



2022 Annual Report

ESPERION[®] | REACHING GOALS

Reinforcing Our Commitment to Patients

As we reflect on the accomplishments of the past year, I feel extremely grateful and proud of our company's achievements. Our team has worked tirelessly and cohesively to execute our strategy, and the results speak for themselves. We have made tremendous progress on multiple fronts and achieved exceptional results on all metrics, such as timely delivery of positive data from CLEAR Outcomes, persistent franchise growth and continued fiscal discipline.

The pinnacle of our success this year was undoubtedly the positive readout from our landmark CLEAR Outcomes trial, which confirmed bempedoic acid's cardiovascular benefits and clinically meaningful risk reduction. This was a major milestone for our company, and we are excited to capitalize on the significant revenue growth opportunity it represents and set the stage for long-term success. Providers are moving toward reducing LDL-cholesterol levels as low as possible, as soon as possible; we provide the next steps to help get patients there.

At the recent American College of Cardiology conference (ACC.23/WCC), we presented detailed results from CLEAR Outcomes, together with Dr. Steven Nissen, a world-renowned leader in cardiovascular medicine from the Cleveland Clinic.

CLEAR Outcomes showed that NEXLETOL® (bempedoic acid) tablets significantly reduced the risk of hard MACE-4 and MACE-3 by 13% and 15%, respectively, and significantly reduced the risk of heart attack and coronary revascularization by 23% and 19%, respectively, as compared to placebo. These results were seen in a broad population of primary and secondary prevention patients who are unable to maximize or tolerate a statin. The proportions of patients experiencing adverse events and serious adverse events were similar between the active and placebo treatment groups. Bempedoic acid (contained in NEXLEOL and NEXLIZET® (bempedoic acid and ezetimibe) tablets) now becomes the first LDL-C lowering therapy since statins proven to lower hard ischemic events, not only in those with ASCVD but also in the large number of primary prevention patients for whom limited therapies exist.

The feedback we continue to receive from healthcare providers and payers following the release of the results has been overwhelmingly enthusiastic. In addition, we are proud to have had results from the trial published in the prestigious *New England Journal of Medicine*.

We are already planning the next phase of our commercialization efforts and are confident that these efforts will enable us to generate an inflection in our revenue trajectory as well as to begin development efforts for our early-stage pipeline.

We aim to build on the success of bempedoic acid with a strong early pipeline in areas of high unmet need. We are continually evolving beyond cholesterol lowering with next-generation ACLY inhibitors, which have the potential to unlock additional therapeutic opportunities in metabolically-driven diseases such as in liver, kidney, cancer, and neurology indications.

Looking ahead, we plan to submit regulatory filings for label expansion in the first half of 2023. There is still a lack of oral add-on options for patients who struggle to reach their LDL-C goals and cannot tolerate other lipid-lowering therapies, and we firmly believe that bempedoic acid has the potential to fill this unmet need. We remain committed to our goal of improving clinical management for the millions of patients with or at risk for cardiovascular disease.

We would like to take a moment to express our gratitude to all of our stakeholders for their unwavering support of Esperion. Our commitment to driving growth, fostering innovation, and providing value remains at the forefront of our mission. With great optimism, we look forward to the coming years. We are thrilled about the future of our company and the opportunities that lie ahead.



A handwritten signature in black ink, appearing to read 'Sheldon Koenig'.

Sheldon Koenig
President & Chief
Executive Officer

**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, 2022

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.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

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, 2022, based upon the closing price of \$6.36 of the registrant's common stock as reported on the NASDAQ Global Market, was \$422.3 million. 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, 2023, there were 76,572,830 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 2023 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, 2022.

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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:

- 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) tablet 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.
- While we successfully completed our CLEAR cardiovascular outcomes trial, or CVOT, for bempedoic acid and the trial met its primary endpoint, regulatory authorities may not approve any expanded indications for our products in the U.S. or other territories, and as a result, we may not receive significant milestone payments from our ex-U.S. commercial partners which 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. If such cash is not available, we will have to delay, reduce or cease operations.
- 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) tablet 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 managing our commercial infrastructure and successfully launch, market, and sell our approved drugs and any current or future drug candidate (or additional indications) for which we may receive marketing approval;
- our ability to achieve clinical, regulatory or commercial milestones with our existing cash resources;
- our ability to secure regulatory approval in the U.S. and other territories for additional indications based on the results of the CVOT of bempedoic acid, obtain applicable milestone payments from our partners and generate additional revenue as a result of the expanded indications for our products;
- our ability to realize the intended benefits of the commercial collaboration and license arrangement with Daiichi Sankyo Europe GmbH, or DSE, Otsuka Pharmaceutical Co., Ltd., or Otsuka, and Daiichi Sankyo Co. Ltd, or DS, 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 tablet, 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 tablet as LDL-C or cardiovascular risk 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 tablet 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 and cardiovascular risk lowering markets and the rate and degree of bempedoic acid and the bempedoic acid / ezetimibe combination tablet's 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, among others, the outbreak of COVID-19 or an inflationary environment, 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

Esperion is a pharmaceutical company singularly focused on developing and commercializing accessible, oral, once-daily, non-statin medicines for patients struggling with elevated low-density lipoprotein cholesterol, or LDL-C. Through commercial execution and completion of our CLEAR Outcomes trial as well as advancing our pre-clinical pipeline, we continue to evolve into a differentiated, global cardiometabolic biotech. 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 tablet are oral, once-daily, non-statin, LDL-C lowering medicines for patients with atherosclerotic cardiovascular disease, or ASCVD, or heterozygous familial hypercholesterolemia, or HeFH.

We recently completed a global cardiovascular outcomes trial, or CVOT, —known as **C**holesterol **L**owering via **B**empedoic Acid, an **A**CL-inhibiting **R**egimen (CLEAR) Outcomes. The trial was designed to evaluate whether treatment with bempedoic acid reduced 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 was 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 was an event-driven trial and concluded once the predetermined number of MACE endpoints occurred. On December 7, 2022, we announced that the study had met its primary endpoint. We anticipate reporting full results from the study at ACC.23 Annual Scientific Session & Expo together with the World Congress of Cardiology (ACC.23/WCC) on March 4, 2023. We intend to use results from this CVOT to support submissions for a CV risk reduction indication in the U.S., Europe and other territories and plan to submit applications for such regulatory approvals in the first half of 2023.

On November 23, 2022, we entered into a waiver and amendment to our Revenue Interest Purchase Agreement, or RIPA, with Eiger III SA LLC, or Oberland, in which we agreed to make a one-time partial call payment with regards to the Revenue Interests (as defined in the RIPA) in an amount equal to \$50 million from our restricted cash account (the “Partial Call”). Under this amendment, the amount of the Cumulative Purchaser Payments (as defined in the RIPA) was reduced to \$177,777,778. Refer to Note 10 in our audited financial statements appearing elsewhere in this Annual Report on Form 10-K for further information.

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, has estimated there are approximately 875,000 deaths in the United States annually caused by cardiovascular disease in its 2022 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 LDL and other similar lipid-containing particles in the walls of arteries. This process leads to the formation of atherosclerotic plaque lesions in the artery walls. Depending upon their location, continued progression of atherosclerotic plaques can lead to heart attacks, strokes and peripheral artery 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. Since then, numerous additional studies across a variety of settings have reinforced this relationship.

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 and established the benefit of LDL-lowering in a broad range of patients. The relationship between the extent of absolute 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.

Examples of Major Completed Clinical Outcomes Studies with Statin Therapies

Study name	4S	WOSCOPS	AFCAPS/ TexCAPS	TNT	JUPITER
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.

In 2017 and 2018, the results of two CVOTs that utilized monoclonal antibodies that targeted PCSK9 (a key regulator of LDL receptor expression) were reported. The FOURIER study enrolled 27,564 patients with prior ASCVD and LDL-C levels >70 mg/dl receiving background statin therapy. Patients were then blindly randomized to receive evolocumab or placebo and followed until at least 1630 key secondary endpoints (cardiovascular death, myocardial infarction or stroke) occurred. In a patient population with a median baseline LDL-C level of 92 mg/dl, evolocumab reduced LDL-C by 59% as compared to placebo resulting in a 56 mg/dl absolute difference. This reduction in LDL-C translated to a 15% reduction in the primary endpoint (cardiovascular death, myocardial infarction, stroke, hospitalization for unstable angina, or coronary revascularization). Similarly, the ODYSSEY Outcomes study enrolled 18,924 patients who had an acute coronary syndrome 1 to 12 months prior to study entry and LDL-C levels >70 mg/dl on high-intensity statin treatment. Patients were blindly randomized to receive alirocumab or placebo and followed until at least 1,613 patients experienced a primary endpoint of death from coronary heart disease, nonfatal myocardial infarction, fatal or nonfatal ischemic stroke or unstable angina requiring hospitalization. From a mean baseline of 92 mg/dl, LDL-C levels were reduced by 62.7% as compared to placebo, to a mean of 38 mg/dl. This treatment resulted in a 15% relative risk reduction in the primary MACE endpoint. Together, these trials demonstrated the cardiovascular risk reduction benefits of a second non-statin mechanism for lowering LDL-C levels.

The direct relationship between lower LDL-C levels and reduced risk for major cardiovascular events has been consistently demonstrated in at least 27 statin cardiovascular outcomes studies involving more than 175,000 patients. A patient-level meta-analysis of these studies have demonstrated a strong, consistent relationship between absolute risk reduction in LDL-C and the reduction in risk for major cardiovascular events. Overall, it was observed that for every 1 mmol/L (38.7 mg/dl) reduction in LDL-C, there was a 22% reduction in the risk for major cardiovascular events. 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. Overall these guidelines recognize four separate patient populations that physicians should focus on for LDL-C treatment: 1) Secondary ASCVD, 2) Severe Hypercholesterolemia (LDL-C ≥ 190 mg/dl), 3) Diabetes Mellitus in Adults and 4) Primary Prevention. 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 as the initial treatment to

achieve LDL-C thresholds, and then consider adding non-statin medicines for those patients still above their LDL-C treatment threshold level.

For the first time in an LDL-C guideline, these 2018 recommendations encouraged physicians to consider the cost-effectiveness of drug treatment options, specifically referencing the relatively 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. In patients with statin-associated side effects, use of non-statins (with initial preference to oral drugs) is recommended.

2018 AHA/ACC Guidelines on the Management of Blood Cholesterol

Patient Cardiovascular Disease Risk	LDL-C Threshold for Treatment
Patients with ASCVD	≥ 70 mg/dL
Patients with LDL-C ≥ 190 mg/dL at baseline and/or HeFH	≥ 100 mg/dL
Patients with diabetes	≥ 70 mg/dL
Primary prevention patients	Dependent upon age and risk level

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.

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 patients 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

Novartis AG developed inclisiran and the new drug application, or NDA, for inclisiran was submitted to the FDA in December 2019. Inclisiran (which is marketed in the U.S. as Leqvio®) received FDA approval on December 22, 2021. 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 the 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 β -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, as an adjunct to diet to reduce triglyceride, or TG, levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. In clinical trials, icosapent ethyl lowered triglycerides by approximately 27 percent.

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 (which is marketed in the U.S. as Vascepa®) 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 (≥ 150 mg/dL) and established cardiovascular disease or diabetes mellitus and two or more additional risk factors for cardiovascular disease.

Other Clinical Studies

Global Cardiovascular Outcomes Trial—CLEAR Outcomes

CLEAR Outcomes was a Phase 3, event driven, randomized, multicenter, double-blind, placebo-controlled clinical study designed to evaluate whether treatment with 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 was 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 was 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.

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 concluded once the predetermined number of MACE endpoints occurred. 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.

On December 7, 2022, we announced that the study had met its primary endpoint. We anticipate reporting full results from the study at ACC.23/WCC on March 4, 2023. We intend to use results from this CVOT to support submissions for a CV risk reduction indication in the U.S., Europe and other territories and plan to submit applications for such regulatory approvals in the first half of 2023.

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, 2022, we recognized \$55.9 million in net product sales of NEXLETOL and NEXLIZET and \$19.6 million in collaboration revenue, primarily related to sales of bulk tablets under supply agreements and royalty revenue received from collaboration partners. During the year ended December 31, 2021, we recognized \$40.0 million in net product sales of NEXLETOL and NEXLIZET and \$38.4 million in collaboration revenue, related to the initial recognition of the upfront payment from our license and collaboration agreement with DS, sales of bulk tablets under supply agreements, and royalty revenue received from collaboration partners.

If we fail to complete the development of bempedoic acid or the bempedoic acid / ezetimibe combination tablet (including obtaining additional potential indications), or any other product candidates we may develop, and do not secure additional approvals from regulatory authorities in the U.S., Europe and other territories, 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, 2022, were \$118.9 million, which was primarily related to clinical development costs relating to the CLEAR Outcomes CVOT 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. We announced collaboration agreements for the commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablet with DSE in 2019, with Otsuka in 2020 and with DS in 2021.

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 unpartnered territories outside of the United States 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.

We expect our selling, general and administrative expenses to increase at the end of 2023 after we report full results from the CLEAR Outcomes trial in connection with potential additional global regulatory submissions for new product indications, expanded commercialization and market access initiatives for NEXLETOL and NEXLIZET and increases in our associated headcount.

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.

On April 26, 2021, we entered into a license and collaboration agreement with DS. Pursuant to the agreement, we granted DS exclusive development and commercialization rights to bempedoic acid and the bempedoic acid / ezetimibe combination tablet in South Korea, Taiwan, Hong Kong, Thailand, Vietnam, Brazil, Macao, Cambodia and Myanmar, or the DS Territory. The agreement allows for potential expansion across geographies including Saudi Arabia, Kuwait, Oman, UAE, Qatar, Bahrain, Yemen, Colombia and other Latin American countries. Except for certain development activities in South Korea and Taiwan, DS will be responsible for development and commercialization in these territories.

For additional details on the DSE, Otsuka, Serometrix and DS 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 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, 2022, our patent estate, including patents we own, on a worldwide basis, included approximately 26 issued United States patents and 16 pending United States patent applications and over 25 issued patents and over 130 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, 10,118,881 and 10,941,095, 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 24 national patents validated from one of the granted European patents, which, if approved, could extend our patent protection in those countries until 2028. Additionally, we have one patent family that includes U.S. Patent No. 11,407,705, directed to the method of manufacturing high purity bempedoic acid, one pending U.S. patent application directed to the same, two pending U.S. patent applications directed to compositions of matter of high purity bempedoic acid, and 25 pending patent applications outside of the United States. U.S. Patent No. 11,407,705 and the other patent family members, if issued, are scheduled to expire in June 2040.

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. Methods of treating familial hypercholesterolemia with the bempedoic acid / ezetimibe combination tablet are claimed in U.S. Patent No. 10,912,751 that is scheduled to expire in March 2036. We also have one pending U.S. patent application and 7 issued patents and 17 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 25 pending applications outside of the U.S. directed to the manufacturing of our bempedoic acid / ezetimibe combination tablet. We also have one issued U.S. patent, one pending U.S. patent application, and six issued patents and 21 pending applications outside the U.S., with claims directed to fixed dose combinations of bempedoic acid and one or more statins and/or methods of using said fixed dose combinations.

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 2023 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 or the bempedoic acid / ezetimibe combination tablet in the U.S., in Europe and, if approved, in 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 application, 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 practices, 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;

- review and input from an advisory committee, if requested by FDA; 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. A 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.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their www.clinicaltrials.gov website. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Although sponsors are obligated to disclose the results of their clinical trials after completion, disclosure of the results can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. The NIH's Final Rule on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and both the NIH and FDA have signaled the government's willingness to begin enforcing those requirements against non-compliant clinical trial sponsors.

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), and limitations on industry-sponsored scientific and educational activities. 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, and those supplying products, ingredients, and components of them, 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 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, diligently spent, 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. 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, Reimbursement and Healthcare Reform

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. Factors payors consider in determining reimbursement are based on whether the product 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.

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. Net prices for NEXLETOL and NEXLIZET or any future approved drugs may also be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower

prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products.

In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter is incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program or could require us to issue refunds to 340B covered entities.

Significant civil monetary penalties can be applied if we are found to have knowingly submitted any false pricing information to CMS, or if we fail to submit the required price data on a timely basis. Such conduct also could be grounds for CMS to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. Significant civil monetary penalties also can be applied if we are found to have knowingly and intentionally charged 340B covered entities more than the statutorily mandated ceiling price. We cannot assure you that our submissions will not be found by CMS or HRSA to be incomplete or incorrect.

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.

In March 2010, the 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.

Since its enactment, there have been judicial, Congressional and executive challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted:

- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

- On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.
- On December 20, 2019, former President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repealed the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future.
- In August 2022, the Inflation Reduction Act of 2022 (the “IRA”) was signed into law. The IRA includes several provisions that will impact our business to varying degrees, including provisions that create a \$2,000 out-of-pocket cap for Medicare Part D beneficiaries, impose new manufacturer financial liability on all drugs in Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. The effect of IRA on our business and the healthcare industry in general is not yet known.

