



# 2023 Annual Report

What a year we had! We are so proud of the significant progress we made in our efforts to bring an oral, non-statin, LDL-C lowering, and cardiovascular risk reducing medication to millions of patients worldwide. On March 22, 2024, the FDA approved expanded labels for NEXLETOL® (bempedoic acid) and NEXLIZET® (bempedoic acid and ezetimibe), which now include indications for cardiovascular risk reduction and expanded LDL-C lowering to both primary and secondary prevention patients. We were thrilled to receive these labels, which are based on our unprecedented CLEAR Outcomes data and reflect expansion to primary prevention as well as elimination of the statin use requirement. I am proud of our world-class team and would like to thank each and every member of the Esperion family for their hard work and tireless commitment to turning our vision into reality, and for getting us to this point. It has been no small feat and I am grateful.

Our new labels critically enable patients who are at risk for a cardiovascular event – not just those who have already had one – to be eligible for our life-saving, preventive therapies, increasing accessibility of NEXLETOL and NEXLIZET to more than 70 million patients in the U.S. alone. This is what we believe to be the future of medicine – preventing events before they occur, rather than waiting until they do.

In addition, looking beyond the U.S, we were pleased to have recently received a positive opinion from the CHMP on our pending European label submissions. The opinion recommends our treatments to be indicated for the reduction of LDL-C and cardiovascular risk, and to expand to primary prevention patients. This recommendation further reinforces our expectation for a positive decision from the European Medicines Agency in the second quarter of 2024.

These achievements would not have been possible without our robust CLEAR Outcomes data, which we shared at six major medical meetings across the United States and Europe in 2023. These conferences enabled us to showcase the clear benefit and highly differentiated features of bempedoic acid across many high-risk and diverse populations. Our data was further validated by additional published analyses in multiple top tier medical journals, including *New England Journal of Medicine*, *Journal of the American Medical Association*, *Circulation* and more.

We maintained strong engagement with the medical and scientific communities throughout the year, and I would like to highlight a few of our most notable announcements that differentiate bempedoic acid from other LDL-lowering therapies. First, at ADA in June, we demonstrated the efficacy of bempedoic acid in the prevention of cardiovascular events in patients who are at risk for, but who have not yet had, an event. Second, at ESC in August, we showed that bempedoic acid is not associated with new onset diabetes, a key differentiator compared to statins, which elevate blood glucose. This means that our new indications are statin-like but without the side effects so common to statins. Third, at AHA in November, we demonstrated that bempedoic acid actually reduces vascular inflammation, which is an important contributing factor to cardiovascular disease.

In totality, these highly differentiating features position NEXLETOL and NEXLIZET as the non-statin of *first choice*, and represent a change agent in the LDL-lowering and cardiovascular risk reduction treatment paradigms. We believe bempedoic acid will be a practice-changing therapy for millions of at-risk patients who have until now been underserved by existing LDL lowering therapies.

In closing, I would like to extend my sincere gratitude to the countless stakeholders who have shown unwavering support over this transformational year for Esperion. With a body of evidence supporting the broad potential of NEXLETOL and NEXLIZET going forward, we feel better positioned than ever to bring these products to the millions of patients in need of better treatment options. The future has never looked brighter for Esperion, and I look forward to the continued success we will achieve in 2024.



**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, 2023

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, 2023, based upon the closing price of \$1.39 of the registrant's common stock as reported on the NASDAQ Global Market, was \$142.5 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 15, 2024, there were 185,052,705 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 2024 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, 2023.





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From time to time, we may use our website, our X (formerly Twitter) account (@EsperionInc) or our LinkedIn profile at [www.linkedin.com/company/esperion-therapeutics](http://www.linkedin.com/company/esperion-therapeutics) to distribute material information. Our financial and other material information is routinely posted to and accessible on the Investors & Media section of our website, available at [www.esperion.com](http://www.esperion.com). Investors are encouraged to review the Investors & Media section of our website because we may post material information on that site that is not otherwise disseminated by us. Information that is contained in and can be accessed through our website or our LinkedIn page is not incorporated into, and does not form a part of, this Annual Report on Form 10-K.

We use various trademarks and trade names in our business, including without limitation our corporate name and logo. This Annual Report on Form 10-K may also contain trademarks, service marks and trade names of third parties, which are the property of their respective owners. Our use or display of third parties’ trademarks, service marks, trade names or products in this Annual Report on Form 10-K is not intended to, and does not imply a relationship with, or endorsement or sponsorship by us. Solely for convenience, the trademarks and trade names in this Annual Report on Form 10-K may be referred to without the ® and ™ symbols, but the omission of such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

## 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 continued 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 corporate 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 payers, and others in the medical community.
- We have obtained regulatory approval from the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA (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 statin therapy for the treatment of primary hyperlipidemia in adults with heterozygous familial hypercholesterolemia, or HeFH, or atherosclerotic cardiovascular disease, or ASCVD, who require additional lowering of low density lipoprotein cholesterol, or LDL-C. Daiichi Sankyo Co. Ltd, or DS, received its first regional approval for Hong Kong and launched in late 2023 and we expect additional approvals in the DS Territory in 2024. We have also submitted Supplemental New Drug Applications (“sNDAs”) to the FDA seeking to add the use of both NEXLETOL and NEXLIZET for cardiovascular risk reduction and also seeking to remove the statin limitation in the LDL-C indication and we have also submitted a Type II(a) variation with the EMA for our oral non-statin products marketed as NILEMDO® (bempedoic acid) tablets and NUSTENDI® (bempedoic acid and ezetimibe) tablets in Europe asking EMA to approve both NILEMDO and NUSTENDI to reduce cardiovascular risk in patients with or at high risk for atherosclerotic cardiovascular disease. We cannot be certain that we will be able to obtain approval for these expanded indications from FDA or European Commission, or EC, or 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 Securities and Exchange Commission, or 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 and the timeline 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, including receiving potential milestone or royalty payments from collaboration partners;
- our ability to realize the intended benefits 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, or cardiovascular risk 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 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 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 and market disruptions that may result from, among others, global conflicts, economic sanctions, 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 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

