics, Inc.**

**Notes to Financial Statements (Continued)**

**16. Income Taxes (Continued)**

Significant components of the Company's deferred tax assets are summarized in the table below:

	December 31,	
	2020	2019
(in thousands)		
Deferred tax assets:		
Federal and state operating loss carryforwards	\$ 172,530	\$ 154,912
Equity compensation	21,454	17,217
R&D tax credits, net of reserves	23,452	—
Other	10,361	2,089
Total deferred tax assets	227,797	174,218
Deferred tax liabilities:		
Convertible debt	(24,795)	—
Other	(159)	—
Total deferred tax liabilities	(24,954)	—
Valuation allowance	(202,843)	(174,218)
Net deferred tax assets	\$ —	\$ —

**17. Net Loss Per Common Share**

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common stock equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, warrants for common stock, stock options, unvested RSUs, shares issuable under the ESPP and shares issuable upon conversion of the convertible notes are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The shares outstanding at the end of the respective periods presented below were excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	December 31, 2020	December 31, 2019	December 31, 2018
Warrants for common stock	—	—	8,230
Common shares under option	4,176,518	4,677,929	5,303,723
Unvested RSUs	401,234	245,966	37,475
Shares issuable related to the ESPP	16,828	—	—
Shares issuable upon conversion of convertible notes	8,460,237	—	—
Total potential dilutive shares	13,054,817	4,923,895	5,349,428

**18. Statements of Cash Flows**

The following table provides a reconciliation of cash and cash equivalents and restricted cash presented on the balance sheets to the same amounts presented on the statements of cash flows on December 31, 2020 and 2019.

	December 31, 2020	December 31, 2019
Cash and cash equivalents	\$ 304,962	\$ 166,130
Restricted cash	—	928
Total cash, cash equivalents and restricted cash shown on the statements of cash flows	\$ 304,962	\$ 167,058

## Notes to Financial Statements (Continued)

## 19. Selected Quarterly Financial Data (Unaudited)

The following table summarizes the unaudited quarterly financial data for the last two years:

	2020			
	March 31	June 30	September 30	December 31
(in thousands, except share and per share data)				
<b>Revenues:</b>				
Product sales, net	\$ 858	\$ 609	\$ 3,331	\$ 8,167
Collaboration revenue	982	211,627	502	1,471
Total Revenues	1,840	212,236	3,833	9,638
<b>Operating expenses:</b>				
Cost of goods sold	\$ 31	\$ 398	\$ 275	\$ 1,688
Research and development	34,702	34,987	35,283	41,964
Selling, general and administrative	41,553	47,681	48,826	61,555
Total operating expenses	76,286	83,066	84,384	105,207
<b>Gain (loss) from operations:</b>	(74,446)	129,170	(80,551)	(95,569)
Interest expense	(4,171)	(4,640)	(4,928)	(8,931)
Other income, net	368	81	42	24
<b>Net gain (loss)</b>	<u>\$ (78,249)</u>	<u>\$ 124,611</u>	<u>\$ (85,437)</u>	<u>\$ (104,476)</u>
Net gain (loss) per common share – basic (1)	<u>\$ (2.84)</u>	<u>\$ 4.50</u>	<u>\$ (3.07)</u>	<u>\$ (3.89)</u>
Net gain (loss) per common share – diluted (1)	<u>\$ (2.84)</u>	<u>\$ 4.32</u>	<u>\$ (3.07)</u>	<u>\$ (3.89)</u>
Weighted-average shares outstanding - basic	<u>27,519,229</u>	<u>27,665,728</u>	<u>27,830,281</u>	<u>26,882,830</u>
Weighted-average shares outstanding - diluted	<u>27,519,229</u>	<u>28,854,445</u>	<u>27,830,281</u>	<u>26,882,830</u>

Esperion Therapeutics, Inc.

Notes to Financial Statements (Continued)

19. Selected Quarterly Financial Data (Unaudited) (Continued)

	2019			
	March 31	June 30	September 30	December 31
	(in thousands, except share and per share data)			
<b>Revenues:</b>				
Collaboration revenue	\$ 145,419	\$ 982	\$ 981	\$ 982
Total Revenues	145,419	982	981	982
<b>Operating expenses:</b>				
Research and development	\$ 46,308	\$ 42,788	\$ 48,281	\$ 38,234
General and administrative	12,182	13,492	18,468	21,712
Total operating expenses	58,490	56,280	66,749	59,946
<b>Gain (loss) from operations:</b>	86,929	(55,298)	(65,768)	(58,964)
Interest expense	—	—	(3,996)	(4,124)
Other income, net	450	1,077	1,387	1,142
<b>Net income (loss)</b>	<u>\$ 87,379</u>	<u>\$ (54,221)</u>	<u>\$ (68,377)</u>	<u>\$ (61,946)</u>
Net gain (loss) per common share - basic (1)	<u>\$ 3.26</u>	<u>\$ (2.01)</u>	<u>\$ (2.52)</u>	<u>\$ (2.26)</u>
Net gain (loss) per common share - diluted (1)	<u>\$ 3.07</u>	<u>\$ (2.01)</u>	<u>\$ (2.52)</u>	<u>\$ (2.26)</u>
Weighted-average shares outstanding - basic	<u>26,842,785</u>	<u>26,968,818</u>	<u>27,171,769</u>	<u>27,371,067</u>
Weighted-average shares outstanding - diluted	<u>28,449,767</u>	<u>26,968,818</u>	<u>27,171,769</u>	<u>27,371,067</u>

(1) Due to the use of weighted average shares outstanding for each quarter for calculating net loss per common share, the sum of the quarterly net loss per common share amounts may not equal the net loss per common share amount for the full year.