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. Since its inception, there have been multiple changes to the 340B drug pricing program. 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 fiscal years 2019 and 2018 reimbursement formula on specified covered outpatient drugs, or 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. Plaintiffs-appellees filed a petition for a writ of certiorari at the Supreme Court on February 10, 2021. On June 15, 2022, the Supreme Court unanimously reversed the Court of Appeals' decision, holding that HHS's 2018 and 2019 reimbursement rates for 340B hospitals were contrary to the statute and unlawful. It is unclear how these developments may impact the sale of our current and future products and the rates that we may charge in the future. 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 Health Resources and Services Administration, or HRSA, which administers the 340B program, issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. We also are required to report our 340B ceiling prices to HRSA on a quarterly basis. Implementation of the civil monetary penalties regulation and the issuance of any other final regulations and guidance could affect our obligations under the 340B program in ways we cannot anticipate. 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 the 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, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Following the temporary suspension, a 1% payment reduction will occur beginning April 1, 2022 through June 30, 2022, and the 2% payment reduction resumed on July 1, 2022.
- 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.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient support programs. At a federal level, President Biden signed an Executive Order on July 9, 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. 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. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates.

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 would 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. However, on December 29, 2021 CMS rescinded the Most Favored Nations rule. Additionally, on November 30, 2020, HHS published 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. Pursuant to a court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. This deadline was pushed back to January 1, 2027 by the Bipartisan Safer Communities Act. The IRA further delayed implementation of this rule to January 1, 2032.

Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. Federal Government will pay for healthcare drugs and services, which could result in reduced demand for our drug candidates or additional pricing pressures.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

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. Federal enforcement agencies also have showed increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement and co-pay support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. 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.
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

- 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 extended 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, creates new individual privacy rights and protections for California consumers (as defined in the law), and places increased privacy and security obligations on entities handling personal data of consumers or households. Further, a new California privacy law amending the CCPA, the California Privacy Rights Act, or CPRA, was passed by California voters on November 3, 2020. As of January 1, 2023, the CPRA has created additional obligations with respect to processing and safeguarding personal information. The CCPA and CPRA provide for civil penalties for violations and a private right of action for data breaches. Among other provisions, the CCPA and CPRA require covered "business" to provide certain disclosures to consumers about their 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 and CPRA may impact our business activities if we become a "business" regulated by the scope of the CCPA and CPRA or a service provider to a regulated business.

In addition to the CCPA and CPRA, new privacy and data security laws have been enacted in a number of states and 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. The effects of state and federal privacy 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.

In the U.S., to help patients access our approved products, we may utilize programs to assist them, including patient assistance programs and co-pay coupon programs for eligible patients. PAPs are regulated by and subject to guidance from CMS OIG. In addition, at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain specialty drugs the insurer identified. Our co-pay coupon programs could become the target of similar insurer actions. In September 2014, the OIG of the HHS issued a Special Advisory Bulletin warning manufacturers that they may be subject to sanctions under the federal anti-kickback statute and/or civil monetary penalty laws if they do not take appropriate steps to exclude Part D beneficiaries from using co-pay coupons. Accordingly, companies exclude these Part D beneficiaries from using co-pay coupons. Further, on December 31, 2020, CMS published a new rule, effective January 1, 2023, requiring manufacturers to ensure the full value of co-pay assistance is passed on to the patient or these dollars will count toward the Average Manufacturer Price and Best Price calculation of the drug. On May 21, 2021, PhRMA sued the HHS in the U.S. District Court for the District of Columbia, to stop the implementation of the rule claiming that the rule contradicts federal law surrounding Medicaid rebates. On May 17, 2022, the U.S. District Court for the District of Columbia granted PhRMA's motion for summary judgment invalidating the accumulator adjustment rule.

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

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.

In the event we conduct clinical trials in the European Economic Area (“EEA”) and United Kingdom (“UK”), we will be subject to additional data protection restrictions. The collection and use of personal data in the EEA, is governed by the General Data Protection Regulation, or the GDPR, which became effective on May 25, 2018. The GDPR applies to the processing of personal data of data subjects in the EEA by any company established in the EEA and to companies established outside the EEA to the extent they process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The GDPR sets forth data protection obligations for data controllers of personal data, including stringent requirements relating to notifying data subjects about how their personal data is being handled and how they can exercise their data protection rights, ensuring there is a valid legal basis to process personal data (if this is consent, the requirements for obtaining consent carries a higher threshold), requirements to conduct privacy impact assessments for certain “high risk” processing, requirements to appoint a data protection officer where sensitive personal data is processed on a “large scale”, limitations on retention of personal data, mandatory data breach notification in certain circumstances, requirements to ensure appropriate technical measures are in place to safeguard personal data, and “privacy by design” requirements, and also creates direct obligations on service providers acting as data processors. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA, which may deviate slightly from the GDPR, may result in fines of up to 4% of a company’s global revenues for the preceding financial year, or €20,000,000, whichever is greater. Moreover, the GDPR grants data subjects the right to claim material and non-material damages resulting from infringement of the GDPR. Given the breadth and depth of changes in data protection obligations, maintaining compliance with the GDPR will require significant time, resources and expense, and we may be required to put in place additional controls and processes to ensure compliance with the new data protection rules.

In addition, further to the UK’s exit from the EU on January 31, 2020, the GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the UK’s European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set forth the UK’s data protection regime, which is independent from but aligned to the EU’s GDPR. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. Although the UK is regarded as a third country under the EU’s GDPR, the European Commission has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as

providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing.

European Union Drug Development

Similar to the U.S., the various phases of preclinical and clinical research in Europe are subject to significant regulatory controls.

In April 2014, the EU adopted a new Clinical Trials Regulation 536/2014, or the Regulation, which replaced the previous Clinical Trials Directive on January 31, 2022. The new Regulation is directly applicable in all EU Member States meaning no national implementing legislation in each EU Member State is required. The new Regulation seeks to simplify and streamline the approval of clinical trials in the EU. For example, the sponsor can submit a single application for approval of a clinical trial in various Member States via an 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 portal.

Marketing Authorization

In the EU, 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 EU, and in the additional Member States of the European Economic Area (Iceland, Liechtenstein and Norway). The CP is mandatory for specific products, including for medicinal products produced by certain biotechnological processes, advanced-therapy medicinal products (gene-therapy, somatic cell-therapy or tissue-engineered medicines), products designated as 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 EU, 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 EU 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 EU, 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 product characteristics (SmPC), 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, SmPC, 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 EU make an assessment of the risk benefit balance of the product on the basis of scientific criteria concerning its quality, safety, and efficacy.

Data and Market Exclusivity

In the EU, innovative medicinal products approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. Data exclusivity prevents applicants for authorization of generics or biosimilars of these innovative products from referencing the innovator's pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU, during a period of eight years from the date on which the reference product was first authorized in the EU. During an additional two-year period of market exclusivity, a generic or biosimilar marketing authorization application can be submitted and authorized, and the innovator's data may be referenced, but no generic or biosimilar medicinal product can be placed on the EU market until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. There is no guarantee that a product will be considered by the EMA to be an innovative medicinal product, and products may not qualify for data exclusivity. Even if a product is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company obtained marketing authorization based on a marketing authorization application with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Periods of Authorization and Renewals

A marketing authorization has an initial validity for five years in principle. The marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State for a nationally authorized product. Once subsequently definitively renewed, the marketing authorization shall be valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (in the case of the centralized procedure) or on the market of the authorizing EU Member State for a nationally authorized product within three years after authorization, ceases to be valid (the so-called sunset clause).

Brexit and the Regulatory Framework in the United Kingdom

The UK formally left the EU on January 31, 2020, and the UK and EU have signed an EU-UK Trade and Cooperation Agreement, or the TCA, which became provisionally applicable on January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of Good Manufacturing Practice, or GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, Great Britain has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework will continue to apply in Northern Ireland). The regulatory regime in Great Britain therefore currently aligns with EU regulations in many ways, however it is possible that these regimes will diverge more significantly in future now that Great Britain's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation.

For example, Great Britain is no longer covered by centralized marketing authorizations (under the Northern Ireland 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 three 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 EU 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.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the EU Member States, plus Norway, Liechtenstein and Iceland.

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 or clinical trial application 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, 2022, we had 199 full-time employees. Nine of our employees have Ph.D. degrees, two have M.D. degrees and five have PharmD degrees. 43 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.

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 have entered into an amendment to our current lease agreement that, effective as of November 1, 2023, will reduce our leased office space to approximately 11,500 square feet. 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 March 12, 2021, the parties agreed to a settlement in principle of the securities class action, and on April 26, 2021, the parties entered into a stipulation of settlement to resolve all legal claims, in which defendants expressly deny that they have committed any act or omission giving rise to any liability under Section 10(b) of the Securities Exchange Act of 1934. Under the terms of the stipulation of settlement, which the court approved on August 24, 2021, the Company and certain of the Company's insurance carriers caused a payment of \$18.25 million to be made to the plaintiff class. As a result of this settlement agreement, during the three months ended March 31, 2021, we recorded a loss on settlement of \$13.25 million in selling, general, and administrative expenses on the statements of operations and comprehensive loss, which represents the litigation settlement of \$18.25 million offset by \$5.0 million in insurance claim proceeds from our insurance carriers.

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. 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.

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 Impact of Uncertain Capital Markets

We have in the past relied in part on sales of our common shares through our at-the-market (ATM) offering program. Increased volatility and decreases in market prices of equity securities generally and of our common shares in particular may have an adverse impact on our willingness and/or ability to continue to sell our common shares through our ATM offering. Decreases in these sales would/could affect the cost or availability of equity capital, which could in turn have an adverse effect on our business, including current operations, future growth, revenues, net income and the market prices of our common shares.

On August 3, 2021, we commenced an at-the-market, or ATM, program to raise capital under an automatically effective registration statement on Form S-3ASR, which was replaced on April 15, 2022 with a new registration statement on Form S-3. Under our current ATM program, we have entered into a sales agreement to sell common shares, up to a maximum aggregate market value of \$70 million, through one or more at-the-market offerings. Given the volatility in the capital markets, we may not be willing or able to continue to raise equity capital through our ATM program. We may, therefore, need to turn to other sources of funding that may have terms that are not favorable to us, or reduce our business operations given capital constraints.

Alternative financing arrangements, if we pursue any, could involve issuances of one or more types of securities, including common stock, preferred stock, convertible debt, warrants to acquire common stock or other securities. These securities could be issued at or below the then prevailing market price for our common shares. In addition, if we issue debt securities, the holders of the debt would have a claim to our assets that would be superior to the rights of stockholders until the principal, accrued and unpaid interest and any premium or make-whole has been paid.

Recent volatility in capital markets and lower market prices for our securities may affect our ability to access new capital through sales of shares of our common stock or issuance of indebtedness, which may materially harm our liquidity, limit our ability to grow our business, pursue acquisitions or improve our operating infrastructure and restrict our ability to compete in our markets.

Our operations consume substantial amounts of cash, and our future capital requirements may be significantly different from our current estimates and will depend on many factors, including the need to:

- finance unanticipated working capital requirements;
- develop or enhance our technological infrastructure and our existing solutions; and
- respond to competitive pressures.

Accordingly, we may need to pursue equity or debt financings to meet our capital needs. With uncertainty in the capital markets and other factors, such financing may not be available on terms favorable to us or at all. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and

any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. Any debt financing secured by us in the future could involve additional restrictive covenants relating to our capital-raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. If we are unable to obtain adequate financing or financing on terms satisfactory to us, we could face significant limitations on our ability to invest in our operations and otherwise suffer harm to our business.

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.

In 2022, we generated \$55.9 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) tablet, 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) tablet 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 tablet in Europe. Since 2020, Daiichi Sankyo launched NILEMDO and NUSTENDI in multiple EU countries. 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 and may alter to commercialize these products 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. Additionally, coverage by a third-party payor does not guarantee reimbursement. For example, the terms of certain agreements require or may require practitioners to seek prior authorization from the third-party payor. Payors have implemented prior authorization requirements for our products which has impacted utilization and, thus, our ability to generate revenue from commercial sales of NEXLIZET and NEXLETOL in the United States. The Company implemented a prior authorization support program to support patients and physician practices in facilitating prior authorizations. In addition, we have created a bridge program for patients who have been prescribed our product but are experiencing delays in obtaining insurance coverage. If patients continue to experience difficulty in obtaining prior authorization for our products and/or our programs on a timely basis, this may adversely impact ongoing sales of our products.

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, Marketing Authorisation Application, or 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 our planned submissions for a CVD risk reduction indication in the U.S. and Europe. 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 completed the CLEAR Outcomes CVOT, and we intend to use the data from this trial to support future regulatory submissions.

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;
- 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 reducing cardiovascular risk or 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 initial or additional regulatory approvals 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 commercially launched our approved drugs in the U.S. and DSE has commercially launched in multiple countries in the EU, 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 for 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 order to meet our estimated commercial requirements. 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, ongoing regulatory oversight 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. 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, and a lactation study to analyze milk in lactating women who have received therapeutic doses of NEXLETOL and NEXLIZET.

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 unannounced inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practices and other regulations. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. Additionally, 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. Additionally, under the Food and Drug Omnibus Reform Act of 2020, or FDORA, sponsors of approved drugs must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed. 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.

If the FDA, EMA or other comparable foreign regulatory authorities approve generic or other versions of bempedoic acid or the bempedoic acid / ezetimibe combination tablet, the sales of our approved products could be adversely affected.

Once a new drug application, or NDA, is approved, the product covered thereby becomes a “reference listed drug” in the FDA’s publication, “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly known as the Orange Book. Under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act to the Federal Food, Drug, and Cosmetic Act, or FDCA, a company may seek approval of generic versions of reference listed drugs through submission of abbreviated new drug applications, or ANDAs, in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials to assess safety and efficacy. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labelling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product.

Under the Hatch-Waxman Act, a company may also submit an NDA under Section 505(b)(2) of the FDCA that references the FDA’s prior approval of the innovator product. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. The Hatch-Waxman Act also provide for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and review) of an ANDA or 505(b)(2) NDA until any applicable period of non-patent exclusivity for the reference listed drug has expired. For example, a new drug containing a new chemical entity, or NCE, may be eligible for five years of marketing exclusivity in the United States following regulatory approval if that drug is classified as a new chemical entity, or NCE. A drug can be classified as a NCE if the FDA has not previously approved any other drug containing the same active moiety.

In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed in the Orange Book. If there are patents listed in the Orange Book for a product, an ANDA or 505(b)(2) applicant that seeks to market its product before expiration of the innovator drug patents must include in their applications what is known as a “Paragraph IV” certification, challenging the validity or enforceability, or claiming non-infringement, of the listed patent or patents. Notice of the certification must be given to the patent owner and NDA holder and if, within 45 days of receiving notice, either the patent owner or NDA holder sues for patent infringement, approval of the ANDA or 505(b)(2) NDA is stayed for up to 30 months, or as lengthened or shortened by a court.

Accordingly, competitors could file ANDAs for generic versions or 505(b)(2) NDAs that reference our NEXLETOL and NEXLIZET products, which were granted marketing approval by the FDA on February 21, 2020 and February 26, 2020, respectively. For example, given that NEXLETOL was granted market exclusivity by the FDA on February 21, 2020, an ANDA or 505(b)(2) NDA referencing our NEXLETOL NDA may not be submitted to the FDA until the expiration of five years, e.g., February 21, 2025, unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference listed drug is either invalid or will not be infringed by the generic or 505(b)(2) product, in which case the applicant may submit its application four years following approval of the reference listed drug, e.g., February 21, 2024, for NEXLETOL. Competitors may seek to launch generic or 505(b)(2) versions of NEXLETOL following the expiration of the applicable exclusivity period for NEXLETOL, even if we still have regulatory exclusivity and/or patent protection for NEXLETOL, and the same could happen for any of our other drug products upon approval. Competition that NEXLETOL could face from an approved generic and other versions of NEXLETOL could materially and adversely affect our future revenue, profitability, and cash flows and substantially limit our ability to obtain a return on the investments we have made in developing NEXLETOL. The same could happen for NEXLIZET.

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.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described in the section entitled “*Business – Other Healthcare Laws*”, 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. 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.

Third party patient assistance programs that receive financial support from companies have become the subject of enhanced government and regulatory scrutiny. Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. The U.S. government has established guidelines that suggest that it is lawful for pharmaceutical manufacturers to make donations to charitable organizations who provide co-pay assistance to Medicare patients, provided that such organizations, among other things, are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria and do not link aid to use of a donor's product. However, donations to patient assistance programs have received some negative publicity and have been the subject of multiple government enforcement actions, related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives. Specifically, in recent years, there have been multiple settlements resulting out of government claims challenging the legality of their patient assistance programs under a variety of federal and state laws. It is possible that we may make grants to independent charitable foundations that help financially needy patients with their premium, co-pay, and co-insurance obligations. If we choose to do so, and if we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties, or other criminal, civil, or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls, policies, and procedures will be sufficient to protect against acts of our employees, business partners, or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could impact our business practices, harm our reputation, divert the attention of management, increase our expenses, and reduce the availability of foundation support for our patients who need assistance. Further, it is possible that changes in insurer policies regarding co-pay coupons and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, and therefore could have a material adverse effect on our sales, business, and financial condition. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs. We cannot predict how the implementation of and any further changes to these rules will affect our business.