*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 currently 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 biotech. Our team of experts are dedicated to lowering LDL-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 (FDA), European Medicines Agency (EMA), and Swiss Agency for Therapeutic Products (Swissmedic), in 2020. NEXLETOL® (bempedoic acid) and NEXLIZET® (bempedoic acid and ezetimibe) tablets are oral, once-daily, non-statin medicines for the treatment of primary hyperlipidemia in adults with heterozygous familial hypercholesterolemia (HeFH) or atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL-C.

We 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 adult 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 nearly 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.

On March 4, 2023, we announced the full results from the CLEAR Outcomes trial. The study showed that bempedoic acid demonstrated significant cardiovascular risk reductions and significantly reduced the risk of heart attack and coronary revascularization 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 NEXLETOL and NEXLIZET (bempedoic acid and ezetimibe) tablets, became the first LDL-C lowering therapy since statins to demonstrate the ability 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.

On June 1, 2023, we announced that we submitted Supplemental New Drug Applications, or sNDAs, to the FDA seeking to add the use of both NEXLETOL and NEXLIZET for cardiovascular risk reduction and also seeking to remove the statin limitation in the LDL-C indication. Subsequently, the FDA accepted the sNDAs with an anticipated Prescription Drug User Fee Act date, or target action date, of March 31, 2024. On June 28, 2023, we announced that the application was filed for a Type II(a) variation with the EMA for our oral non-statin products marketed as NILEMDO® (bempedoic acid) tablets and NUSTENDI® (bempedoic acid and ezetimibe) tablets in Europe. The application asks EMA to approve both NILEMDO and NUSTENDI to reduce cardiovascular risk in patients with or at high risk for atherosclerotic cardiovascular disease. We anticipate EMA approval in the second quarter of 2024. On December 13, 2023, we announced that the FDA approved an updated LDL-cholesterol lowering indication for NEXLETOL and NEXLIZET to include the treatment of primary hyperlipidemia as a qualifier for existing approved populations. Additionally, the maximally tolerated qualifier for statin use has been removed, and the prior limitation of use stating “the effect of NEXLIZET or NEXLETOL on cardiovascular morbidity and mortality has not been determined” has also been removed.

#### Our Strategy

We are focused on discovering, developing, and commercializing innovative medicines to help improve outcomes for patients. Our strategy for accomplishing this includes the following:

- *Completion of global, landmark CLEAR Outcomes trial involving nearly 14,000 patients in 32 countries generated robust data, driving global awareness of significant cardiovascular risk reduction benefits of bempedoic acid. Dissemination of additional, powerful sub-group analyses at medical conferences and in top tier journals further serves to educate the market and support commercialization efforts.*

- *Obtain significant label expansions for our existing products in the United States and Europe, which we anticipate will remove existing limitations and enable access to our life-saving therapies by millions more patients around the globe.* We filed broad cardiovascular risk reduction labels in both jurisdictions and anticipate approvals in the first half of 2024.
- *Execution of our strategic commercialization plan in order to generate significant growth for our currently approved products.* We expect our anticipated label expansions and promotional efforts to unlock significant growth potential for NEXLETOL and NEXLIZET in the United States, with additional, commensurate growth potential in Europe driven by our partner's efforts in that territory.
- *Continue to advance our preclinical pipeline.* We are leveraging our existing research and development capabilities to advance and grow our internal preclinical pipeline candidates, including next-generation ACLY inhibitors, which have potential for broad therapeutic application.

## Product Overview

NEXLETOL® is a first-in-class ATP Citrate Lyase, or ACL, inhibitor that lowers LDL-C and cardiovascular risk by reducing cholesterol biosynthesis and up-regulating the LDL receptors. Completed Phase 3 studies whose primary endpoint was LDL-C lowering were conducted in more than 3,000 patients, with over 2,000 patients treated with NEXLETOL, and demonstrated an average 18% placebo corrected LDL-C lowering when used in patients on moderate or high-intensity statins. The completed Phase 3 Cholesterol Lowering via Bempedoic acid, an ACL-Inhibiting Regimen (CLEAR) Outcomes trial in patients unwilling or unable to take statins and who had, or were at high risk for, cardiovascular disease demonstrated an average 21.1% placebo corrected LDL-C lowering, and a resulting 13% lower risk of major cardiovascular events versus placebo. NEXLETOL was approved by the FDA in February 2020 and is currently indicated as an adjunct to diet and statin therapy for the treatment of primary hyperlipidemia in adults with HeFH or 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% compared to placebo when added on to maximally tolerated statins. NEXLIZET was approved by the FDA in February 2020 and is currently indicated as an adjunct to diet and statin therapy for the treatment of primary hyperlipidemia in adults with HeFH or ASCVD who require additional lowering of LDL-C.

NILEMDO® is a first-in-class ACL inhibitor that lowers LDL-C and cardiovascular risk 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.



## Global Cardiovascular Outcomes Trial—CLEAR Outcomes

CLEAR Outcomes was a Phase 3 clinical study designed to evaluate if 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. We initiated CLEAR Outcomes in December 2016 and completed enrollment in August 2019. 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").

The study included nearly 14,000 patients from 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 by mouth or matching placebo. The median duration of follow-up was 3.4 years. The average LDL-C level at the start of the study was 139 mg/dL.