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the following Registration Statements:

- Registration Statement (Form S-8 No. 333-243757) pertaining to the 2020 Employee Stock Purchase Plan, as amended of Esperion Therapeutics, Inc.
- Registration Statement (Form S-8 No. 333-236712) pertaining to the Amended and Restated 2013 Stock Option and Incentive Plan of Esperion Therapeutics, Inc. and the 2017 Inducement Equity Plan of Esperion Therapeutics, Inc.
- Registration Statement (Form S-8 No. 333-228994) pertaining to the Amended and Restated 2013 Stock Option and Incentive Plan of Esperion Therapeutics, Inc.
- Registration Statement (Form S-8 No. 333-223105) pertaining to the Amended and Restated 2013 Stock Option and Incentive Plan of Esperion Therapeutics, Inc.
- Registration Statement (Form S-8 No. 333-218084) pertaining to the 2017 Inducement Equity Plan of Esperion Therapeutics, Inc.
- Registration Statement (Form S-8 No. 333-216169) pertaining to the Amended and Restated 2013 Stock Option and Incentive Plan of Esperion Therapeutics, Inc.
- Registration Statement (Form S-8 No. 333-208702) pertaining to the Amended and Restated 2013 Stock Option and Incentive Plan of Esperion Therapeutics, Inc.
- Registration Statement (Form S-8 No. 333-206180) pertaining to the Amended and Restated 2013 Stock Option and Incentive Plan of Esperion Therapeutics, Inc.
- Registration Statement (Form S-8 No. 333-201378) pertaining to the 2013 Stock Option and Incentive Plan of Esperion Therapeutics, Inc.
- Registration Statement (Form S-8 No. 333-194536) pertaining to the 2013 Stock Option and Incentive Plan of Esperion Therapeutics, Inc.
- Registration Statement (Form S-8 No. 333-189738) pertaining to the 2008 Incentive Stock Option and Restricted Stock Plan and the 2013 Stock Option and Incentive Plan of Esperion Therapeutics, Inc.

of our reports dated February 23, 2021, with respect to the financial statements of Esperion Therapeutics, Inc. and the effectiveness of internal control over financial reporting of Esperion Therapeutics, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Detroit, Michigan  
February 23, 2021

## CERTIFICATIONS UNDER SECTION 302

I, Tim M. Mayleben, certify that:

1. I have reviewed this annual report on Form 10-K of Esperion Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 23, 2021

/s/ TIM M. MAYLEBEN

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Tim M. Mayleben

*President and Chief Executive Officer*

*(Principal Executive Officer)*



## CERTIFICATIONS UNDER SECTION 302

I, Richard B. Bartram, certify that:

1. I have reviewed this annual report on Form 10-K of Esperion Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 23, 2021

/s/ RICHARD B. BARTRAM

Richard B. Bartram

*Chief Financial Officer*

*(Principal Financial Officer and*

*Principal Accounting Officer)*

**CERTIFICATIONS UNDER SECTION 906**

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Esperion Therapeutics, Inc., a Delaware corporation (the “Company”), does hereby certify, to such officer’s knowledge, that:

The Annual Report for the year ended December 31, 2020 (the “Form 10-K”) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 23, 2021

/s/ TIM M. MAYLEBEN

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Tim M. Mayleben  
*President and Chief Executive Officer*  
*(Principal Executive Officer)*

/s/ RICHARD B. BARTRAM

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Richard B. Bartram  
*Chief Financial Officer*  
*(Principal Financial Officer and*  
*Principal Accounting Officer)*

# Esperion Leadership

## Tim M. Mayleben

President and Chief Executive Officer

## Rick Bartram

Chief Financial Officer

## Sheldon Koenig

Chief Operating Officer

## Ashley Hall

Chief Development Officer

## Ken Fiorelli

Chief Technical Operations Officer

# Esperion Board of Directors

## Tim M. Mayleben

## Jeffrey Berkowitz

JD

## Alan Fuhrman

## Antonio M. Gotto, Jr.

MD, DPhil

## Daniel Janney

## Mark E. McGovern

MD, FACC, FACP

## Jay Shepard

## Nicole Vitullo

## Tracy M. Woody



# ESPERION<sup>®</sup> **The Lipid Management Company**

Esperion is The Lipid Management Company. Our goal is lipid management for everybody, that's why we work hard to make our medicines easy to get, easy to take and easy to have. We discover, develop and commercialize innovative medicines and combinations to lower cholesterol, especially for patients whose needs aren't being met by the status quo. Our entrepreneurial team of industry leaders is inclusive, passionate and resourceful. We are singularly focused on managing cholesterol so you can improve your health easily.

#### **Investor Relations**

##### **Esperion Therapeutics, Inc.**

3891 Ranchero Drive, Ste 150  
Ann Arbor, MI 48108  
Phone: (734) 887-3903  
[investorrelations@esperion.com](mailto:investorrelations@esperion.com)  
[investor.esperion.com](http://investor.esperion.com)

#### **Independent Registered Public Accounting Firm**

##### **Ernst & Young**

One Kennedy Square  
Suite 1000  
777 Woodward Avenue  
Detroit, MI 48226  
Phone: (313) 628-7100

#### **General Counsel**

##### **Goodwin Procter LLP**

100 Northern Ave  
Boston, MA 02210  
Phone: (617) 570-1000

#### **Register and Transfer Agent**

##### **Computershare**

462 South 4th St,  
Ste 1600  
Louisville, KY 40202  
Phone: (877) 373-6374