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.

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. See the section entitled "*Business – Coverage, Reimbursement and Healthcare Reform.*"

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 patient population for bempedoic acid and the bempedoic acid / ezetimibe combination tablet is over 65 years of age and, therefore, many such patients will be covered by Medicare.

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. See “*Business – Coverage, Reimbursement and Healthcare Reform*” for more discussion on healthcare reform efforts. 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.

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 EEA, including personal health data, is subject to the EU General Data Protection Regulation 2016/679, or EU GDPR, which became effective on May 25, 2018. Following the United Kingdom's ("U.K.") withdrawal from the EU on January 31, 2020 and the end of the transitional arrangements agreed between the U.K. and EU as of January 1, 2021, the EU GDPR has been incorporated into U.K. domestic law by virtue of section 3 of the European Union (Withdrawal) Act 2018 and amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 ("U.K. GDPR" and, together with the EU GDPR, "GDPR"). 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, where required obtaining consent of the individuals to whom the personal data relates or ensuring there is another valid legal basis to process the personal data, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, where required providing notification of data breaches, maintaining records of processing activities and documenting data protection impact assessments where there is high risk processing 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 EEA or the U.K., including the United States (see below), and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million (£17.5 million GBP) 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. 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 and U.K. activities.

Adequate safeguards must be implemented to enable the transfer of personal data outside of the EEA or the U.K., in particular to the U.S., in compliance with European and U.K. data protection laws. On June 4, 2021, the European Commission (EC) issued new forms of standard contractual clauses for data transfers from controllers or processors in the EEA (or otherwise subject to the EU GDPR) to controllers or processors established outside the EEA (and not subject to the EU GDPR). The new standard contractual clauses replace the standard contractual clauses that were adopted previously under the Data Protection Directive. The U.K. is not subject to the EC's new standard contractual clauses but has published its own standard clauses, which enable transfers from the U.K. We may be required to implement these new safeguards when conducting restricted data transfers under the GDPR and doing so will require significant effort and cost. On June 28, 2021, the European Commission announced a decision of "adequacy" concluding that the U.K. ensures an equivalent level of data protection to the GDPR, which provides some relief regarding the legality of continued personal data flows from the EEA, to the U.K. Some uncertainty remains, however, as this adequacy determination must be renewed after four years and may be modified or revoked in the interim. The U.K. Government has confirmed that transfers from the U.K. to the EEA may continue to flow freely. Changes with respect to any of these matters may lead to additional costs and increase our overall risk exposure.

In addition, California 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 requires 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 became enforceable by the California Attorney General beginning on July 1, 2020. 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 or a service provider to a regulated business.

Additionally, a new California ballot initiative, the California Privacy Rights Act, or CPRA, was passed in November 2020. Effective starting on January 1, 2023, the CPRA imposes additional obligations on companies covered by the legislation and significantly modifies the CCPA, including by expanding consumers' rights with respect to certain sensitive personal

information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. The effects of the CCPA and the CPRA are potentially significant and may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply and increase our potential exposure to regulatory enforcement and/or litigation.

In addition, on March 2, 2021, Virginia enacted the Consumer Data Protection Act (the “CDPA”). The CDPA became effective January 1, 2023. The CDPA regulates how businesses (which the CDPA refers to as “controllers”) collect and share personal information. While the CDPA incorporates many similar concepts of the CCPA and CPRA, there are also several key differences in the scope, application, and enforcement of the law that will change the operational practices of controllers. The new law will impact how controllers collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests. Also, on July 8, 2021, Colorado’s governor signed the Colorado Privacy Act (“CPA”), into law. The CPA will become effective July 1, 2023. The CPA is rather similar to Virginia’s CPDA but also contains additional requirements. In addition, on March 24, 2022, Utah’s governor signed the Utah Consumer Privacy Act into law, which will take effect on December 31, 2023 and on May 10, 2022, Connecticut’s Governor signed an Act Concerning Personal Data Privacy and Online Monitoring into law. This measure will become effective July 1, 2023.

In addition to these laws, many other states have proposed or enacted their own versions of a broad consumer privacy law. The existence of comprehensive privacy laws in different states in the country will make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. The effects of the CCPA, and other similar state 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.

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. 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 Juxtapid® (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;
- Small interfering RNA therapy, such as Leqvio® (inclisiran), marketed by Novartis; 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. Based on the results of the CLEAR Outcomes CVOT, we expect to seek a cardiovascular risk reduction indication in the U.S., Europe and other jurisdictions. 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. 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 across various promotional media and outreach activities 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 though 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 though 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 patients on maximally tolerated statin therapy for LDL-C lowering, or bempedoic acid and the bempedoic acid / ezetimibe combination tablet's ability to achieve CV risk reduction, 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 or CV risk 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

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 natural disasters, terrorism, war, telecommunication and electrical failures, and sophisticated cyber-attacks, including the theft and subsequent misuse of employee credentials, denial-of-service attacks, ransomware attacks, business email compromises, computer malware, viruses, and social engineering (including phishing). 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, or physical facilities in which data is stored or through which data is transmitted, 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, including costs to deploy additional personnel and protection technologies, train employees, and engage third-party experts and consultants, which could materially and adversely affect our business, financial condition and results of operations. 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. The TCJA included a number of tax provisions that were subjected to sunset for tax years beginning after December 31, 2021. Companies are required to capitalize all domestic and foreign research and development expenditures (including software development costs), and amortize them over a 5 or 15 year period, respectfully. Additionally, taxpayers are no longer able to add back depreciation, amortization, and depletion into their computation of adjusted taxable income when calculating the limitation of deductible business interest expense.

In the third quarter of 2022, Pennsylvania House Bill 1342 was enacted, which in part phased in a corporate net income tax (CNIT) rate reduction over nine years. The CNIT rate for the 2022 tax year is 9.99%. The CNIT rate will be reduced to 8.99% for the 2023 tax year. Starting with the 2024 tax year, the rate is reduced by 0.5% annually until it reaches 4.99% for the 2031 tax year and each year thereafter. The company assessed the impact of the law change but do not expect that it will have a material impact on the financial statements.

On August 16, 2022, H.R. 5376 (commonly called the Inflation Reduction Act of 2022) was signed into law, which, among other things, implemented a corporate alternative minimum tax (CAMT) of 15 percent on book income of certain large

corporations. The CAMT imposes a minimum tax on net income adjusted for certain items prescribed by the legislation and is effective for tax years beginning after December 31, 2022. The company does not anticipate being subjected to the new CAMT.

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.

Changes in tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our business. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

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

At December 31, 2022, we had United States federal net operating loss carryforwards of approximately \$950.8 million and state net operating loss carryforwards of approximately \$698.4 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. Some of the U.S. Federal and State net operating loss and credit carryforwards are subject to annual limitations due to ownership changes. The annual limitation may result in the expiration of net operating losses or credit carryforwards before utilization. As of result of stock transactions, we expect the Company experienced an ownership change in 2021. 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 ongoing 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 any of our future clinical trials could result in increased costs to us and could delay, prevent or limit our ability to generate revenue and continue our business.

In December 2022, we announced completion of the CLEAR Outcomes CVOT. In the future, we may conduct additional clinical studies of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, as well as clinical studies of additional product candidates we may develop. The conduct and completion of any of our 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 full results of our 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. Although we have announced positive topline results from our CLEAR Outcomes CVOT, we may be unable to successfully obtain regulatory approval for and commercialize bempedoic acid and the bempedoic acid / ezetimibe combination tablet for additional indications.

There is a high failure rate for drugs proceeding through clinical studies. 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 CLEAR Outcomes CVOT or any future studies of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, nor do the positive topline results we announced from our CLEAR Outcomes CVOT in December 2022 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, or by the EMA or any other regulatory authorities for any future indications 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 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 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 are required to conduct clinical studies in addition to our CVOT to support a CV risk reduction indication, 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 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 CV 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 programs, such as our program to develop an oral small molecule PCSK9 inhibitor and our next generation ACL inhibitor. 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. On March 12, 2021, the parties agreed to a settlement in principle of the securities class action, and on April 26, 2021, the parties entered into a stipulation of settlement to resolve all legal claims, in which defendants expressly deny that they have committed any act or omission giving rise to any liability under Section 10(b) of the Securities Exchange Act of 1934. Under the terms of the stipulation of settlement, which the court approved on August 24, 2021, the Company and certain of the Company's insurance carriers caused a payment of \$18.25 million to be made to the plaintiff class. As a result of this settlement agreement, during the three months ended March 31, 2021, the Company recorded a loss on settlement of \$13.25 million in selling, general, and administrative expenses on the

statements of operations and comprehensive loss, which represents the litigation settlement of \$18.25 million offset by \$5.0 million in insurance claim proceeds from our insurance carriers.

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 included organizing and staffing our company, conducting research and development activities for bempedoic acid and the bempedoic acid / ezetimibe combination tablet, as well as commercializing these products. Since the launch of our products, we have generated \$108.9 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 and warrants, 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 \$233.7 million and \$269.1 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of \$1.3 billion. 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 will continue to manage our spending for clinical trials, marketing approvals, and commercialization, and we may attempt to secure additional cash resources or reduce spend in certain areas as needed to continue commercialization and further development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet.

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 our research and development and commercialization activities, as well as other related personnel and activities. Our research and development expenses are expected to be reduced in the foreseeable future after we report the full results of the CLEAR Outcomes CVOT. We expect to continue to incur research and development expenses related to costs associated with obtaining CV risk reduction indications and as they relate to 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 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 continued commercialization efforts and any additional clinical studies that we undertake for the further 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 and under our collaboration agreements are sufficient to fund operations for the foreseeable future. We may look to secure additional cash resources should positive corporate events or milestones provide sufficient opportunities. 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:

- our ability to secure a CV risk reduction indication for bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the U.S. and Europe;
- 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, DS, and Otsuka's ability to successfully commercialize bempedoic acid and the bempedoic acid / ezetimibe combination tablet in their respective territories;
- our ability to receive milestone payments from our collaboration partners;
- 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, DS 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 manage 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, the DS 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. Pursuant to the RIPA Amendment, we received the final \$50.0 million in April 2021. 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 3.33% to 10% of our net sales in the covered territory. See in Note 10 "Liability Related to the Revenue Interest Purchase Agreement" in the notes 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. Further, as we failed to achieve the Specified Net Revenue thresholds for the quarter ended September 30, 2021, we deposited \$50 million into the Blocked Account, which reduced our unrestricted cash. On November 23, 2022, we entered into Amendment #3 to the RIPA and agreed to make a one-time partial call payment with regards to the Revenue Interests (as defined in the RIPA) in an amount equal to \$50 million paid from the Blocked Account.

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. In October 2021, we announced that we had negotiated an exchange agreement with two co-managed holders of the notes to exchange with the Company \$15.0 million aggregate principal amount of Notes held in the aggregate by them (and accrued interest thereon) for shares of the Company's common stock, par value \$0.001 per share. 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.

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, Otsuka and DS 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, 2022, 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 67% 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.

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, 2022, our patent estate, including patents we own, on a worldwide basis, included approximately 26 issued United States patents and 16 pending United States patent applications and over 25 issued patents and over 130 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, 10,118,881 and 10,941,095, 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 24 national patents validated from one of the granted European patents, which, if approved, could extend our patent protection in those countries until 2028. Additionally, we have one patent family that includes U.S. Patent No. 11,407,705, directed to the method of manufacturing high purity bempedoic acid, one pending U.S. patent application directed to the same, two pending U.S. patent applications directed to compositions of matter of high purity bempedoic acid, and 25 pending patent applications outside of the United States. U.S. Patent No. 11,407,705 and the other patent family members, if issued, are scheduled to expire in June 2040.

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. Methods of treating familial hypercholesterolemia with the bempedoic acid / ezetimibe combination tablet are claimed in U.S. Patent No. 10,912,751 that is scheduled to expire in March 2036. We also have one pending U.S. patent application and 7 issued patents and 17 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 25 pending applications outside the U.S. directed to the manufacturing of our bempedoic acid / ezetimibe combination tablet. We also have one issued U.S. patent, one pending U.S. patent application, and six issued patents and 21 pending applications outside the U.S., with claims directed to fixed dose combinations of bempedoic acid and one or more statins and/or methods of using said fixed dose combinations.

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. For example, a European Unified Patent Court (UPC) is scheduled to come into force during 2023. The UPC will be a common patent court to hear patent infringement and revocation proceedings effective for member states of the European Union. This could enable third parties to seek revocation of any of our European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. Any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect our ability to enforce our European patents or defend the validity thereof. We may decide to opt out our European patents and patent applications from the UPC. If certain formalities and requirements are not met, however, our European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC. Moreover, 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.

Furthermore, it is possible that, in February 2024, one or more of our competitors may file with the FDA, an ANDA for a generic version of, or an 505(b)(2) NDA that references, one or both of bempedoic acid or bempedoic acid / ezetimibe combination tablet, in which the competitor would claim that our patents are invalid or not infringed. Competition that our approved products could face from an approved generic and other versions of our approved products could materially and adversely affect our future revenue, profitability, and cash flows and substantially limit our ability to obtain a return on the investments we have made in developing bempedoic acid or bempedoic acid / ezetimibe combination tablet. For further details, please see our risk factor entitled *"If the FDA, EMA or other comparable foreign regulatory authorities approve generic or other versions of bempedoic acid or the bempedoic acid / ezetimibe combination tablet, the sales of our approved products could be adversely affected."*

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. In April 2021, we entered into a license and collaboration agreement with DS, pursuant to which DS will be responsible for the commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination in South Korea, Taiwan, Hong Kong, Thailand, Vietnam, Brazil, Macao, Cambodia and Myanmar, or the DS Territory. Except for certain development activities in South Korea and Taiwan, DS will be responsible for development and commercialization in these territories. 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, Japan, or the DS Territory, 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, Otsuka, DS 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, Otsuka or DS 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. Pursuant to the collaboration agreement with DS, we will receive significant commercial milestone payments, as well as tiered royalties ranging from five percent (5%) to twenty percent (20%) on net sales in the DS Territory. 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, and on our ability to obtain the relevant regulatory approvals. 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, DS 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, Otsuka, DS 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 the 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 or approved by 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, in the case of the contract manufacturers that supply our product candidates, 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 pandemic, 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.

Risks Related to the COVID-19 Pandemic

The ongoing COVID-19 pandemic, including recurring surges, new variants 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 the commercial performance of NEXLETOL and NEXLIZET, our commercial performance of NILEMDO and NUSTENDI led by DSE in the EU, 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. New variants of coronavirus have continued to emerge, including, for example, the Omicron strain at the end of 2021. 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 pandemic 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 and treatments against the virus are developed, approved and distributed. Many countries, as well as 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 many of these restrictions have been 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 as well as our home office personnel are following internal guidelines and respective state and local 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. To date, most of our manufacturing partners and CROs have continued to produce at anticipated levels despite these COVID-19 challenges, but we may experience other delays, such as delays in the timing for the review and approval of expanded indications such as cardiovascular risk reduction in various jurisdictions.

The extent to which the ongoing 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, new variants of the disease, or the broad availability and utilization 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 continuing COVID-19 pandemic may also have the effect of heightening many of the risks described herein, including the below:

- Our ability to successfully commercialize, and generate net product sales from NEXLETOL and NEXLIZET may be adversely affected by the economic impact of the ongoing COVID-19 pandemic. 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 commercial 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.
- 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 products in quantities we require, which may impair the commercialization of NEXLETOL, NEXLIZET, NILEMDO and NUSTENDI. Since the beginning of the COVID-19 pandemic, several vaccines for COVID-19 have received Emergency Use Authorization by the FDA and a number of those later received marketing approval.

Additional vaccines may be authorized or approved in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials and commercial product, which could lead to delays in these trials and/or issues with our commercial supply.

- Health regulatory agencies globally may experience disruptions in their operations as a result of the ongoing 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. Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities.
- 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 or label expansion of our drugs or drug candidates.

While it is not possible at this time to estimate the entirety of the impact that the ongoing 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, regulatory approvals, commercialization efforts including any revenue from sales or milestone payments from partners, supply chain continuity, and general business operations, and our business, prospects, financial condition, and results of operations could be materially harmed as a result.

General Risk Factors

The price of our common stock is likely to be volatile, which could result in substantial losses for purchasers of our common stock.

The trading price of our common stock has been, and may continue to be, volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies.

The market price for our common stock may be influenced by many factors, including:

- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- the timing and results of clinical trials of product candidates, or our competitors' product candidates;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- commencement or termination of collaborations for our development programs;
- failure or discontinuation of any of our development programs;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;

- the results of our efforts to develop additional product candidates;
- actual or anticipated changes in estimates as to financial results or development timelines;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders, including shares issuable upon exercise of outstanding stock options and upon vesting of stock units under our stock incentive plans;
- variations in our financial results or results of companies that are perceived to be similar to us;
- whether an active trading market for our shares is sustained;
- changes in estimates, evaluations or recommendations by securities analysts, that cover our stock or the failure by one or more securities analysts to continue to cover our stock;
- changes in the structure of healthcare payment systems;
- the societal and economic impact of public health epidemics, such as the ongoing COVID-19 pandemic and any recession, depression or sustained market event resulting from the pandemic;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

We also cannot guarantee that an active trading market for our shares will be sustained. An inactive trading market for our common stock may impair our ability to raise capital to continue to fund our operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

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 2022 year end audit, due to a change in filing status our independent registered public accounting firm was not required and did not issue a report on the effectiveness of our internal controls over financial reporting. Management assessed our internal controls over financial reporting, including by using a third-party firm, and determined that their internal controls were effective as of December 31, 2022.