On December 7, 2022, we announced that the study had met its primary endpoint. On March 4, 2023, we announced the full results from the CLEAR Outcomes trial at the Scientific Sessions of the American College of Cardiology with a simultaneous publication in the *New England Journal of Medicine*. The study showed that bempedoic acid demonstrated a significant 13% cardiovascular risk reduction in MACE-4 events and significantly reduced the risk of heart attack by 23% and coronary revascularization by 19% 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 bempedoic acid and placebo treatment groups. Bempedoic acid, contained in NEXLETOL® and NEXLIZET® (bempedoic acid and ezetimibe) tablets, became the first LDL-C lowering therapy since statins to demonstrate the ability 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. When comparing these results in the context of other similar statin trials (based on the Cholesterol Treatment Trialists', "CTT", meta-analysis), when normalized to a 1.0 mmol/L (39 mg/dL) LDL-C reduction, the CV risk reduction with bempedoic acid shown via the CTT major vascular event endpoint is comparable to the normalized risk reduction observed with statins. The beneficial effect of bempedoic acid on major vascular event reduction generally improved over time, similar to what was observed in statin CVOTs.

On June 23, 2023, a prespecified analysis of the primary prevention population of the CLEAR Outcomes trial was presented at the American Diabetes Association Scientific Sessions and simultaneously published in the *JAMA* (Journal of the American Medical Association). Results from this primary prevention analysis show a significant 30% reduction in cardiovascular risk in the primary prevention population making bempedoic acid the first LDL-lowering therapy since statins to demonstrate cardiovascular risk reduction in a primary prevention population.

On August 26, 2023, a prespecified analysis of the total number of cardiovascular events in the CLEAR Outcomes trial population was presented at the European Society of Cardiology and subsequently published in *JAMA Cardiology*. The results reflect the totality of the benefit of bempedoic acid on CV risk reduction, not just the first event. Treatment with bempedoic acid was associated with a risk reduction of 20% in total MACE-4 events (composite of major adverse cardiovascular events including non-fatal myocardial infarction, non-fatal stroke, coronary revascularization and cardiovascular death), 17% in total MACE-3 events (composite of major adverse cardiovascular events including non-fatal myocardial infarction, non-fatal stroke and cardiovascular death), 31% in total myocardial infarctions, and 22% in total coronary revascularizations. We believe these data reinforce the importance of cholesterol lowering in high-risk patients with the potential to prevent multiple events over time.

On August 26, 2023, a prespecified analysis of the CLEAR Outcomes trial population by patient diabetes status at enrollment (e.g., diabetes, prediabetes, normoglycemic) was presented at the European Society of Cardiology and subsequently published in *The Lancet Diabetes and Endocrinology*. Of the nearly 14,000 patients included in CLEAR Outcomes, 45.6% had diabetes, 41.5% were pre-diabetic, and 12.9% had normoglycemia. Bempedoic acid demonstrated a benefit in patients with diabetes at baseline, showing a 17% reduction in cardiovascular risk. Importantly, bempedoic acid use was not associated with an increased rate of new onset diabetes, which is a key differentiating feature compared to statins.

## Product Pipeline

### *Next Generation ACLYi*

ATP-citrate lyase, or ACLY, is an enzyme strategically positioned at the intersection of nutrient catabolism and cholesterol and fatty acid biosynthesis. We are leading the investigation of ACLY biology, having brought the first ACLY inhibitor to the market. While preclinical studies and Mendelian randomized trials support a causal role for ACLY in dyslipidemia and

ASCVD, they also suggest potential additional effects on metabolism that may benefit other disease states such as type 2 diabetes and metabolic associated fatty liver disease (NAFLD)/metabolic associated steatohepatitis (NASH)<sup>1,2</sup>. Furthermore, emerging evidence implicates ACLY as a key metabolic checkpoint utilized by multiple cell types to sense nutrient availability and coordinate metabolic adaptations with cell-specific functions<sup>3,4</sup>. This expanded understanding has provided key insight into novel connections between chronic positive energy balance and aberrant metabolism and the maladaptation of multiple inflammatory, immune, fibrotic, extra-cellular matrix remodeling, and proliferative processes<sup>5-8</sup>. Our scientific team is exploring this novel insight into ACLY biology. Along with the implementation of leading-edge discovery technology and data science approaches, we aim to reveal new therapeutic opportunities and develop next-generation inhibitors optimized to address multiple life-threatening diseases.

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

Atherosclerotic cardiovascular disease, or ASCVD, is a chronic, progressive disease; the presence of increasing low-density lipoprotein cholesterol, or LDL-C, is causal in the development of ASCVD and plays a central role in the multifactorial disease process of lipid accumulation and systemic inflammation. ASCVD is the underlying cause of many major cardiovascular, or CV, events including myocardial infarction, or MI, and ischemic stroke, or IS. In practice, ASCVD can include a spectrum of diagnoses, including acute events such as MI or stroke, coronary revascularization procedures, as well as conditions such as peripheral artery disease, or PAD, coronary artery disease, or CAD, or angina.

Extensive evidence has shown that LDL-C is a major risk factor for ASCVD. Studies further suggests that the causal effect of LDL-C on the risk of ASCVD is determined by both the degree and length of time LDL is elevated. The relationship between LDL-C levels and ASCVD risk has important implications, including:

- Lower LDL-C level attained using therapies that target LDL receptors yield greater clinical benefit in CV risk reduction than therapies that do not;
- There is a straight-line relationship between absolute reductions in LDL-C and reductions in the incidence of major vascular events (e.g., lower LDL-C is related to proportionally lower event rates);
- Cumulative LDL-C burden is a determinant of when ASCVD starts and/or gets worse; and
- Lowering LDL-C levels in patients with high CV risk earlier (rather than later) is recommended, especially for patients with familial hypercholesterolemia (FH).