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. 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.

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 have entered into an amendment to our current lease agreement that, effective as of November 1, 2023, will reduce our leased office space to approximately 11,500 square feet. 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 5 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”.

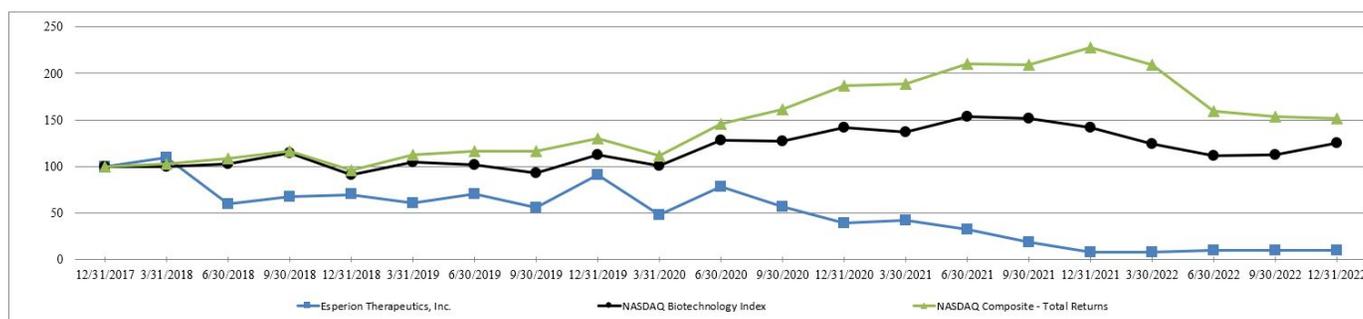
Stockholders

As of February 1, 2023, 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, 2017, 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, 2017 through December 31, 2022, with the comparative cumulative total return of such amount on (i) the 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, 2017 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 \$55.16, 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.

On October 22, 2021, we entered into a privately negotiated exchange agreement, or the Exchange Agreement, with two co-managed holders, or the Holders, of our notes. Under the terms of the Exchange Agreement, the Holders agreed to exchange with us \$15.0 million aggregate principal amount of the notes held in the aggregate by them (and accrued interest thereon) for shares of our common stock. Pursuant to the Exchange Agreement, the number of shares of common stock to be issued by us to the Holders upon consummation of the Exchange was determined based upon the volume-weighted-average-price per share of common stock, subject to a floor of \$5.62 per share, during the five trading-day averaging period, commencing on the trading day immediately following the date of the Exchange Agreement. The Exchange closed on November 3, 2021, resulting in an issuance of 1,094,848 shares of our common stock. Refer to Note 11 in our audited financial statements appearing elsewhere in this Annual Report on Form 10-K for further information.

The issuance of the Exchange Shares under the Exchange Agreement was made in reliance on the exemption from registration pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended. We relied on this exemption from registration based in part on representations made by the Holders in the Exchange Agreement.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

Not applicable.

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 a pharmaceutical company singularly focused on developing and commercializing accessible, oral, once-daily, non-statin medicines for patients struggling with elevated low-density lipoprotein cholesterol, or LDL-C. Through commercial execution and completion of our CLEAR Outcomes trial as well as advancing our pre-clinical pipeline, we continue to evolve into a differentiated, global cardiometabolic biotech. 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 tablet are oral, once-daily, non-statin, LDL-C lowering medicines for patients with atherosclerotic cardiovascular disease, or ASCVD, or heterozygous familial hypercholesterolemia, or HeFH.

We recently completed a global cardiovascular outcomes trial, or CVOT, —known as Cholesterol Lowering via Bempedoic Acid, an ACL-inhibiting Regimen (CLEAR) Outcomes. The trial was designed to evaluate whether treatment with bempedoic acid reduced 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 was 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 was an event-driven trial and concluded once the predetermined number of MACE endpoints occurred. On December 7, 2022, we announced that the study had met its primary endpoint. We anticipate reporting full results from the study at ACC.23 Annual Scientific Session & Expo together with the World Congress of Cardiology (or ACC.23/WCC) on March 4, 2023. We intend to use results from this CVOT to support submissions for a CV risk reduction indication in the U.S., Europe and other territories and plan to file for such regulatory approvals in the first half of 2023.

On November 23, 2022, we entered into a waiver and amendment to our Revenue Interest Purchase Agreement, or RIPA, with Eiger III SA LLC, or Oberland, in which we agreed to make a one-time partial call payment with regards to the Revenue Interests (as defined in the RIPA) in an amount equal to \$50 million from the restricted cash account, or the Partial Call. Under this amendment, the amount of the Cumulative Purchaser Payments (as defined in the RIPA) was reduced to \$177,777,778. Refer to Note 10 to our audited financial statements appearing elsewhere in this Annual Report on Form 10-K for further information.

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 and commercializing 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. While we began to generate revenue from the sales of our products in 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 and warrants, 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 \$233.7 million and \$269.1 million for the years ended December 31, 2022 and 2021, 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 in connection with our ongoing activities, including, among others:

- commercializing NEXLETOL and NEXLIZET in the U.S; and

- pursuing other research and development activities.

Accordingly, we may need additional financing to support our continuing operations and further the development and commercialization 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, 2022, we incurred \$83.5 million in direct expenses related to our CLEAR Outcomes CVOT and other ongoing clinical studies.

During the year ended December 31, 2021, we incurred \$65.9 million in direct expenses related to our CLEAR Outcomes CVOT and other ongoing clinical studies.

The COVID-19 Pandemic

The full extent to which the ongoing COVID-19 pandemic, or the future outbreak of any other highly infectious or contagious diseases, may impact our business, including our 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, the emergence and prevalence of more contagious variants, such as the "Omicron" variant and the BA.2 subvariants of the virus, or the global availability and utilization of effective vaccines, 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 has had a material adverse effect on our business, financial condition, and results of operations. The ongoing COVID-19 pandemic may also have the effect of heightening the risks to which we are subject, including the reliance on third parties in our supply chain for materials and manufacturing and delivery of our drugs and drug candidates, our ability to effectively promote and market our approved products, 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.

Because COVID-19 infections have been reported throughout the U.S. and worldwide, and as new strains continue to be identified, certain national, state, and local governmental authorities have issued orders, proclamations, and/or directives aimed at minimizing the spread of COVID-19. Although many of these restrictions have been 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 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 has been and may continue to be adversely affected by the economic impact of the ongoing COVID-19 pandemic. Physicians' offices and other medical institutions had limited access for nonpatients, which included our sales personnel. In addition, social distancing or testing 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 limited our interactions with physicians and payors and adapted 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 have affected and may continue to 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 or testing requirements, prioritization of healthcare resources to address the pandemic, and/or fear of exposure to the virus, which we believe has adversely affected and could continue to have an adverse impact on new patient starts and overall patient treatment volume.

While it is not possible at this time to estimate the entirety of the impact that the ongoing COVID-19 pandemic will have on our business or operations, the continued spread or future waves of COVID-19 or other highly infectious or contagious diseases, 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 product sales. However, such interruptions may occur due to supply chain issues related to COVID-19, such as the demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, which may make it more difficult to obtain materials or manufacturing capacity at our third-party manufacturers to the products needed for our clinical trials and commercial product, which could lead to delays in our future trials and/or issues with our commercial supply. We remain focused on maintaining a strong balance sheet, liquidity and financial flexibility and continue to monitor developments. We will continue to work diligently with our partners and stakeholders to continue supporting patient access to our approved medicines, advancing our products under regulatory review as well as in 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 Daiichi Sankyo and Otsuka. Collaboration revenue in the year ended December 31, 2022, was primarily related to sales of bulk tablets under supply agreements and royalty revenue received from collaboration partners. Collaboration revenue in the year ended December 31, 2021, was primarily related to the initial recognition of the upfront payment from our license and collaboration agreement with DS, sales of bulk tablets under supply agreements, and royalty revenue received from collaboration partners. 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 record 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.

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 tablet. 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 closing-out activities for the CLEAR Outcomes CVOT and any other development programs or additional indications we choose to pursue. We expect research and development expenses to decrease after we report the full results of the CLEAR Outcomes CVOT. 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 tablet. The duration, costs and timing associated with the development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet 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 tablet, 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 tablet.

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 expect our selling, general and administrative expenses will increase at the end of 2023 after we report full results from the CLEAR Outcomes CVOT in connection with potential additional global regulatory submissions for new product indications, expanded commercialization initiatives for NEXLETOL and NEXLIZET and increases in our associated headcount.

Interest Expense

Interest expense for the years ended December 31, 2022 and December 31, 2021 was related to our Revenue Interest Purchase Agreement, or RIPA, with Eiger III SA LLC, or Oberland, an affiliate of Oberland Capital and our Convertible Notes issued in November 2020.

Other Income

Other income, net, for the year ended December 31, 2022 primarily relates to the sale of lease vehicles associated with the reduction in force, interest income and the accretion or amortization of premiums and discounts earned on our cash, cash equivalents and investment securities. Other income, net, for the year ended December 31, 2021 included a gain on extinguishment of our convertible debt in addition to the sale of lease vehicles associated with the reduction in force, interest income and the accretion or amortization 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, recognize revenue at the point in time when the customer is deemed to have obtained control of the product, which generally occurs upon receipt by the customer. Product sales are recorded at the net selling price, which includes variable considerations for rebates, chargebacks, co-pay assistance programs, distribution related fees, product returns, and other sales-related discounts and fees. Calculating these net product sales involves judgments and estimates. We estimate a range of possible outcomes which are probability-weighted for relevant factors such as contracts with customers, healthcare providers, payors and government agencies, statutorily-defined discounts applicable to government-funded programs, forecasted payor mix, customer buying and payment patterns, and other relevant factors. The 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. Each period, we review our estimates of rebates, co-pay assistance programs, distribution fees and other applicable provisions. If actual results vary from estimates, we adjust these estimates, which would affect net product revenue and earnings in the period such variances become known. A 3% change to our year ended December 31, 2022 net product sales would have an impact of approximately \$1.7 million.

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. This estimate is complex and highly judgmental as it is based on our future revenue projections and expectations about future economic and market conditions. 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. 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 \$10.0 million or 10.0% 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 \$3.3 million or 3.3% for every \$100 million of sales above the threshold. Issuance costs in connection with the RIPA are amortized to interest expense over the estimated term of the RIPA.

Recent Accounting Pronouncements Adopted

For information on new accounting standards adopted and the impact, 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, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021:

	Year Ended December 31,		
	2022	2021	Change
	(in thousands)		
Revenues:			
Product sales, net	\$ 55,863	\$ 40,047	\$ 15,816
Collaboration revenue	19,612	38,400	(18,788)
Operating Expenses:			
Cost of goods sold	26,967	14,217	12,750
Research and development	118,927	105,975	12,952
Selling, general and administrative	109,082	184,985	(75,903)
Loss from operations	(179,501)	(226,730)	47,229
Interest expense	(56,810)	(46,353)	(10,457)
Other income, net	2,652	3,975	(1,323)
Net loss	\$ (233,659)	\$ (269,108)	\$ 35,449

Product sales, net

Product sales, net for the year ended December 31, 2022 was \$55.9 million compared to \$40.0 million for the year ended December 31, 2021, an increase of approximately \$15.9 million. The increase is primarily due to prescription growth of NEXLETOL and NEXLIZET. NEXLETOL and NEXLIZET became commercially available in the U.S. on March 30, 2020 and June 4, 2020, respectively.

Collaboration revenue

Collaboration revenue recognized from our collaboration agreements for the year ended December 31, 2022 was \$19.6 million compared to \$38.4 million for the year ended December 31, 2021, a decrease of \$18.8 million primarily related to the recognition of \$28.0 million in revenue related to the initial recognition of the upfront payment from our license and collaboration agreement with Daiichi Sankyo in April 2021, partially offset by increases in product sales to collaboration partners under our supply agreements and royalty revenue.

Cost of goods sold

Cost of goods sold for the year ended December 31, 2022, was \$27.0 million compared to \$14.2 million for the year ended December 31, 2021, an increase of \$12.8 million. The increase is primarily related to increased product sales to our collaboration partners under our supply agreements and increased net product sales of NEXLETOL and NEXLIZET.

Research and development expenses

Research and development expenses for the year ended December 31, 2022, were \$118.9 million compared to \$106.0 million for the year ended December 31, 2021, an increase of approximately \$12.9 million. The increase in research and development expenses was primarily attributable to an increase in CVOT costs as we achieved 100% MACE accumulations and continued close-out activities.

Selling, general and administrative expenses

Selling, general and administrative expenses for the year ended December 31, 2022, were \$109.1 million compared to \$185.0 million for the year ended December 31, 2021, a decrease of \$75.9 million. The decrease in selling, general and administrative expenses was primarily attributable to decreases in compensation costs related to the reduction in force in the fourth quarter of 2021 and a \$13.3 million one-time charge associated with a legal settlement in 2021.

Interest expense

Interest expense for the year ended December 31, 2022, was \$56.8 million, compared to \$46.4 million for the year ended December 31, 2021, an increase of approximately \$10.4 million. The increase in interest expense for the year ended December 31, 2022 was primarily due to additional non-cash interest expense attributable to our RIPA with Oberland.

Other income, net

Other income, net for the year ended December 31, 2022, was \$2.7 million compared to \$4.0 million for the year ended December 31, 2021, a decrease of \$1.3 million. This decrease was primarily due to a \$2.6 million gain on extinguishment on the exchange of our convertible notes for shares of our common stock and a gain on sale of our lease vehicles due to the reduction in force in the year ended December 31, 2021, partially offset by higher interest income on our investments due to higher interest rates in the year ended December 31, 2022.

Liquidity and Capital Resources

While we began to generate revenue from the sales of our products in 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 and warrants, the incurrence of indebtedness, milestone payments from collaboration agreements and our revenue interest purchase agreement. Pursuant to the license and collaboration agreements with Daiichi Sankyo and Otsuka, we are eligible for substantial additional sales and regulatory milestone payments and royalties. Pursuant to the license and collaboration agreements entered into April 2021 with Daiichi Sankyo, we received an upfront cash payment of \$30.0 million in May 2021 and are eligible for substantial additional sales milestone payments and royalties. In December 2021, we entered into an underwriting agreement where we sold shares of common stock and accompanying warrants to purchase shares of our common stock and received net proceeds of \$208.7 million. On April 15, 2022, we filed a new registration statement on Form S-3, which registers the offering, issuance and sale of up to \$239 million of common stock from time to time in “at-the-market” offerings (the “New ATM Program”). During 2022, we issued 13,043,797 shares of common stock resulting in net proceeds of approximately \$90.8 million. On February 21, 2023, we terminated the open market sales agreement with Jefferies LLC and entered into a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co., as sales agent, to provide for the issuance and sale by the Company of up to \$70 million of common stock from time to time in “at-the-market” offerings, or the 2023 ATM Program, pursuant to our existing Form S-3 and the prospectus supplement to be filed on February 21, 2023. We may continue to use the 2023 ATM program or issue stock through other capital markets to address potential funding requirements. We anticipate that we will incur losses for the foreseeable future as we continue to incur substantial expenses related to the ongoing commercialization of NEXLETOL and NEXLIZET and expenses associated with our research and development activities. We anticipate that our current cash, cash equivalents, investments, expected future net product sales of NEXLETOL and NEXLIZET, and expected future revenue under our collaboration agreements is sufficient to fund continuing operations for the foreseeable future.

As of December 31, 2022, our primary sources of liquidity were our cash and cash equivalents and available-for-sale investments which totaled \$166.9 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,	
	2022	2021
	(in thousands)	
Net cash used in operating activities	(174,827)	(263,809)
Net cash provided by (used in) investing activities	8,104	(50,484)
Net cash provided by financing activities	32,606	268,223
Net decrease in cash, cash equivalents and restricted cash	(134,117)	(46,070)

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 tablet.

Net cash used in operating activities totaled \$174.8 million for the year ended December 31, 2022, consisting of net product sales of NEXLETOL and NEXLIZET fully 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 tablet, adjusted for non-cash expenses such as stock-based compensation expense, 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 \$263.8 million for the year ended December 31, 2021, consisting of net product sales of NEXLETOL and NEXLIZET and \$30.0 million in upfront fees from our collaboration agreement with DS fully 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 tablet, adjusted for non-cash expenses such as stock-based compensation expense, interest expense related to our RIPA with Oberland and convertible notes, depreciation and amortization and changes in working capital. The decrease in cash used in operating activities for the year ended December 31, 2022 compared to the year ended December 31, 2021 was primarily related to management implementing certain cost optimization measures, including a reduction in force in the fourth quarter of 2021, to align operational and expense structure to better enable future growth for their approved products and to prioritize their investment in the CLEAR Outcomes trial.

Investing Activities

Net cash provided by investing activities of \$8.1 million for the year ended December 31, 2022 consisted primarily of proceeds from the sales of highly liquid, interest bearing investment grade and government securities. Net cash used in investing activities of \$50.5 million for the year ended December 31, 2021 consisted primarily of purchases of highly liquid, interest bearing investment grade and government securities.

Funds invested in available-for-sale investments in the year ended December 31, 2022 will become available for our use over the next twelve months.

Financing Activities

Net cash provided by financing activities of \$32.6 million for the year ended December 31, 2022, related primarily to proceeds from our ATM program, partially offset by a one-time partial call payment with regards to the Revenue Interests (as defined in the RIPA) in an amount equal to \$50.0 million from the restricted cash account under the waiver and amendment of our RIPA with Oberland, and payments on our revenue interest liability. Net cash provided by financing activities of \$268.2 million for the year ended December 31, 2021, related primarily to net \$208.7 million received from our offering of common stock and warrants in December 2021, \$50.0 million in cash from our RIPA with Oberland, proceeds from the issuance of common stock through the "at-the-market" offering and cash received from stock option exercises, offset by payments on our revenue interest liability.

On August 3, 2021, we filed an automatically effective registration statement on Form S-3ASR, or Registration Statement, with the SEC which registers the offering, issuance and sale of an unspecified amount of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof. We simultaneously entered into an open market sale agreement with Jefferies LLC, as sales agent, to provide for the issuance and sale by the Company of up to \$250 million of common stock from time to time in "at-the-market" offerings under the Registration Statement and related prospectus filed with the Registration Statement, or the ATM Program. During the year ended December 31, 2021, we issued 897,364 shares of common stock resulting in net proceeds of approximately \$9.7 million after deducting underwriting discounts and commissions and other expenses, pursuant to the ATM Program. On April 15, 2022, we filed a new registration statement on Form S-3, which registers the offering, issuance and sale of up to \$239 million of common stock from time to time in "at-the-market" offerings, or the New ATM Program. During the year ended December 31, 2022, we issued 13,043,797 shares of common stock, resulting in net proceeds of approximately \$90.8 million after deducting \$3.1 million of underwriting discounts and commissions and other expenses, pursuant to the New ATM Program. On February 21, 2023, we terminated the open market sales agreement with Jefferies LLC and entered into a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co., as sales agent, to provide for the issuance and sale by the Company of up to \$70 million of common stock from time to time in "at-the-market" offerings, or the 2023 ATM Program, pursuant to our existing Form S-3 and the prospectus supplement to be filed on February 21, 2023. We may continue to use the 2023 ATM Program to address potential short-term or long-term funding requirements that may arise. Such program will continue to be subject to the volatility of the price of our common stock and general market conditions.

In December 2021, we entered into an underwriting agreement where we sold 32,142,858 shares of common stock and accompanying warrants to purchase up to an aggregate of 32,142,858 shares of our common stock. We also granted the underwriters a 30-day option to purchase up to 4,821,428 additional shares of common stock and/or accompanying warrants to purchase an aggregate of up to 4,821,428 shares of our common stock. The underwriters exercised the option to purchase additional warrants to purchase 4,821,428 shares of Common Stock. The aggregate net proceeds received by us from the

offering was \$208.7 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us and excluding the net proceeds, if any, from the exercise of the common warrants. The warrants are immediately exercisable and will expire two years from the date of issuance, at an exercise price of \$9.00 per share, which may provide us with additional funding, if such warrants are exercised by their holders.

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 were eligible to receive an additional \$50.0 million at our option upon reaching certain sales thresholds. In April 2021, we entered into Amendment No. 2 to the RIPA and Oberland waived the original trailing six-month world-wide net sales condition to the third installment payment under the RIPA and released the final \$50 million payment payable to us under the terms of the RIPA. The amendment also updated the tiered payment percentage. As the quarterly net revenue from sales of NEXLETOL and NEXLIZET and certain other products in the United States did not exceed \$15.0 million for the quarter ended September 30, 2021, we deposited \$50.0 million in a deposit account with Oberland, which reduced our unrestricted cash. On November 23, 2022, we entered into a waiver and amendment to the RIPA with Oberland, in which we agreed to make a one-time partial call payment with regards to the Revenue Interests (as defined in the RIPA) in an amount equal to \$50 million from the restricted cash account (the "Partial Call"). Under this amendment, the amount of the Cumulative Purchaser Payments (as defined in the RIPA) was reduced to \$177,777,778. 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 ranging from 3.3% to 10% of our net sales in the covered territory (as detailed in the RIPA). 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 \$24.8 million in the next year to a maximum total payment of \$363.3 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 \$10.0 million or 10% 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. As the U.S. net sales were less than \$350 million for the year ended December 31, 2021, the Covered Territory was expanded to include worldwide sales beginning in 2022. 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 10 to our audited financial statements appearing elsewhere in this Annual Report on Form 10-K for further information.

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. On October 22, 2021, we entered into the Exchange Agreement with the Holders, of our Convertible Notes. Under the terms of the Exchange Agreement the Holders agreed to exchange with us \$15.0 million aggregate principal amount of the Convertible Notes held in the aggregate by them (and accrued interest thereon) for shares of our common stock, which closed on November 3, 2021. Future payments under the convertible notes include annual interest of \$10.6 million and a principal payment of \$265.0 million in 2025. Refer to Note 11 to our audited financial statements appearing elsewhere in this Annual Report on Form 10-K.

Plan of Operations and Funding Requirements

We expect to continue to incur significant expenses and operating losses for the foreseeable future in connection with closing our CLEAR Outcomes CVOT and our continued commercialization activities associated with NEXLETOL and NEXLIZET in the U.S. Pursuant to the license and collaboration agreements with DSE, Otsuka, and DS, we are eligible for substantial additional sales and regulatory milestone payments and royalties. We estimate that current cash resources, proceeds to be received in the future for product sales and proceeds under the collaboration agreements with Daiichi Sankyo and Otsuka 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 look to secure additional cash resources should positive corporate events or milestones provide sufficient opportunities. We may need to secure additional cash resources or implement certain additional cost reduction initiatives to continue to fund the commercialization and further development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, particularly if our net product sales do not meet our expectations. 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 tablet. 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 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, including receiving potential milestone payments from collaboration partners;
- 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, Otsuka and DS, 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.

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, cash equivalents and available-for-sale investments of approximately \$166.9 million at December 31, 2022. 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, 2022.

The warrants currently have an exercise price of \$9 per share and holders of the warrants may not exercise if the market price of our common stock is below \$9. As a result, we may be unable to obtain potential proceeds from the exercise of these warrants if the market price of our common stock does not exceed \$9 per share.

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 November 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, 2022.

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, 2022, 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, 2022, 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, 2022, 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, 2022, based on those criteria.

Changes in Internal Control over Financial Reporting

There were no changes to our internal control over financial reporting that occurred during the three months ended December 31, 2022, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not Applicable.

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 2023 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 2023 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 2023 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 2023 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

Our independent public accounting firm is Ernst & Young LLP, Detroit, Michigan, PCAOB Auditor ID 42.

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 2023 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:

Report of Independent Registered Public Accounting Firm (PCAOB Auditor ID 42)	F-2
Balance Sheets	F-4
Statements of Operations and Comprehensive Loss	F-5
Statements of Stockholders' Equity (Deficit)	F-6
Statements of Cash Flows	F-7
Notes to Financial Statements	F-8

(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
<u>3.1</u>	<u>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)</u>
<u>3.2</u>	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on May 26, 2022)</u>
<u>3.3</u>	<u>Certificate of Validation dated September 20, 2022 relating to Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant dated May 26, 2022 (incorporated by reference to Exhibit 3.3 to the Registrant's Quarterly Report on Form 10-Q, File No. 001-35986, filed on November 1, 2022)</u>
<u>3.4</u>	<u>Second Amended and Restated Bylaws of the Registrant dated April 29, 2021 (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q, File No. 001-35986, filed on May 4, 2021)</u>
<u>4.1</u>	<u>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)</u>
<u>4.2</u>	<u>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)</u>
<u>4.3</u>	<u>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)</u>
<u>4.4</u>	<u>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)</u>
<u>4.5</u>	<u>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)</u>
<u>4.6</u>	<u>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)</u>
<u>4.7</u>	<u>Registration Rights and Securityholder Agreement by and between the Registrant and Pfizer Inc. dated April 28, 2008 (incorporated by reference to Exhibit 4.6 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-188595) filed on May 14, 2013).</u>
<u>4.8</u>	<u>Form of Warrant to Purchase Preferred Stock dated September 4, 2012 (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-188595) filed on May 14, 2013).</u>
<u>10.1*</u>	<u>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)</u>
<u>10.2</u>	<u>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)</u>
<u>10.3</u>	<u>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)</u>
<u>10.4</u>	<u>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)</u>
<u>10.5#</u>	<u>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).</u>
<u>10.6#</u>	<u>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)</u>
<u>10.7#</u>	<u>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).</u>

- [10.8](#) [First Amendment to Valley Ranch Business Park Lease, dated July 6, 2018, between the Registrant and Blackbird Ann Arbor, LLC \(incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, File No. 001-35986, filed on August 2, 2018\)](#)
- [10.9*](#) [License and Collaboration Agreement by and between Daiichi Sankyo Europe GmbH and the Company, dated as of January 2, 2019 \(incorporated by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K, File No. 001-35986 filed on February 28, 2019\)](#)
- [10.10](#) [Revenue Interest Purchase Agreement by and between the Company, Eiger III SA LLC, and the Purchasers named therein, dated June 26, 2019 \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on June 26, 2019\)](#)
- [10.11#](#) [First Amendment to 2017 Inducement Equity Plan \(incorporated by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K, File No. 001-35986, filed on February 27, 2020\)](#)
- [10.12#](#) [Esperion Therapeutics, Inc. 2020 Employee Stock Purchase Plan, as amended \(incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q, File No. 001-35986, filed on August 10, 2020\)](#)
- [10.13*](#) [License and Collaboration Agreement by and between the Company and Otsuka Pharmaceutical Co., Ltd. dated April 17, 2020 \(incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q, File No. 001-35986, filed on August 10, 2020\)](#)
- [10.14*](#) [1st Amendment to the License and Collaboration Agreement by and between the Registrant and Daiichi Sankyo Europe GMBH dated June 18, 2020 \(incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q, File No. 001-35986, filed on August 10, 2020\)](#)
- [10.15](#) [Form of Capped Call Confirmation \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on November 16, 2020\)](#)
- [10.16](#) [Forward Stock Purchase Confirmation, dated November 11, 2020, by and between the Company and Morgan Stanley & Co. LLC \(incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on November 16, 2020\)](#)
- [10.17](#) [Amendment No. 1 to the Revenue Interest Purchase Agreement, dated November 11, 2020, by and among the Registrant, the purchasers from time to time party thereto and Eiger III SA LLC, as the purchaser agent, dated effective as of June 26, 2019 \(incorporated by reference to Exhibit 10.22 to the Registrant's Annual Report on Form 10-K, File No. 001-35986, filed on February 23, 2021\)](#)
- [10.18*](#) [Exchange Agreement, dated October 22, 2021, by and between the Registrant and the Holders \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on October 25, 2021\)](#)
- [10.19*](#) [License and Collaboration Agreement, by and between the Registrant and Daiichi Sankyo Company, Limited dated April 26, 2021 \(incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, File No. 001-35986, filed on August 3, 2021\)](#)
- [10.20](#) [Amendment No. 2 to the Revenue Interest Purchase Agreement, by and among the Registrant and the parties thereto dated April 26, 2021 \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on April 26, 2021\)](#)
- [10.21](#) [2nd Amendment to the License and Collaboration Agreement by and between the Registrant and Daiichi Sankyo Europe GMBH dated March 19, 2021 \(incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, File No. 001-35986, filed on May 4, 2021\)](#)
- [10.22#](#) [2022 Stock Option and Incentive Plan and forms of agreements thereunder \(incorporated by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form S-8, File No. 333-265247, filed on May 26, 2022\)](#)
- [10.23#](#) [Employment Agreement, dated November 16, 2022, by and between the Registrant and Benjamin Halladay \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on November 16, 2022\)](#)
- [10.24**](#) [Waiver and Amendment No. 3 to Revenue Interest Purchase Agreement and Amendment No. 2 to Security Agreement, by and among the Registrant, the purchasers party thereto, and Eiger III SA LLC, as the collateral agent and administrative agent, dated effective as of November 23, 2022](#)
- [10.25#](#) [Employment Agreement, dated June 9, 2022, by and between the Registrant and Sheldon Koenig \(incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on June 13, 2022\)](#)
- [10.26#](#) [Employment Agreement, dated June 9, 2022, by and between the Registrant and JoAnne Foody \(incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on June 13, 2022\)](#)
- [10.27#](#) [Employment Agreement, dated June 9, 2022, by and between the Registrant and Eric Warren \(incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on June 13, 2022\)](#)
- [10.28#](#) [Employment Agreement, dated June 9, 2022, by and between the Registrant and Benjamin Looker \(incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on June 13, 2022\)](#)

<u>21.1</u>	<u>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)</u>
<u>23.1**</u>	<u>Consent of Ernst & Young LLP</u>
<u>31.1**</u>	<u>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</u>
<u>31.2**</u>	<u>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</u>
<u>32.1***</u>	<u>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</u>
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 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 21, 2023

By: /s/ SHELDON L. KOENIG
 Sheldon L. Koenig
 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/ SHELDON L. KOENIG </u> Sheldon L. Koenig	President, Chief Executive Officer and Director (Principal Executive Officer)	February 21, 2023
<u> /s/ BENJAMIN HALLADAY </u> Benjamin Halladay	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 21, 2023
<u> /s/ JEFFREY BERKOWITZ, J.D. </u> Jeffrey Berkowitz, J.D.	Director	February 21, 2023
<u> /s/ J. MARTIN CARROLL </u> J. Martin Carroll	Director	February 21, 2023
<u> /s/ SETH H.Z. FISCHER </u> Seth H.Z. Fischer	Director	February 21, 2023
<u> /s/ ALAN FUHRMAN </u> Alan Fuhrman	Director	February 21, 2023
<u> /s/ ANTONIO M. GOTTO, M.D., D. PHIL </u> Antonio M. Gotto, M.D., D. Phil	Director	February 21, 2023
<u> /s/ STEPHEN ROCAMBOLI </u> Stephen Rocamboli	Director	February 21, 2023
<u> /s/ JAY SHEPARD </u> Jay Shepard	Director	February 21, 2023
<u> /s/ NICOLE VITULLO </u> Nicole Vitullo	Director	February 21, 2023
<u> /s/ TRACY M. WOODY </u> Tracy M. Woody	Director	February 21, 2023

Esperion Therapeutics, Inc.
Index to the Financial Statements

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Report of Independent Registered Public Accounting Firm

To the Shareholders 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, 2022 and 2021, the related statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

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 Public Company Accounting Oversight Board (United States) (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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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 matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosure to which it relates.

Valuation of revenue interest liability

Description of the matter

As described in Notes 2 and 10 to the financial statements, the Company maintains a Revenue Interest Purchase Agreement (“RIPA”) with Eiger III SA LLC. Pursuant to the RIPA, the Company has received Cumulative Purchaser Payments of \$177.8 million at December 31, 2022. The carrying amount of the RIPA at December 31, 2022 was \$243.6 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 net sales. The Company evaluates the interest rate quarterly based on its current net 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 net revenue projections which are affected by expectations about future economic and market conditions.

How we addressed the matter in our audit

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 net revenue projections, 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 21, 2023

Esperion Therapeutics, Inc.