### **Blood Cholesterol Guidelines**

LDL-C is the main focus of healthcare provider efforts to improve the cholesterol profile in individuals at risk for or with established ASCVD, and the evidence overwhelmingly shows that the amount the risk of a poor outcome is lowered is related to the magnitude of LDL-C reduction, and that lowering LDL-C levels earlier (rather than later) is recommended, especially for patients with FH. Over the past 20 years since the inception of lipid targets in the NCEP ATP III (National Cholesterol Education Program Adult Treatment Panel III), guidelines have evolved to include lower LDL-C treatment targets in patients with established ASCVD.

The goal of treatment with intensive lipid-lowering strategies is to prevent subsequent CV events in patients with established ASCVD (secondary prevention) as well as to prevent the first CV event from occurring in patients who may be at high-risk for ASCVD (primary prevention).

### **Marketing Opportunity for Bempedoic Acid and the Bempedoic Acid / Ezetimibe Combination Tablet**

Overall, 71 million adults in the US are at high risk of ASCVD and eligible for statin therapy according to the AHA/ACC guidelines. The estimated US prevalence of risk groups based on NHANES is provided below.

## US Prevalence Estimates by Statin-Eligible Groups

<b>Patient Subgroup</b>	<b>Estimated Prevalence (in Millions)</b>
ASCVD and age $\geq$ 21 years	24.6
LDL-C $\geq$ 190 mg/dL	2.3
Diabetes mellitus (DM), age 40–75 years	15
ASCVD risk $\geq$ 20%	9.4
Intermediate ASCVD ( $\geq$ 7.5% to $<$ 20%) risk and $\geq$ 1 risk enhancer(s)	20
Total	71.3

### ***Patients with HeFH or established ASCVD who require additional lowering of LDL-C***

We initially developed bempedoic acid and the bempedoic acid / ezetimibe combination tablet as an adjunct to diet and statin therapy for patients with HeFH or ASCVD who require additional lowering of LDL-C. We further developed bempedoic acid as a treatment to reduce cardiovascular risk for patients with HeFH and ASCVD. The severity of elevated LDL-C in these patients, their level of cardiovascular disease risk and their therapeutic options vary widely.

Despite the prevalence of statins, many patients with ASCVD are still not achieving their LDL-C goals and need additional LDL-C lowering beyond that achieved with statin monotherapy. It is estimated that approximately 10 million patients with ASCVD in the United States currently taking statins require additional LDL-C lowering. Approximately 60% to 70% of patients receiving statins do not meet their LDL-C goals, and estimates are worse among high CV risk groups, such as adults with severe hypercholesterolemia (98%) or ASCVD (80%). There are also potentially 2 million additional patients with ASCVD not being treated per current guidelines because they cannot or will not take a high enough dose of a statin.

### ***Patients at High Risk of Developing ASCVD (Primary Prevention)***

Difficulty in achieving guideline recommended LDL-C goals is not limited to the established ASCVD population. Several recent estimates indicate that there may be up to 15 million US adults currently on statin medications for primary prevention who are not at goal and need treatment optimization, either via statin intensification or additional therapies. An additional 3 million adults who are eligible for statins for primary prevention may be statin intolerant, and unwilling or unable to initiate, continue, or maximize statin medications.

### ***Untreated Patients***

Due to a myriad of reasons, up to an additional 40 million adults in the US with ASCVD or at high-risk for ASCVD remain untreated with statins. This gap in care represents an important public health opportunity.

### ***Unable or Unwilling to Take Guideline Recommended Doses of Statins***

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 and cardiovascular risk 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 many are only able to tolerate less than the lowest approved daily starting dose of their statin and are therefore considered to be statin intolerant.

## **Other Approved LDL-C Lowering Therapies**

### ***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 cannot or will not 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 continued unmet need for oral, once-daily, non-statin medicines to treat patients with elevated LDL-C.

### ***Ezetimibe***

Ezetimibe is a cholesterol absorption inhibitor that directly binds to NPC1L1 and prevents the transportation of dietary cholesterol from the gut lumen to intestinal enterocytes, resulting in decreased amounts of cholesterol delivered to the liver and an upregulation of hepatic LDL receptors. Ezetimibe also inhibits cholesterol absorption in the small intestine. Ezetimibe is indicated for monotherapy as an adjunctive therapy to diet for the reduction of elevated TC, LDL-C, Apo B, and non-HDL-C in patients with primary hyperlipidemia (HeFH and nonfamilial). It is also approved for combination therapy with a statin or fenofibrate. The standard dose of 10 mg/day lowers LDL-C by approximately 15% to 20% when used alone, in addition to the reduction achieved with statins. However, based on a retrospective real-world database study, it has been estimated that (depending on baseline LDL-C level) 70% or more of patients who switch to or add ezetimibe to statin therapy still require additional LDL-C lowering to achieve treatment goals (with therapeutic targets reached by only 30% of patients with baseline LDL-C levels of 70 to 99 mg/dL).

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.

Ezetimibe has been found to be generally well tolerated, and the ACC ECDP recommends that ezetimibe be considered the first non-statin agent added when LDL-C goal is not met with high-intensity statin therapy and diet and lifestyle modifications. However, the use of ezetimibe is markedly low in the US; in the GOULD registry (Getting to an Improved Understanding of Low-Density Lipoprotein Cholesterol and Dyslipidemia Management; 2016-2018) of adults with ASCVD, only 6.8% of patients with LDL-C  $\geq 100$  mg/dL had ezetimibe added for LLT intensification. Similar data from NHANES (2015-2018) showed that only 5.1% and 1.9% of high-risk and very high-risk ASCVD patients were receiving a statin plus ezetimibe, despite 61% and 74% of these patients having LDL-C  $\geq 70$  mg/dL.