Balance Sheets

(in thousands, except share data)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 124,775	\$ 208,892
Short-term investments	42,086	50,441
Accounts receivable	33,729	22,934
Inventories, net	35,201	34,394
Prepaid clinical development costs	1,026	1,138
Other prepaid and current assets	9,866	11,173
Total current assets	<u>246,683</u>	<u>328,972</u>
Restricted cash	—	50,000
Property and equipment, net	164	664
Right of use operating lease assets	1,036	1,898
Intangible assets	56	56
Total assets	<u>\$ 247,939</u>	<u>\$ 381,590</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 23,040	\$ 17,559
Accrued clinical development costs	5,426	7,013
Other accrued liabilities	35,191	30,410
Revenue interest liability	24,760	11,295
Deferred revenue from collaborations	3,507	5,683
Operating lease liabilities	384	1,392
Total current liabilities	<u>92,308</u>	<u>73,352</u>
Convertible notes, net of issuance costs	259,899	258,280
Revenue interest liability	218,845	245,744
Operating lease liabilities	665	524
Deferred revenue from collaborations	—	634
Total liabilities	<u>\$ 571,717</u>	<u>\$ 578,534</u>
Commitments and contingencies (Note 5)		
Stockholders' (deficit) equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized and no shares issued or outstanding as of December 31, 2022 and December 31, 2021	\$ —	\$ —
Common stock, \$0.001 par value; 240,000,000 shares authorized as of December 31, 2022 and 120,000,000 shares authorized as of December 31, 2021; 76,564,396 shares issued at December 31, 2022 and 62,873,694 shares issued at December 31, 2021	75	61
Additional paid-in capital	1,071,183	964,401
Treasury stock, at cost; 1,994,198 shares at December 31, 2022 and December 31, 2021	(54,998)	(54,998)
Accumulated other comprehensive loss	(2)	(31)
Accumulated deficit	(1,340,036)	(1,106,377)
Total stockholders' deficit	<u>(323,778)</u>	<u>(196,944)</u>
Total liabilities and stockholders' deficit	<u>\$ 247,939</u>	<u>\$ 381,590</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,	
	2022	2021
Revenues:		
Product sales, net	\$ 55,863	\$ 40,047
Collaboration revenue	19,612	38,400
Total Revenues	<u>75,475</u>	<u>78,447</u>
Operating expenses:		
Cost of goods sold	26,967	14,217
Research and development	118,927	105,975
Selling, general and administrative	109,082	184,985
Total operating expenses	<u>254,976</u>	<u>305,177</u>
Loss from operations	(179,501)	(226,730)
Interest expense	(56,810)	(46,353)
Other income, net	2,652	3,975
Net loss	<u>\$ (233,659)</u>	<u>\$ (269,108)</u>
Net loss per common share (basic and diluted)	<u>\$ (3.52)</u>	<u>\$ (9.31)</u>
Weighted-average shares outstanding (basic and diluted)	<u>66,407,242</u>	<u>28,902,507</u>
Other comprehensive (loss) gain:		
Unrealized gain (loss) on investments	\$ 29	\$ (31)
Total comprehensive loss	<u>\$ (233,630)</u>	<u>\$ (269,139)</u>

See accompanying notes to the financial statements.

Esperion Therapeutics, Inc.

Statements of Stockholders' Equity (Deficit)

(in thousands, except share data)

	Common Stock		Additional	Accumulated	Treasury	Accumulated	Total
	Shares	Amount	Paid-In Capital	Deficit	Stock	Other Comprehensive Loss	Stockholders' Equity (Deficit)
Balance December 31, 2020	25,916,168	\$ 26	\$ 797,655	\$ (838,817)	\$ (54,998)	\$ —	\$ (96,134)
Adoption of new accounting pronouncement	—	—	(93,475)	1,548	—	—	(91,927)
Issuance of common stock and warrants from offering, net of issuance costs	32,142,858	32	208,698	—	—	—	208,730
Issuance of common stock from ATM Program, net of issuance costs	897,364	1	9,702	—	—	—	9,703
Exchange of convertible notes to equity, net of issuance costs	1,094,848	1	11,659	—	—	—	11,660
Exercise of stock options	491,700	1	3,761	—	—	—	3,762
Vesting of restricted stock units	203,344	—	—	—	—	—	—
Vesting of ESPP Shares	133,214	—	2,095	—	—	—	2,095
Stock-based compensation	—	—	24,306	—	—	—	24,306
Other comprehensive loss	—	—	—	—	—	(31)	(31)
Net loss	—	—	—	(269,108)	—	—	(269,108)
Balance December 31, 2021	60,879,496	\$ 61	\$ 964,401	\$ (1,106,377)	\$ (54,998)	\$ (31)	\$ (196,944)
Issuance of common stock from ATM Program, net of issuance costs	13,043,797	13	90,835	—	—	—	90,848
Vesting of restricted stock units	440,697	1	—	—	—	—	1
Vesting of ESPP Shares	206,208	—	732	—	—	—	732
Stock-based compensation	—	—	15,215	—	—	—	15,215
Other comprehensive gain	—	—	—	—	—	29	29
Net loss	—	—	—	(233,659)	—	—	(233,659)
Balance December 31, 2022	<u>74,570,198</u>	<u>\$ 75</u>	<u>\$ 1,071,183</u>	<u>\$ (1,340,036)</u>	<u>\$ (54,998)</u>	<u>\$ (2)</u>	<u>\$ (323,778)</u>

See accompanying notes to the financial statements.

Esperion Therapeutics, Inc.

Statements of Cash Flows

(in thousands)

	Year Ended December 31,	
	2022	2021
Operating activities		
Net loss	\$ (233,659)	\$ (269,108)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	500	612
Amortization of premiums and discounts on investments	279	12
Amortization of discount and issuance costs on convertible notes	1,621	1,621
Gain on extinguishment of convertible debt	—	(2,646)
Non-cash interest expense related to the revenue interest liability	44,590	33,907
Stock-based compensation expense	15,215	24,306
Changes in assets and liabilities:		
Accounts receivable	(10,795)	(10,546)
Prepays and other assets	1,419	99
Deferred revenue	(2,810)	4,655
Inventories	(807)	(18,258)
Accounts payable	5,603	(34,099)
Other accrued liabilities	4,017	6,926
Other long-term liabilities	—	(1,290)
Net cash used in operating activities	(174,827)	(263,809)
Investing activities		
Purchases of investments	(59,897)	(50,484)
Proceeds from sales/maturities of investments	68,001	—
Net cash provided by (used in) investing activities	8,104	(50,484)
Financing activities		
Proceeds from revenue interest liability, net of issuance costs	—	49,917
Proceeds from issuance of common stock and warrants from offering, net of issuance costs	—	208,975
Proceeds from issuance of common stock from ATM Program, net of issuance costs	90,849	9,713
Proceeds from exercise of common stock options	—	3,762
Payment for debt issuance costs on convertible notes	—	(440)
Payments on revenue interest liability	(8,024)	(3,389)
Repayment of principal on revenue interest liability	(50,000)	—
Payment for other issuance costs	(219)	(315)
Net cash provided by financing activities	32,606	268,223
Net decrease in cash, cash equivalents and restricted cash	(134,117)	(46,070)
Cash, cash equivalents and restricted cash at beginning of period	258,892	304,962
Cash, cash equivalents and restricted cash at end of period	<u>\$ 124,775</u>	<u>\$ 258,892</u>
Supplemental disclosure of cash flow information:		
Issuance costs not yet paid	\$ 1	\$ 269
Non cash right of use asset	5	\$ (7)

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 a pharmaceutical company singularly focused on developing and commercializing accessible, oral, once-daily, non-statin medicines for patients struggling with elevated low density lipoprotein cholesterol ("LDL-C"). Through commercial execution and completion of the CLEAR Outcomes trial as well as advancing the Company's pre-clinical pipeline, the Company continues to evolve into a differentiated, global cardiometabolic biotech. 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 tablet are oral, once-daily, non-statin, LDL-C lowering medicines for patients with atherosclerotic cardiovascular disease ("ASCVD") or heterozygous familial hypercholesterolemia ("HeFH").

The Company recently completed a global cardiovascular outcomes trial ("CVOT"), —known as Cholesterol Lowering via Bempedoic Acid, an ACL-inhibiting Regimen ("CLEAR") Outcomes. The trial was designed to evaluate whether treatment with bempedoic acid reduced the risk of cardiovascular events in patients who are statin averse and who have cardiovascular disease ("CVD") or are at high risk for CVD. The Company 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 was the effect of bempedoic acid on four types of major adverse cardiovascular events ("MACE") (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, or coronary revascularization; also referred to as "four-component MACE"). CLEAR Outcomes was an event-driven trial and concluded once the predetermined number of MACE endpoints occurred. On December 7, 2022, the Company announced that the study had met its primary endpoint. The Company anticipates reporting full results from the study at ACC.23 Annual Scientific Session & Expo together with the World Congress of Cardiology ("ACC.23/WCC") on March 4, 2023. The Company intends to use results from this CVOT to support submissions for a CV risk reduction indication in the U.S., Europe and other territories and plans to file for such regulatory approvals in the first half of 2023.

On November 23, 2022, the Company entered into a waiver and amendment to the Revenue Interest Purchase Agreement ("RIPA") with Eiger III SA LLC ("Oberland"), in which the Company agreed to make a one-time partial call payment with regards to the Revenue Interests (as defined in the RIPA) in an amount equal to \$50 million from the restricted cash account (the "Partial Call"). Under this amendment, the amount of the Cumulative Purchaser Payments (as defined in the RIPA) was reduced to \$177,777,778. Refer to Note 10 "Liability Related to the Revenue Interest Purchase Agreement" for further information.

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, raising capital, and commercializing its products. 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; successfully manage relationships with its collaboration partners; 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. The Company's ability to successfully launch, commercialize and generate revenue from NEXLETOL, NEXLIZET, NILEMDO and NUSTENDI has been and may continue to be adversely affected by the economic impact of the ongoing COVID-19 pandemic. While management believes current cash resources and future cash received from the Company's net product sales and collaboration agreements with Daiichi Sankyo Europe GmbH ("DSE"), Otsuka Pharmaceutical Co., Ltd ("Otsuka"), and Daiichi Sankyo Co. Ltd ("DS"), entered into on January 2, 2019, April 17, 2020 and April 26, 2021, respectively, 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.

Esperion Therapeutics, Inc.

Notes to Financial Statements (Continued)

1. The Company and Basis of Presentation (Continued)

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. Pursuant to the Amendment and Waiver (as defined below), in 2021 the Company deposited \$50.0 million in a deposit account that was subject to a block account control agreement. Oberland had the sole control over the funds deposited in the account and such funds could be withdrawn only with the consent of Oberland. On November 23, 2022, pursuant to the Waiver and Amendment No.3, the Company agreed to make a one-time partial call payment with regards to the Revenue Interests (as defined in the RIPA) in the amount of \$50.0 million, the full amount that was subject to the block account control agreement. Refer to Note 10 "Liability Related to the Revenue Interest Purchase Agreement" for further information on the Amendment and Waiver.

Investments

Investments are considered to be available-for-sale and are carried at fair value. Unrealized gains and losses, if any, are reported in accumulated other comprehensive income (loss). 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 \$11.3 million and \$13.7 million for the years ended December 31, 2022 and December 31, 2021, respectively.

Esperion Therapeutics, Inc.**Notes to Financial Statements (Continued)****2. Summary of Significant Accounting Policies (Continued)****Concentration of Credit Risk**

Cash, cash equivalents, and investments 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, 2022, eleven customers accounted for all of the Company's net trade receivables and as of December 31, 2021 nine customers accounted for all 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 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 accounts receivable, 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.

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 and right-of-use operating lease assets, 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, 2022.

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

Esperion Therapeutics, Inc.**Notes to Financial Statements (Continued)****2. Summary of Significant Accounting Policies (Continued)**

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

In August 2020, the FASB issued Accounting Standards Update ("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"). ASU 2020-06 simplified 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 required 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 resulted in the reclassification of the portion of the Company's convertible notes from equity to debt, which also reduced reported interest expense and increased 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 was 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 early adopted this standard on January 1, 2021 which resulted 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 tax impact of the adoption was not material to the Company.

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 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.

Esperion Therapeutics, Inc.**Notes to Financial Statements (Continued)****2. Summary of Significant Accounting Policies (Continued)**

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.

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 \$55.9 million and \$40.0 million for the year ended December 31, 2022 and December 31, 2021, respectively.

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 in the balance sheets.

Esperion Therapeutics, Inc.**Notes to Financial Statements (Continued)****2. Summary of Significant Accounting Policies (Continued)***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 historical returns sales information and visibility into the inventory remaining in the distribution channel.

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 and tablets supplied to collaboration partners under 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.

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.

Esperion Therapeutics, Inc.**Notes to Financial Statements (Continued)****2. Summary of Significant Accounting Policies (Continued)****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. The fair value for stock options and performance-based stock options is calculated using a Black-Scholes option-pricing model. If the instruments contain performance conditions, compensation expense is recognized only if achievement of the performance condition is probable. The Company accounts for forfeitures as they occur. Expense is recognized during the period the related services are rendered.

Recent Accounting Pronouncements

The Company does not expect adoption of any recently issued accounting pronouncements to have a material impact on the financial statements.

3. Collaborations with Third Parties**DSE Agreement Terms**

On January 2, 2019, the Company entered into a license and collaboration agreement with DSE, which was further amended on June 18, 2020. Pursuant to the agreement (as amended), the Company granted DSE exclusive commercialization rights to bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the European Economic Area, Turkey and Switzerland (“DSE Territory”). DSE will be responsible for commercialization in the DSE Territory. 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. The Company remains responsible for clinical development, regulatory and manufacturing activities for the licensed products globally, included in the DSE Territory outside of Turkey.

Pursuant to the agreement, the Company received upfront cash of \$150.0 million in 2019, and a \$150.0 million cash payment to the Company in 2020 following the completion of the NUSTENDI Marketing Authorisation Applications (“MAA”). The Company 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.

Collaboration Revenue

During the years ended December 31, 2022 and December 31, 2021, the Company recognized collaboration revenue of \$18.2 million and \$9.9 million, respectively, related to royalty revenue from DSE as well as the sales of bulk tablets to DSE pursuant to the supply agreement that was executed with DSE.

Esperion Therapeutics, Inc.**Notes to Financial Statements (Continued)****3. Collaborations with Third Parties (Continued)**

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 occur.

Otsuka Agreement Terms

On April 17, 2020, the Company entered into a license and collaboration agreement ("the Otsuka Agreement") with 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. 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 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 inclusion of the CV risk reduction indication in 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.

Collaboration Revenue

During the year ended December 31, 2022, the Company recognized \$0.6 million of collaboration revenue related to sales of bulk tablets to Otsuka pursuant to the supply agreement that was executed with Otsuka. During the year ended December 31, 2021, the Company did not recognize any revenue related to the agreement.

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.

DS Agreement Terms

Pursuant to the license and collaboration agreement ("DS Agreement"), executed in April 2021, the Company granted DS exclusive rights to develop and commercialize bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the DS Territory. The agreement allows for potential expansion across geographies including Saudi Arabia, Kuwait, Oman, UAE, Qatar, Bahrain, Yemen, Colombia and other Latin American countries. Except for certain development activities in South Korea and Taiwan, DS will be responsible for development and commercialization in these territories. In addition, DS will fund all development costs associated with the program in the DS Territory. Pursuant to the agreement, the consideration consists of a \$30.0 million upfront cash payment that is non-refundable, non-reimbursable and non-creditable. The Company will be eligible to receive additional one-time payments of up to \$175.0 million if certain commercial milestones are achieved by DS. Also, the Company will receive tiered royalties of five percent (5%) to twenty percent (20%) of net sales in the DS Territory.

Collaboration Revenue

The Company considered the guidance under ASC 606 and concluded that the DS Agreement was in the scope of ASC 606. The Company concluded that the upfront payment of \$30.0 million should be included in the transaction price and related to the following performance obligations under the DS Agreement: 1) the license to the Company's intellectual property and 2) the obligation to provide ongoing development activities. The Company used the adjusted market assessment approach in

Esperion Therapeutics, Inc.

Notes to Financial Statements (Continued)

3. Collaborations with Third Parties (Continued)

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 development activities. Accordingly, during the year ended December 31, 2021, the Company recognized \$28.5 million of collaboration revenue related to the \$30.0 million upfront payment. The \$28.5 million relates 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 year ended December 31, 2021, in the amounts of \$28.0 million and \$0.5 million, respectively. During the year ended December 31, 2022, the Company recognized \$0.8 million of collaboration revenue related to the ongoing regulatory and development activities. The remaining \$0.7 million of the upfront payment was deferred as of December 31, 2022 due to an on-going performance obligation related to the developmental activities in South Korea and Taiwan. This deferred revenue will be recognized ratably over the period leading up to the completion of these developmental activities.

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.

Other Agreements

In 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 low to mid-single-digit percentages.

4. Inventories, net

Inventories, net consist of the following:

	December 31,	
	2022	2021
	(in thousands)	
Raw materials	\$ 26,558	\$ 31,850
Work in process	6,548	663
Finished goods	2,095	1,881
	\$ 35,201	\$ 34,394

5. Commitments and Contingencies

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

Esperion Therapeutics, Inc.
Notes to Financial Statements (Continued)
5. Commitments and Contingencies (Continued)

stock price between August 18, 2015, and September 28, 2015, as well as attorneys' fees and costs. On March 12, 2021, the parties agreed to a settlement in principle of the securities class action, and on April 26, 2021, the parties entered into a stipulation of settlement to resolve all legal claims, in which defendants expressly deny that they have committed any act or omission giving rise to any liability under Section 10(b) of the Securities Exchange Act of 1934. Under the terms of the stipulation of settlement, which the court approved on August 24, 2021, the Company and certain of the Company's insurance carriers caused a payment of \$18.25 million to be made to the plaintiff class. As a result of this settlement agreement, the Company recorded a loss on settlement of \$13.25 million during 2021 in selling, general, and administrative expenses on the statements of operations and comprehensive loss, which represents the litigation settlement of \$18.25 million offset by \$5.0 million in insurance claim proceeds from our insurance carriers.

6. Property and Equipment, net

Property and equipment, net, consist of the following:

	December 31,	
	2022	2021
	(in thousands)	
Computer equipment	\$ 278	\$ 278
Software	968	968
Furniture, fixtures and other	1,170	1,170
Leasehold improvements	299	299
Subtotal	2,715	2,715
Less accumulated depreciation and amortization	2,551	2,051
Property and equipment, net	<u>\$ 164</u>	<u>\$ 664</u>

Depreciation expense was \$0.5 million and \$0.6 million for the years ended December 31, 2022 and 2021, respectively.