### ***PCSK9 Inhibitors, Monoclonal Antibodies***

PCSK9 inhibitors block an enzyme involved in the degradation of LDL receptors. PCSK9 inhibitors are injectable, monoclonal antibodies to lower LDL-C. 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%. 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% 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. 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). 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% 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. 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. In April 2019, the FDA approved alirocumab to reduce the risk of heart attack, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease. 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.

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.

#### ***PCSK9 inhibitors, small interfering ribonucleic acid (siRNA)***

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. Recruitment of ORION-4 was completed September 30, 2023. Inclisiran received an updated indication in July 2023 for use as an adjunct to diet and statin therapy for the treatment of adults with primary hyperlipidemia, including HeFH, to reduce LDL-C.

#### **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, 2023, we recognized \$78.3 million in net product sales of NEXLETOL and NEXLIZET and \$38.0 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, 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.

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, 2023, were \$86.1 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 Daiichi Sankyo Europe GmbH, or DSE in 2019, with Otsuka Pharmaceutical Co., Ltd., or Otsuka, in 2020 and with Daiichi Sankyo Co. Ltd, or 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 in 2024 in anticipation of potential additional global approvals for new product indications, expanded commercialization initiatives for NEXLETOL and NEXLIZET and increases in our associated headcount to expand our sales team. Selling, general and administrative expenses in 2023 increased primarily due to increased legal expenses associated with our litigation with DSE, including the close out costs associated with the settlement, and increases in headcount, consulting and other promotional related expenses.

### **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, in connection with the transfer of certain manufacturing responsibilities to DSE, 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 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 January 3, 2024, we announced that after a transition period, DSE will assume sole responsibility for the manufacture of

NILEMDO and NUSTENDI for the DSE Territory and that we granted DSE the exclusive rights for clinical development, regulatory activities, manufacture and commercialization of a bempedoic acid/ezetimibe/statin triple combination pill in the DSE Territory.

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 July 6, 2023, the Company provided notice to Serometrix of its intent to terminate the licensing agreement between the Company and Serometrix dated December 3, 2020. The agreement terminated as of August 5, 2023. The Company expects to continue to advance its internal pipeline assets, including next-generation ACLY inhibitors.

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. On January 3, 2024, we announced that after a transition period, DS will assume sole responsibility for the manufacture of NILEMDO and NUSTENDI for the DS Territory and that we granted DS the exclusive rights for clinical development, regulatory activities, manufacture and commercialization of a bempedoic acid/ezetimibe/statin triple combination pill in the DS Territory.

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, 2023, our patent estate, including patents we own, on a worldwide basis, included approximately 10 issued United States patents and 17 pending United States patent applications and over 25 issued patents and over 80 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. We have one granted European patent that has been validated in numerous European countries including France, Germany, Great Britain, Ireland, Italy, the Netherlands, Spain, Sweden and Switzerland. We obtained five year patent term extensions via supplementary protection certificates for 24 national patents validated from this granted European patent, which extends 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, U.S. Patent No. 11,613,511 directed to compositions of matter of high purity bempedoic acid, one pending U.S. patent application directed to the same, U.S. Patent No. 11,760,714 directed to pharmaceutical formulations containing the same, one pending U.S. patent application directed to methods of treatment using



the same, and 15 pending patent applications outside of the United States. U.S. Patent Nos. 11,407,705, 11,613,511 and 11,760,714, 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 Nos. 10,912,751 and 11,744,816 that are scheduled to expire in March 2036. We also have one pending U.S. patent application, and 9 issued patents and 14 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 7 issued patents and 23 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, i.e., U.S. Patent No. 11,116,739, one pending U.S. patent application, and 9 issued patents and 15 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. U.S. Patent No. 11,116,739 is scheduled to expire in March 2036.

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 our asset transfer agreement with Pfizer.

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. 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 relating to bempedoic acid, including patent term extensions we may be eligible for, will expire on dates ranging from late-2025 to mid-2040. 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 and commercializing 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 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 the 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](http://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 culminated in November 2023. The FDA established a one-year stabilization period from November 2023 to November 2024 for trading partners to continue to build and validate interoperable systems and processes to meet certain requirements of the DSCSA. 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 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 Outcomes 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, adds six months to existing exclusivity periods for all formulations, dosage forms, and indications of the drug and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection and, for drugs, patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining.

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, 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 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 70% 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.

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 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs.
- 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 until January 1, 2032 the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. 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. 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. Recently, there have also been several changes to the 340B drug pricing program. On November 3, 2023, the U.S. District Court of South Carolina issued an opinion in *Genesis Healthcare Inc. v. Becerra et al.* that may lead to an expansion of the scope of patients eligible to access prescriptions at 340B pricing. The outcome of this judicial proceeding is uncertain. We continue to review developments impacting the 340B program.

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

- The Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year and, due to subsequent legislative amendments to the statute, will remain in effect through 2031.
- 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.
- On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our approved products or future product candidates for which we may obtain

regulatory approval or the frequency with which any such approved product or future product candidate is prescribed or used.

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.

President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. 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 products or 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. The federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery. 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), certain other licensed health care practitioners and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.
- 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 the United States, there is a growing body of stringent privacy and data security legislation. In California, for example, 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, gives California residents expanded privacy rights and protections, and places stringent privacy and security obligations on business covered by the law. Further, the California Privacy Rights Act, or CPRA, amended the CCPA and as of January 1, 2023, created additional obligations with respect to processing and safeguarding personal information. The CCPA provides for civil penalties for violations and a private right of action for data breaches. Among other provisions, the CCPA requires covered "businesses" 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 sharing of personal information. While there is an exception for protected health information that is subject to HIPAA and clinical trial regulations, the CCPA may impact our business activities if we become a "business" regulated by the scope of the CCPA or a service provider to a regulated business.

In addition to the CCPA, new privacy and data security laws have been enacted in numerous other states and have been proposed in even more states as well as in the U.S. Congress, reflecting a trend toward more stringent privacy legislation in the U.S., which may accelerate. Furthermore, a smaller number of states have passed or are considering laws that are specifically focused upon the protection of consumer health data, such as Washington's My Health My Data Act. 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.

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, or EEA, and United Kingdom, or UK, we will be subject to additional data protection restrictions, such as the GDPR (as defined below). The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR. 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 potential European activities.

### ***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 was provisionally applicable since 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 provide for wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, Great Britain, or GB, 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 continues to apply in Northern Ireland at present). The regulatory regime in GB therefore aligns with current EU regulations in many ways, however it is possible that these regimes will diverge more significantly in the future now that GB's regulatory system is independent from the EU. For example, the EU Clinical Trials Regulation has not been implemented into UK law, and a separate application must be submitted for clinical trial authorization in the UK. However, notwithstanding that there is no wholesale recognition of EU pharmaceutical legislation under the TCA, under a new framework mentioned above which will be put in place by the Medicines and Healthcare products Regulatory Agency, or MHRA, from January 1, 2024, the MHRA has stated that it will take into account decisions on the approval of MAs from the EMA (and certain other regulators) when considering an application for a GB MA.

On February 27, 2023, the UK government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework". This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. In particular, the MHRA, the UK medicines regulator, will be responsible for approving all medicinal products destined for the UK market (i.e., GB and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single UK-wide MA will be granted by the MHRA for all medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the UK. The Windsor Framework was approved by the European Union-United Kingdom Joint Committee on March 24, 2023, and the UK government and the EU will therefore enact legislative measures to bring it into law. On June 9, 2023, the MHRA announced that the medicines aspects of the Windsor Framework will apply from January 1, 2025.

### ***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 (or additional indication), 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, 2023, we had 240 full-time employees. Seven of our employees have Ph.D. degrees, two have M.D. degrees and ten have PharmD degrees. 39 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.

We are committed to the adoption of inclusive workforce policies and initiatives. As of December 31, 2023, 54% of our workforce, 38% of our executive management team and 22% of our board of directors were women. As of December 31, 2023, approximately 22% of our workforce identified as racially or ethnically diverse. We review diversity data related to hiring, promotions, and retention on an ongoing basis.

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 11,500 square feet of office space. We believe that our existing facilities are adequate for our current needs.

### **Legal Proceedings**

On March 27, 2023, we filed a complaint in the United States District Court for the Southern District of New York seeking declaratory judgment against DSE regarding the Company's right to receive a \$300 million milestone payment upon inclusion of cardiovascular risk reduction in the EU label that correlates with a relative risk reduction rate of at least 20%, based on the

results of the CLEAR Outcomes CVOT. On May 4, 2023, we filed an amended complaint against DSE in the Southern District of New York which seeks a judicial declaration, on an expedited basis, that DSE is contractually required to make a \$300 million milestone payment to us upon applicable regulatory approval. On June 20, 2023, DSE filed a response to our amended complaint.

On January 2, 2024, we entered into a settlement agreement with DSE to amicably resolve and dismiss the commercial dispute that was pending in the Southern District of New York, or the Settlement Agreement. Under the Settlement Agreement, DSE agreed to pay us an aggregate of \$125 million, including (1) a \$100-million payment within 15 business days of the effective date of the Settlement Agreement and (2) a \$25-million payment in the calendar quarter immediately following the calendar quarter in which the EMA renders a decision on the application that was filed with the EMA for a Type II(a) variation for our oral non-statin products marketed as NILEMDO® (bempedoic acid) tablets and NUSTENDI® (bempedoic acid and ezetimibe) tablets in Europe. The application asks the EMA to approve both NILEMDO and NUSTENDI to reduce cardiovascular risk in patients with or at high risk for atherosclerotic cardiovascular disease. The legal action pending in the United States District Court for the Southern District of New York was subsequently dismissed. Pursuant to the Settlement Agreement, also on January 2, 2024, we entered into a 3<sup>rd</sup> Amendment to the License and Collaboration Agreement dated January 2, 2019 with DSE, and a 1<sup>st</sup> Amendment to the License and Collaboration Agreement dated April 26, 2021 with Daiichi Sankyo Company Limited, or DS. The DSE Amendment and the DS Amendment grant each of DSE and DS exclusive rights for clinical development, regulatory activities, manufacture and commercialization of a bempedoic acid/ezetimibe/statin triple combination pill in their existing respective territories of the European Economic Area, UK, Switzerland and Turkey, or the DSE Territory, and South Korea, Taiwan, Hong Kong, Thailand, Vietnam, Brazil, Macao, Cambodia and Myanmar, or the DS Territory. Further, after a transition period, DSE and DS will assume sole responsibility for the manufacture of NILEMDO and NUSTENDI for, respectively, the DSE Territory and DS Territory. As of January 2, 2024, DSE shall have sole authority and control of regulatory communications with the EMA regarding the pending marketing authorization applications for NILEMDO and NUSTENDI.