7. Other Accrued Liabilities

Other accrued liabilities consist of the following:

	December 31,	
	2022	2021
	(in thousands)	
Accrued compensation	\$ 9,053	\$ 8,809
Accrued variable consideration	21,987	16,192
Accrued professional fees	2,547	3,917
Accrued interest on convertible notes	1,325	1,325
Accrued other	279	167
Total other accrued liabilities	<u>\$ 35,191</u>	<u>\$ 30,410</u>

Esperion Therapeutics, Inc.
Notes to Financial Statements (Continued)
8. Investments

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

	December 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
(in thousands)				
Cash equivalents:				
Money market funds	\$ 105,078	\$ —	\$ —	\$ 105,078
U.S. treasury notes	4,994	1	—	4,995
Certificates of deposit	401	—	—	401
Short-term investments:				
U.S. treasury notes	42,089	2	(5)	42,086
Total	\$ 152,562	\$ 3	\$ (5)	\$ 152,560

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
(in thousands)				
Cash equivalents:				
Money market funds	\$ 188,734	\$ —	\$ —	\$ 188,734
Certificates of deposit	400	—	—	400
Short-term investments:				
U.S. treasury notes	50,472	—	(31)	50,441
Total	\$ 239,606	\$ —	\$ (31)	\$ 239,575

During the years ended December 31, 2022 and 2021, other income, net in the statements of operations includes interest income on available-for-sale investments of \$2.4 million and \$0.1 million, respectively. Other income, net in the statements of operations includes amortization of premiums and discounts on investments of \$0.2 million and less than \$0.1 million during the years ended December 31, 2022 and 2021, respectively.

At December 31, 2022, 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.

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 years ended December 31, 2022 and 2021.

Esperion Therapeutics, Inc.

Notes to Financial Statements (Continued)

9. 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
December 31, 2022				
Assets:				
Money market funds	\$ 105,078	\$ 105,078	\$ —	\$ —
Certificates of deposit	401	401	—	—
U.S. treasury notes	47,081	47,081	—	—
Total assets at fair value	\$ 152,560	\$ 152,560	\$ —	\$ —
December 31, 2021				
Assets:				
Money market funds	\$ 188,734	\$ 188,734	\$ —	\$ —
Certificates of deposit	400	400	—	—
U.S. treasury notes	50,441	50,441	—	—
Total assets at fair value	\$ 239,575	\$ 239,575	\$ —	\$ —

There were no transfers between Levels 1, 2 or 3 during the years ended December 31, 2022 or December 31, 2021.

10. 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 was 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”). In March 2020, the Company received \$25.0 million from Oberland upon receiving regulatory approval of NEXLETOL.

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 if annual net sales equal or exceed the Sales Threshold and if the Purchasers receive 100% of their invested

Esperion Therapeutics, Inc.**Notes to Financial Statements (Continued)****10. Liability Related to the Revenue Interest Purchase Agreement (Continued)**

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.

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.

RIPA Amendments

On April 26, 2021, the Company entered into Amendment No. 2 (the "RIPA Amendment 2") to the RIPA with Oberland, as agent for the purchaser parties thereto. Pursuant to the RIPA Amendment 2, Oberland waived the original trailing six-month world-wide net sales condition to the third installment payment under the RIPA and released the final \$50 million payment payable to the Company under the terms of the RIPA. The Company and Oberland also agreed to amend additional terms of the RIPA such that the purchasers will have a right to receive certain revenue interests (the "Revenue Interests") from the Company based on net sales of the Company's certain products, once approved, which will be tiered payments ranging from 3.33% to 10% (the "Third Payment Applicable Percentage") of the Company's net sales in the covered territory (the "Covered Territory"); provided that (a) prior to December 31, 2024, with respect to each country defined in the Daiichi Territory, if the percentage of net sales that Company receives from Daiichi (the "Receivables Percentage") is less than the Third Payment Applicable Percentage, then the Revenue Interest for such country payable to the purchasers will be equal to the Receivables Percentages, (b) if annual net sales equal or exceed \$350 million and if the Purchasers receive 100% of their invested capital (Cumulative Purchaser Payments) by December 31, 2024, the revenue interest rate will be decreased to a single rate of 3.33% of the Company's net sales in the Covered Territory for all subsequent calendar quarters and (c) if the Purchasers receive Revenue Interest payments less than 100% of Cumulative Purchaser Payments by December 31, 2024, the Third Payment Applicable Percentage will be increased to a single rate of the Company's net sales that would have provided 100% of Cumulative Purchaser Payments had such rate applied from the initial funding by the Purchasers. The Covered Territory was originally the United States, but has been expanded to worldwide for all calendar years beginning on or after January 1, 2022.

Under the RIPA Amendment 2, 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 or the Call Option are exercised, the required repurchase price will be 200% 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 225% 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 accordance with the guidance in ASC 470-50, "Debt—Modifications and Extinguishments," the RIPA Amendment 2 was accounted for as a debt modification. The amendment resulted in a \$0.1 million loss on modification of debt, consisting of third-party fees associated with the transaction, which is included in selling, general, and administrative expenses in the statements of operations for the year ended December 31, 2021.

On May 16, 2021, the Company entered into an Amendment to the Security Agreement and Waiver ("Amendment and Waiver") with the same parties to the Security Agreement, by and among the Company, Eiger Partners II LP (the "Purchaser") and Eiger III SA LLC (the "Purchaser Agent"), dated as of June 26, 2019 (the "Security Agreement"). Pursuant to the Amendment and Waiver, if (i) the net revenue from sales of NEXLETOL and NEXLIZET and certain other products in the

Esperion Therapeutics, Inc.**Notes to Financial Statements (Continued)****10. Liability Related to the Revenue Interest Purchase Agreement (Continued)**

United States (as reported in the Company's financial statements as "product sales, net" in accordance with GAAP and excluding, for the avoidance of doubt, upfront or milestone payments and other collaboration revenue) (the "Specified Net Revenue") for the calendar quarter ended September 30, 2021 does not exceed \$15.0 million, or (ii) the Specified Net Revenue for any calendar quarter ending after September 30, 2021 does not exceed \$15.0 million, then the Company shall deposit \$50.0 million in a deposit account that is subject to a block account control agreement in favor of the Purchase Agent, no later than the earlier of (x) the date the Specified Net Revenue for such calendar quarter has been determined and (y) 45 days after the last day of such calendar quarter. Since the Specified Net Revenue for the calendar quarter ended September 30, 2021 did not exceed \$15.0 million, the Company deposited \$50.0 million in a deposit account that is subject to a block account control agreement, which is classified as restricted cash on the balance sheets. The Purchaser Agent shall have sole dominion and control over all funds deposited in the deposited account and such funds may be withdrawn therefrom only with the consent of the Purchaser Agent. Upon the occurrence and during the continuance of a Put Option Event, the Purchaser Agent shall have the right to apply amounts held in the deposit account in payment of certain secured obligations in the manner provided for in the Security Agreement. The Amendment and Waiver does not substitute, replace or release the Pledgors from any other obligations under the RIPA or Security Agreement.

On November 23, 2022, the Company entered into Waiver and Amendment No. 3 to Revenue Interest Purchase Agreement and Amendment No. 2 to Security Agreement (the "RIPA Amendment 3"), by and among the Company, the Purchasers and the Purchaser Agent, which amends (i) the Revenue Interest Purchase Agreement, by and among the Company, the Purchasers, and the Purchaser Agent, dated effective as of June 26, 2019 (as amended by Amendment No. 1 to Revenue Interest Purchase Agreement dated as of November 9, 2020 and Amendment No. 2 to Revenue Interest Purchase Agreement dated as of April 26, 2021, and as may be further amended, restated, supplemented or modified from time to time, the "RIPA") and (ii) the Security Agreement, by the Company in favor of the Purchaser Agent, dated as of June 28, 2019 (as amended by the Amendment to Security Agreement and Waiver by and among the Company, the Purchaser and the Purchaser Agent, effective as of May 16, 2021, and as may be further amended, restated, supplemented or modified from time to time, the "Security Agreement"). Pursuant to the RIPA Amendment 3, among other things, (a) the Company agreed to make a one-time partial call payment with regards to the Revenue Interests (as defined in the RIPA) in an amount equal to \$50 million from the restricted cash account (the "Partial Call"), (b) the amount of the Cumulative Purchaser Payments (as defined in the RIPA) was reduced to \$177,777,778, and (c) the Purchasers and Purchaser Agent waived certain claimed defaults, breaches and Put Option Events under the RIPA and other related documents that may have occurred as a result of the Company's opening of a new bank account.

In accordance with the guidance in ASC 470-50, "Debt—Modifications and Extinguishments," the RIPA Amendment 3 was accounted for as a debt modification. The amendment resulted in a less than \$0.1 million loss on modification of debt, consisting of third-party fees associated with the transaction, which is included in selling, general, and administrative expenses in the statements of operations for the year ended December 31, 2022.

In connection with the arrangement, as of December 31, 2022, the Company has recorded a liability, referred to as the "Revenue interest liability" on the balance sheet, of \$243.6 million, net of \$0.3 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 total redemption amount is equal to 225% of the Cumulative Purchaser Payments, or \$400 million. 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 future net sales will materially impact the revenue interest liability, interest expense and the time period for repayment. The Company recorded approximately \$44.6 million and \$33.9 million in interest expense related to this arrangement for the years ended December 31, 2022 and 2021, 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 225% of the Cumulative Purchaser Payments. 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,

Esperion Therapeutics, Inc.

Notes to Financial Statements (Continued)

10. Liability Related to the Revenue Interest Purchase Agreement (Continued)

less than or equal to \$250 million in an annual aggregate year, would result in a repayment obligation of approximately \$10.0 million or 10.0% 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 \$3.3 million or 3.3% for every \$100 million of sales above the threshold. As the U.S. net sales were less than \$350 million for the year ended December 31, 2021, the Covered Territory was 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 \$24.8 million in the next twelve months.

The effective annual imputed interest rate is 18.3% as of December 31, 2022. 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 years ended December 31, 2022 and 2021:

	(in thousands)
Revenue interest liability at December 31, 2020	\$ 176,604
Oberland funding upon execution of Amendment No. 2, net of issuance costs (\$83)	49,917
Interest expense recognized	33,907
Revenue interest payments	(3,389)
Revenue interest liability at December 31, 2021	<u>\$ 257,039</u>
Repayment upon execution of Amendment No. 3	(50,000)
Interest expense recognized	44,590
Revenue interest payments	(8,024)
Revenue interest liability at December 31, 2022	<u>\$ 243,605</u>

11. Convertible Notes

In November 2020, the Company issued \$280.0 million aggregate principal amount of 4.0% senior subordinated convertible notes due November 2025. The net proceeds the Company received from the offering was approximately \$271.1 million, after deducting the initial purchasers’ discounts and commissions and offering expenses payable by the Company (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 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.

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

Esperion Therapeutics, Inc.**Notes to Financial Statements (Continued)****11. Convertible Notes (Continued)**

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 Company incurred approximately \$8.9 million of issuance costs related to the issuance of the Convertible Notes. Prior to the adoption of ASU 2020-06 on January 1, 2021, 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.

With the adoption of ASU 2020-06 as of January 1, 2021, the Company reports the convertible debt liability at the aggregate principal amount less unamortized issuance costs. This resulted in the reclassification of the \$93.5 million of the Company's convertible notes recognized at December 31, 2020 from additional paid in capital to the convertible debt liability. The portion of interest expense previously recognized for the accretion of the convertible debt liability and the true-up of the amortization of the issuance costs of \$1.5 million was recorded as an adjustment to accumulated deficit.

On October 22, 2021, the Company entered into a privately negotiated exchange agreement (the "Exchange Agreement") with two co-managed holders (the "Holders") of its Convertible Notes. Under the terms of the Exchange Agreement the Holders agreed to exchange (the "Exchange") with the Company \$15.0 million aggregate principal amount of the Convertible Notes held in the aggregate by them (and accrued interest thereon) for shares of the Company's common stock. Pursuant to the Exchange Agreement, the number of shares of common stock to be issued by the Company to the Holders upon consummation of the Exchange was determined based upon the volume-weighted-average-price per share of common stock, subject to a floor of \$5.62 per share, during the five trading-day averaging period, commencing on the trading day immediately following the date of the Exchange Agreement. The Exchange closed on November 3, 2021 with 1,094,848 shares of the Company's common stock being exchanged.

The Company accounted for the Exchange as an extinguishment of a liability and calculated the gain on extinguishment of debt under ASC 470-50-40, which requires the difference between the reacquisition price of the debt and the net carrying amount of the extinguished debt to be recognized in the income statement. The reacquisition price of the Convertible Notes was calculated by the number of shares exchanged times the closing price of the common shares on the day of settlement plus any transactional costs incurred during the reacquisition. The net carrying amount of the debt was calculated by the face value of the notes less the unamortized debt issuance costs associated with the face value of the notes. The Company recognized a gain of

Esperion Therapeutics, Inc.**Notes to Financial Statements (Continued)****11. Convertible Notes (Continued)**

\$2.6 million in "Other Income" on the Statements of Operations and Comprehensive Loss during the year ended December 31, 2021.

As of December 31, 2022, the principal amount of convertible notes was \$265.0 million, and the unamortized debt discount and issuance costs were \$5.1 million, for a net carrying amount of \$259.9 million. As of December 31, 2021, the principal amount of convertible notes was \$265.0 million, and the unamortized debt discount and issuance costs were \$6.7 million, for a net carrying amount of \$258.3 million.

The Company recorded \$12.2 million and \$12.4 million of interest expense during the years ended December 31, 2022 and 2021, respectively, relating to the cash interest on the convertible notes due semi-annually and amortization of the debt issuance costs.

As of December 31, 2022, no Convertible Notes were convertible pursuant to their terms. The estimated fair value of the Convertible Notes was \$145.9 million as of December 31, 2022 and \$140.3 million as of December 31, 2021. The estimated fair value of the Convertible Notes was determined through consideration of quoted market prices. As of December 31, 2022, the if-converted value of the Convertible Notes did not exceed the principal value of those notes.

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, 2022, 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. As of December 31, 2022, 71,174 shares had been delivered 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.

Esperion Therapeutics, Inc.**Notes to Financial Statements (Continued)****12. Stockholders' Deficit***ATM Offering*

On August 3, 2021, the Company filed an automatically effective registration statement on Form S-3ASR (the "Registration Statement") with the SEC which registers the offering, issuance and sale of an unspecified amount of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof. The Company simultaneously entered into an open market sale agreement with Jefferies LLC, as sales agent, to provide for the issuance and sale by the Company of up to \$250 million of common stock from time to time in "at-the-market" offerings under the Registration Statement and related prospectus filed with the Registration Statement (the "ATM Program"). During the year ended December 31, 2021, the Company issued 897,364 shares of common stock resulting in net proceeds of approximately \$9.7 million after deducting \$0.5 million of underwriting discounts and commissions and other expenses, pursuant to the ATM Program.

On April 15, 2022, the Company filed a new registration statement on Form S-3 to replace its prior automatically effective registration statement on Form S-3ASR filed on August 3, 2021, which registers the offering, issuance and sale of up to \$239 million of common stock from time to time in "at-the-market" offerings (the "New ATM Program"). On February 21, 2023, we terminated the open market sales agreement with Jefferies LLC and entered into a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co., as sales agent, to provide for the issuance and sale by the Company of up to \$70 million of common stock from time to time in "at-the-market" offerings, or the 2023 ATM Program, pursuant to our existing Form S-3 and the prospectus supplement to be filed on February 21, 2023. The Company may continue to use the 2023 ATM Program to address potential short-term or long-term funding requirements that may arise. Such program will continue to be subject to the volatility of the price of the Company's common stock and general market conditions. During the year ended December 31, 2022, the Company issued 13,043,797 shares of common stock resulting in net proceeds of approximately \$90.8 million after deducting \$3.1 million of underwriting discounts and commissions and other expenses, pursuant to the New ATM Program.

Offering

On December 2, 2021, the Company entered into an underwriting agreement with H.C. Wainwright & Co., LLC ("Wainwright"). Pursuant to the underwriting agreement, the Company agreed to sell, in a firm commitment offering, 32,142,858 shares of common stock, \$0.001 par value per share, and accompanying warrants to purchase up to an aggregate of 32,142,858 shares of common stock, as well as up to 4,821,428 additional shares of common stock and/or accompanying warrants to purchase an aggregate of up to 4,821,428 shares of its common stock that may be purchased by Wainwright pursuant to a 30-day option granted to Wainwright by the Company (the "Offering"). Each share of common stock was sold together with a common warrant to purchase one share of common stock, at an exercise price of \$9.00 per share. Such common warrants are immediately exercisable and will expire two years from the date of issuance. The combined public offering price of each share of common stock and accompanying common warrant sold in the Offering was \$7.00, and the combined price of each share of common stock and accompanying common warrant purchased by Wainwright from the Company was \$6.51. On December 3, 2021, Wainwright exercised its option to purchase additional warrants to purchase 4,821,428 shares of Common Stock. The Offering, including the additional warrants sold pursuant to the exercise of Wainwright's option to purchase additional warrants, closed on December 7, 2021. The aggregate net proceeds received by the Company from the offering was \$208.7 million, after deducting \$16.3 million of underwriting discounts and commissions and other estimated offering expenses payable by the Company and excluding the net proceeds, if any, from the exercise of the common warrants.