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

#### **Available Information**

Our website address is [www.esperion.com](http://www.esperion.com). Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, 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 SEC. Information on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference. We have included our website address in this Annual Report on Form 10-K solely as an inactive textual reference. Alternatively, these reports may be accessed at the SEC's website at [www.sec.gov](http://www.sec.gov). All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

## Item 1A. Risk Factors

*Except for the historical information contained herein or incorporated by reference, this Annual Report on Form 10-K 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 Annual Report on Form 10-K. 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 Annual Report on Form 10-K and in any documents incorporated in this Annual Report on Form 10-K by reference.*

*You should consider carefully the following risk factors, together with all of the other information included or incorporated in this Annual Report on Form 10-K. 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 stock through our at-the-market (ATM) offering program. Increased volatility and decreases in market prices of equity securities generally and of our common stock in particular may have an adverse impact on our willingness and/or ability to continue to sell our common stock 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 stock.***

On April 15, 2022, we filed a new registration statement on Form S-3 to replace our prior automatically effective registration statement on Form S-3ASR filed on August 3, 2021, which registered 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. 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 us of up to \$70 million of shares of our 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 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. Given the volatility in the capital markets, we may not be willing or able to continue to raise equity capital through the 2023 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 stock. 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.

***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. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Our future funding requirements, both near and long-term will depend on many factors, including, but not limited to 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. For instance, the trading prices for our common stock and for other biopharmaceutical companies have been highly volatile. As a result, we may face difficulties raising capital through sales of our equity or debt securities or such sales may be on unfavorable terms. Similarly, adverse market or macroeconomic conditions or market volatility resulting from global economic developments, political unrest, high inflation, rising interest rates, the post-COVID environment, future public health epidemics or other factors, could materially and adversely affect our ability to consummate an equity or debt financing on favorable terms, or at all. In order to raise additional capital, we may seek a combination of private and public equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent 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.

***Adverse developments affecting the financial services industry could have an adverse effect on our operations and financial results.***

Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. These events exposed vulnerabilities in the banking sector, including legal uncertainties, significant volatility and contagion risk, and caused market prices of regional bank stocks to plummet.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations, or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

## **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 corporate goals.***

In 2023, we generated \$78.3 million in net revenues from the sale of products in the U.S. Our 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. Daiichi Sankyo Co. Ltd, or DS, received its first regional approval for Hong Kong and launched in late 2023 and we expect additional approvals in the DS Territory in 2024. There is no assurance that the commercial launches will be successful or that the planned additional launches will occur on the timing we anticipate and generate the revenues we expect. 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 statin therapy for the treatment of primary hyperlipidemia in adults with HeFH or ASCVD who require additional lowering of LDL-C. We also expect approval decisions on the expanded indications for NEXLETOL and NEXLIZET in the first quarter of 2024. We may never be able to successfully commercialize the products even with their expanded indications 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 ASCVD who require additional lowering of LDL-C or wish to reduce their cardiovascular risk. 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 following approval of the expanded product indications, 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 statin therapy for the treatment of primary hyperlipidemia in adults with HeFH or 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 or cardiovascular risk reduction 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 in any other territory.

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 submissions in 2023 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 completed the CLEAR Outcomes CVOT, and we have used the data from this trial to support further regulatory submissions and may use it to support additional regulatory submissions in the future.

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;
- 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 in their current and planned future indications, 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 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 payers, such as government health programs, commercial insurance and managed healthcare organizations. Adequate coverage and reimbursement from third party payers 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 (of new indications for previously 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. 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 level 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 adequate 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.

***If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.***

We participate in the Medicaid Drug Rebate program, the 340B drug pricing program, and the VA’s FSS pricing program. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the U.S. in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. Our failure to comply with these price reporting and rebate payment obligations could negatively impact our financial results.

The ACA made significant changes to the Medicaid Drug Rebate program. CMS issued a final regulation, which became effective on April 1, 2016, to implement the changes to the Medicaid Drug Rebate program under the ACA. The issuance of the final regulation has increased and will continue to increase our costs and the complexity of compliance, has been and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS challenges the approach we take in our implementation of the final regulation.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service’s 340B drug pricing program in order for federal funds to be available for the manufacturer’s drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B “ceiling price” for the manufacturer’s covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is

calculated using a statutory formula based on the average manufacturer price and Medicaid rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program, and in general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. Any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under the ACA, other legislation, or in regulation could affect our 340B ceiling price calculations and negatively impact our results of operations.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was 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.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, as noted above, we participate in the VA's FSS pricing program. As part of this program, we are obligated to make our products available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price, or FCP, to four federal agencies (the VA, U.S. Department of Defense, or DOD, Public Health Service, and the U.S. Coast Guard). The FCP is based on the Non-Federal Average Manufacturer Price, or Non-FAMP, which we calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to significant penalties for each item of false information. These obligations also contain extensive disclosure and certification requirements.

We also participate in the Tricare Retail Pharmacy program, under which we pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP. We are required to list our covered products on a Tricare Agreement in order for these products to be eligible for DOD formulary inclusion. If we overcharge the government in connection with our FSS contract or Tricare Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the FCA and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

***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 stricter requirements relating to processing health and other sensitive data, ensuring there is a legal basis to justify the processing of personal data, stricter requirements relating to obtaining consent of individuals, expanded disclosures about how personal information is to be used, limitations on retention of information, 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 national laws of EU Member States which may partially deviate from the EU GDPR and impose different and more restrictive obligations from country to country. 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.

The U.K. GDPR and the U.K. Data Protection Act 2018 set out the U.K.'s data protection regime, which is independent from but, currently, aligned to the EU's data protection regime. The EC has adopted an adequacy decision in respect of transfers of personal data to the U.K. for a four-year period (until June 27, 2025). Similarly, the U.K. has determined that it considers all of the EEA to be adequate for the purposes of data protection. This ensures that data flows between the U.K. and the EEA remain unaffected. The U.K. Government has also now introduced a Data Protection and Digital Information Bill (or the UK Bill) into the UK legislative process with the intention for this bill to reform the U.K.'s data protection regime which will likely have the effect of further altering the similarities between the U.K. and EU data protection regime.