Warrants

In connection with the Offering, the Company issued warrants to purchase 36,964,286 shares of common stock at an exercise price of \$9.00. The warrants will terminate on December 7, 2023. The warrants were recorded at fair value of \$61.9 million to additional-paid-in-capital in accordance with ASC 815-10 based upon the allocation of the proceeds between the common shares issued with the Offering and the warrants. The Company estimated the fair value of the warrants using a Black-Scholes option-pricing model, which is based, in part, upon subjective assumptions including but not limited to stock price volatility, the expected life of the warrant, the risk-free interest rate and the fair value of the common stock underlying the warrant. The Company estimates the volatility based on its historical volatility that is in line with the expected remaining life of the warrants. The risk-free interest rate is based on the U.S. Treasury daily rate for a maturity similar to the expected remaining life of the warrants. The expected remaining life of the warrants is assumed to be equivalent to its remaining contractual term.

Esperion Therapeutics, Inc.**Notes to Financial Statements (Continued)****12. Stockholders' Deficit (Continued)**

As of December 31, 2022, the Company had warrants outstanding that were exercisable for a total of 36,964,286 shares of common stock at a weighted-average exercise price of \$9.00 per share.

13. Stock Compensation**2022 Stock Option and Incentive Plan**

In May 2022, the Company's stockholders approved the 2022 Stock Option and Incentive Plan (the "2022 Plan"). The number of shares of common stock available for awards under the 2022 Plan was set to 4,400,000, with any shares underlying awards that are forfeited, canceled, held back upon exercise of an option 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 shares, or otherwise terminated (other than by exercise) under the 2022 Plan may be added back to the shares of common stock available for issuance under the 2022 Plan. The 2022 Plan provides for the award of stock options (both incentive and non-qualified options), stock appreciation rights, restricted stock, restricted stock units ("RSUs"), unrestricted stock, cash-based awards, and dividend equivalent rights. Following the approval of the 2022 Plan, no further awards will be issued under the Company's 2013 Stock Option and Incentive Plan (the "2013 Plan").

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 years ended December 31, 2022 and 2021, the Company recognized \$0.4 million and \$0.7 million of stock compensation expense related to the ESPP, respectively. As of December 31, 2022, there have been 339,422 shares issued and 485,578 shares reserved for future issuance under the ESPP.

2017 Inducement Equity Plan

In May 2017, and as amended in 2019, 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 is 1,150,000, 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.

2013 Stock Option and Incentive Plan

In May 2015, the Company's stockholders approved the amended and restated 2013 Plan which, among other things, increased the number of shares of common stock reserved for issuance 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

Esperion Therapeutics, Inc.

Notes to Financial Statements (Continued)

13. Stock Compensation (Continued)

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.

The Company incurs stock-based compensation expense related to stock options, performance-based stock options ("PBSOs"), RSUs and performance-based restricted stock units ("PBRsUs"). The fair value of RSUs and PBRsUs is determined by the closing market price of the Company's common stock on the date of grant. The fair value of stock options and PBSOs 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 2022 Plan, 2017 Plan, and 2013 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, 2022:

	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	3,214,537	\$ 38.38	4.18	\$ —
Granted	1,321,600	\$ 4.80		
Forfeited or cancelled (vested and unvested)	(693,400)	\$ 33.29		
Exercised	—	\$ —		
Outstanding at December 31, 2022	<u>3,842,737</u>	\$ 27.75	4.86	\$ 1,658
Vested and expected to vest at December 31, 2022	<u>3,842,737</u>	\$ 27.75	4.86	\$ 1,658
Exercisable at December 31, 2022	<u>2,517,412</u>	\$ 37.48	2.64	\$ 185

No stock options were exercised during the year ended December 31, 2022. The total pre-tax intrinsic value of stock options exercised during the years ended December 31, 2021 was \$4.7 million.

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 two years ending December 31, 2022, using the Black-Scholes option-pricing model:

	Year ended December 31,	
	2022	2021
Risk-free interest rate	2.26%	0.79%
Dividend yield	—	—
Weighted-average expected life of options (years)	6.16	6.24
Volatility	81%	83%

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

Esperion Therapeutics, Inc.

Notes to Financial Statements (Continued)

13. Stock Compensation (Continued)

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. The Company estimates volatility based on the Company's historical stock prices over the expected life of the stock options.

The weighted-average grant-date fair values of stock options granted during the years ended December 31, 2022 and 2021, were \$3.38 and \$19.19, respectively. During the years ended December 31, 2022 and 2021, the Company recognized stock-based compensation expense related to stock options of \$5.6 million and \$14.6 million, including \$0.6 million and \$1.5 million that was capitalized into inventory, respectively.

As of December 31, 2022, there was approximately \$7.7 million of unrecognized compensation cost related to unvested options, which will be recognized over a weighted-average period of approximately 2.5 years.

Restricted Stock Units

The following table summarizes the activity relating to the Company's RSUs for the year ended December 31, 2022:

	<u>Number of RSUs</u>	<u>Weighted-Average Fair Value Per Share</u>
Outstanding and unvested at December 31, 2021	698,704	\$ 28.09
Granted	1,905,909	\$ 4.97
Forfeited or expired	(395,731)	\$ 12.61
Vested	<u>(440,697)</u>	\$ 19.39
Outstanding and unvested at December 31, 2022	<u><u>1,768,185</u></u>	\$ 8.80

During the years ended December 31, 2022 and 2021, the Company recognized stock-based compensation expense related to RSUs of \$6.6 million, including \$0.7 million that was capitalized into inventory, and \$8.1 million, including \$0.7 million that was capitalized into inventory, respectively. As of December 31, 2022, there was approximately \$14.3 million of unrecognized stock-based compensation expense related to unvested RSUs, which will be recognized over a weighted-average period of approximately 2.7 years.

Performance-based Restricted Stock Units ("PBRsUs")

In 2021, the Company granted PBRsUs from the 2013 Plan that vest upon various performance-based milestones as set forth in the individual grant agreements, such as achievement of predetermined milestones based on the Company's U.S. net product sales or clinical or regulatory outcomes. The actual number of units (if any) received under these awards will depend on continued employment and actual performance over the performance period. Each quarter, the Company updates their assessment of the probability that the performance milestone will be achieved. The Company amortizes the fair value of the PBRsUs based on the expected performance period to achieve the performance milestone. The fair value of the PBRsUs is based on the quoted market price of the Company's common stock on the date of grant. The Company expects the performance criteria to be met.

Esperion Therapeutics, Inc.

Notes to Financial Statements (Continued)

13. Stock Compensation (Continued)

The following table summarizes the activity relating to the Company's PBRsUs for the year ended December 31, 2022:

	Numbers of PBRsUs	Weighted-Average Fair Value Per Share
Outstanding and unvested at December 31, 2021	639,950	\$ 9.90
Granted	—	\$ —
Forfeited	(178,700)	\$ 10.95
Vested	—	\$ —
Outstanding and unvested at December 31, 2022	<u>461,250</u>	<u>\$ 9.50</u>

Stock-based compensation related to the PBRsUs was approximately \$1.8 million, including \$0.2 million that was capitalized into inventory for the year ended December 31, 2022. Stock-based compensation related to PBRsUs was approximately \$0.8 million for the year ended December 31, 2021. As of December 31, 2022, there was approximately \$1.3 million of unrecognized stock-based compensation expense related to unvested PBRsUs, which will be recognized over a weighted-average period of approximately 1.5 years.

Performance-based stock options ("PBOs")

In 2021 and 2022, the Company granted PBOs from the 2013 Plan and the 2022 Plan, respectively, that vest upon various performance-based milestones as set forth in the individual grant agreements, such as achievement of predetermined clinical or regulatory outcomes. The actual number of units (if any) received under these awards will depend on continued employment and actual performance over the performance period. Each quarter, the Company updates their assessment of the probability that the performance milestone will be achieved. The Company amortizes the fair value of the PBOs based on the expected performance period to achieve the performance milestone. The fair value of the PBOs is based on the Black Scholes model as detailed in the stock option section above. The Company expects the performance criteria to be met. The weighted-average grant-date fair value of PBOs granted during the years ended December 31, 2022 and December 31, 2021 was \$4.36 and \$6.04, respectively.

The following table summarizes the activity relating to the Company's performance-based stock options for the year ended December 31, 2022

	Number of PBOs	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	122,700	\$ 8.94	9.83	\$ —
Granted	403,000	\$ 6.20		
Forfeited	<u>(26,500)</u>	\$ 8.94		
Outstanding at December 31, 2022	<u>499,200</u>	\$ 6.73	9.32	\$ 12
Vested and expected to vest at December 31, 2022	<u>499,200</u>	\$ 6.73	9.32	\$ 12

Stock-based compensation related to the PBOs was approximately \$0.8 million and \$0.1 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, there was approximately \$1.5 million of unrecognized stock-based compensation expense related to unvested PBOs, which will be recognized over a weighted-average period of approximately 1.4 years. There were no PBOs exercisable as of December 31, 2022.

Esperion Therapeutics, Inc.

Notes to Financial Statements (Continued)

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, 2022 and 2021, were \$0.7 million and \$2.2 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 was renewed in December 2022 and has a lease term of 5 years from November 1, 2023, and the automobile leases and IT equipment leases primarily have a term of 3 years. During the years ended December 31, 2022 and December 31, 2021, the Company recognized \$1.3 million and \$2.4 million, respectively, of operating lease costs, recognized on the statements of operations and comprehensive loss, and paid cash for the amounts included in the measurement of lease liabilities of \$1.2 million and \$2.4 million, respectively, which were included in operating cash flows on the statements of cash flows. At December 31, 2022 and December 31, 2021, the weighted-average remaining lease term of operating leases was 4.7 years and 1.4 years, respectively, and the weighted average discount rate was 7.7% and 4.7%, respectively. There was \$0.6 million and \$0.1 million in right-of-use assets obtained in exchange for lease obligations for the twelve months ended December 31, 2022 and December 31, 2021, respectively. The Company had no additional operating and finance leases that have not yet commenced as of December 31, 2022.

The following table summarizes the Company's future maturities of operating lease liabilities as of December 31, 2022:

	(in thousands)
2023	\$ 461
2024	175
2025	159
2026	164
2027	169
2028 and beyond	144
Total lease payments	1,272
Less imputed interest	(223)
Total	\$ 1,049

The following table summarizes supplemental balance sheet information related to leases as of December 31, 2022:

Operating Leases	(in thousands)
Total right of use operating lease assets	\$ 1,036
Operating lease liabilities (short-term)	\$ (384)
Operating lease liabilities (long-term)	(665)
Total lease obligations under operating leases	\$ (1,049)

16. Income Taxes

There was no provision for income taxes for the years ended December 31, 2022 and 2021 because the Company has incurred operating losses since inception. At December 31, 2022, 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.

Esperion Therapeutics, Inc.

Notes to Financial Statements (Continued)

16. Income Taxes (Continued)

As of December 31, 2022 and 2021, the Company had net deferred tax assets, before valuation allowance, of approximately \$352.1 million and \$284.2 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, 2022 and 2021, the Company had federal net operating loss (“NOL”) carryforwards of approximately \$950.8 million and \$894.3 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, 2022 and 2021, the Company had state NOL carryforwards of approximately \$698.4 million and \$662.2 million, respectively. The state NOL carryforwards will expire at various dates beginning in 2022, if not utilized.

The Company has research and developmental tax credits of \$21.0 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,	
	2022	2021
Federal income tax (benefit) at statutory rate	(21.0)%	(21.0)%
Change in state tax rate	(0.5)%	0.9 %
Permanent items	0.1 %	0.1 %
Prior period adjustments	(3.6)%	— %
Other	— %	0.4 %
Change in valuation allowance	25.0 %	19.6 %
Effective income tax rate	<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. Some of the U.S. Federal and State net operating loss and credit carryforwards are subject to annual limitations due to ownership changes. The annual limitation may result in the expiration of net operating losses or credit carryforwards before utilization. The Company determined a change of ownership occurred in 2017 and 2021.

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 no material adjustment for unrecognized income tax benefits. Through December 31, 2022, the Company had accrued \$2.1 million for unrecognized income tax benefits and related interest and penalties against credits.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows. The Company does not expect this amount to change in the next twelve months. At December 31, 2022, 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)

	December 31,	
	2022	2021
	(in thousands)	
Balance at January 1	\$ 2,099	\$ 2,606
Reductions for tax positions of prior year	—	(507)
Balance at December 31	2,099	2,099

Significant components of the Company's deferred tax assets are summarized in the table below:

	December 31,	
	2022	2021
	(in thousands)	
Deferred tax assets:		
Federal and state operating loss carryforwards	\$ 242,584	\$ 219,237
Equity compensation	26,243	22,735
Capitalized research and development	26,480	—
R&D tax credits, net of reserves	18,887	18,887
Disallowed interest	29,979	16,146
Temporary differences	8,340	7,695
Total deferred tax assets	352,513	284,700
Deferred tax liabilities:		
Other	(400)	(546)
Total deferred tax liabilities	(400)	(546)
Valuation allowance	(352,113)	(284,154)
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, PBSOs, unvested RSUs and PBRsUs, 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, 2022	December 31, 2021
Common shares under option	3,842,737	3,214,537
Unvested RSUs	1,768,185	698,704
Shares issuable related to the ESPP	27,558	23,448
Unvested PBRsUs	461,250	639,950
Common shares under PBSOs	499,200	122,700
Shares issuable upon conversion of convertible notes	8,007,010	8,007,010
Warrants for common stock	36,964,286	36,964,286
Total potential dilutive shares	51,570,226	49,670,635

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, 2022 and 2021 (in thousands).

	December 31, 2022	December 31, 2021
Cash and cash equivalents	\$ 124,775	\$ 208,892
Restricted cash	—	50,000
Total cash, cash equivalents and restricted cash shown on the statements of cash flows	<u>\$ 124,775</u>	<u>\$ 258,892</u>

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

- Registration Statement (Form S-3 No. 333-264303)
- Registration Statement (Form S-8 No. 333-265247) pertaining to the 2022 Stock Option and Incentive Plan of Esperion Therapeutics, Inc.
- Registration Statement (Form S-8 No. 333-262881) pertaining to the Amended and Restated 2013 Stock Option and Incentive Plan of Esperion Therapeutics, Inc.
- Registration Statement (Form S-8 No. 333-253414) pertaining to the Amended and Restated 2013 Stock Option and Incentive Plan of Esperion Therapeutics, Inc.
- 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 report dated February 21, 2023, with respect to the financial statements of Esperion Therapeutics, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2022.

/s/ Ernst & Young LLP

Detroit, Michigan
February 21, 2023

CERTIFICATIONS UNDER SECTION 302

I, Sheldon L. Koenig, 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, including its consolidated subsidiaries, 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 21, 2023

/s/ SHELDON L. KOENIG

Sheldon L. Koenig

President and Chief Executive Officer

(Principal Executive Officer)

CERTIFICATIONS UNDER SECTION 302

I, Benjamin Halladay, 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, including its consolidated subsidiaries, 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 21, 2023

/s/ BENJAMIN HALLADAY

Benjamin Halladay

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, 2022 (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 21, 2023

/s/ SHELDON L. KOENIG

Sheldon L. Koenig

President and Chief Executive Officer

(Principal Executive Officer)

/s/ BENJAMIN HALLADAY

Benjamin Halladay

Chief Financial Officer

(Principal Financial Officer and

Principal Accounting Officer)

Esperion Leadership

Sheldon Koenig

President and Chief Executive Officer

Glenn Brame

Chief Technical Operations Officer

JoAnne M. Foody, MD, FACC, FAHA

Chief Medical Officer

Ben Halladay

Chief Financial Officer

Benjamin O. Looker

General Counsel

Betty Jean (BJ) Swartz

Chief Strategy Officer

Eric Warren, R.Ph.

Chief Commercial Officer

Esperion Board of Directors

J. Martin Carroll

Chairman of the Board

Sheldon Koenig

Jeffrey Berkowitz, JD

Seth H.Z. Fischer

Alan Fuhrman

Antonio M. Gotto, Jr., MD, DPhil

Stephen Rocamboli

Jay Shepard

Nicole Vitullo

Tracy M. Woody



ESPERION[®] | REACHING GOALS

Esperion Therapeutics

At Esperion, we discover, develop, and commercialize innovative medicines to help improve outcomes for patients with or at risk for cardiovascular and cardiometabolic diseases. The status quo is not meeting the health needs of millions of people with high cholesterol – that is why our team of passionate industry leaders is breaking through the barriers that prevent patients from reaching their goals. Providers are moving toward reducing LDL-cholesterol levels as low as possible, as soon as possible; we provide the next steps to help get patients there. Because when it comes to high cholesterol, getting to goal is not optional. It is our life's work. For more information, visit esperion.com and esperionscience.com and follow us on Twitter at twitter.com/EsperionInc.

Investor Relations

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General Counsel

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