In addition, we must also ensure that we maintain adequate safeguards to enable the transfer of personal data outside of the EEA or the U.K., in particular to the U.S., in compliance with GDPR. In some cases, we rely upon the EC's approved standard contractual clauses to legitimize transfers of personal data out of the EEA from controllers or processors established outside the EEA (and not subject to the GDPR). The U.K. is not subject to the EC's standard contractual clauses but has published its own transfer mechanism, the International Data Transfer Agreement, which enables transfers from the U.K. Changes with respect to any of these matters may lead to additional costs and increase our overall risk exposure. The EU and U.S. have adopted its adequacy decision for the EU U.S. Data Privacy Framework ("Framework"), which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the EU and the U.S. is comparable to that offered in the EU. Moreover, on September 21, 2023, the U.K. Government adopted the Data Protection (Adequacy) Regulations 2023, also referred to as the "UK-U.S. Data Bridge", which will allow companies to transfer personal data from the U.K. to the U.S. on the basis of the EU-U.S. Data Privacy Framework. This provides a further avenue to ensuring transfers to the US are carried out in line with GDPR. The Framework could be challenged like its predecessor frameworks.

In the United States, state privacy laws may also have an impact on our business; for example, California enacted the California Consumer Privacy Act, or CCPA, which creates broad individual privacy rights for California consumers (as defined in the law) and places stringent privacy and security obligations on business covered by the law. This law, which took effect on January 1, 2020 and became enforceable by the California Attorney General on July 1, 2020, requires covered companies to provide detailed disclosures to consumers about such companies' data collection, use and sharing practices, allow such consumers to opt-out of certain sales or sharing of their personal information. The CCPA also provides for civil penalties for violations and a private right of action for certain data breaches involving personal information, which is expected to increase the likelihood of, and risks associated with, data breach litigation. 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.

The CCPA was amended by the California Privacy Rights Act, or CPRA. As of January 1, 2023, the amendments to the CCPA introduced by the CPRA have imposed additional obligations on companies covered by the legislation, including by expanding consumers' rights with respect to certain sensitive personal information. The amendments introduced by the CPRA also created a new state agency that is vested with authority to implement and enforce the CCPA. The effects of the CCPA 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.

Following California, numerous other states have enacted laws similar to the CCPA and even more have proposed similar laws that have not yet passed. In addition to these comprehensive laws and proposals, other states have passed or are considering more limited privacy laws that are specifically focused upon the protection of consumer health data, such as Washington's My Health My Data Act.

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 state 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.



Compliance with U.S. and international data protection and data security 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 and data security laws and regulations could result in government and/or data protection authority 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.

***Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data.***

Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. We may adopt and integrate generative artificial intelligence tools into our systems for specific use cases reviewed by legal and information security. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact 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 in other territories will be materially adversely affected.***

The LDL-C and cardiovascular risk 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 or cardiovascular risk reducing 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 and cardiovascular risk reducing therapies currently on the market that 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 statin therapy for the treatment of primary hyperlipidemia in adults with HeFH or ASCVD who require additional lowering of LDL-C, the first indication we pursued. Based on the results of the CLEAR Outcomes CVOT, we have submitted supplemental applications seeking an expanded cardiovascular risk reduction indication in the U.S. and Europe. 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 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 and information technology systems and infrastructure, or those of our third-party clinical research organizations or other contractors or consultants, may fail or suffer security compromises or 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 and information technology systems and infrastructure and those of our third-party CROs, vendors, and other contractors and consultants upon which our business relies are vulnerable to breakdown or damage or interruption from, among other things, natural disasters, terrorism, war, telecommunication and electrical failures, and sophisticated cyber-attacks, including the theft, fraud, and subsequent misuse of employee credentials, wrongful conduct by insider employees or vendors, denial-of-service attacks, ransomware attacks, business email compromises, computer malware, malicious codes, viruses, breakdown, wrongful intrusions, data breaches, and social engineering (including phishing attacks). 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. Likewise, we rely on third parties to manufacture our product candidates and will rely on third parties to conduct future clinical trials, and similar events relating to their computer systems and infrastructure could also have similar consequences to our business. To the extent that any disruption or security compromise or breach results in a loss of or damage to, unauthorized access of, or misuse of our data, systems, infrastructure 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 (including in connection with or resulting from litigation or governmental investigations and enforcement actions) and the further development of bempedoic acid or the bempedoic acid / ezetimibe combination tablet could be delayed, the commercialization of our products could be impacted and our business could be otherwise adversely affected.

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 and infrastructure 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 and infrastructure 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 compromise or breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm which could negatively impact our relationship with our customers, partners, vendors and other third parties, and fines and penalties resulting from claims against us by private parties and/or governmental agencies.

***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.***

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 2023 tax year is 8.99%. The CNIT rate will be reduced to 8.49% for the 2024 tax year. Starting with the 2025 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% 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. For example, under Section 174 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. 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, 2023, we had United States federal net operating loss carryforwards of approximately \$1,027.5 million and state net operating loss carryforwards of approximately \$696.1 million. Under Sections 382 and 383 of 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 2017, 2021 and 2023. 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, geopolitical developments or global health crises and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

The occurrence of unforeseen or catastrophic events, including extreme weather events, natural disasters, geopolitical developments or global health crises, depending on their scale, may cause different degrees of damage to the national and local economies, such as recessions, rising interest rates, inflation, fuel prices, foreign currency fluctuations, international tariffs, boycotts, curtailment of trade and other business restrictions, and 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 or our partners 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 and our CLEAR Outcomes CVOT of bempedoic acid are not necessarily predictive of the results 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 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, our Phase 3 1002FDC-053 clinical study of the bempedoic acid / ezetimibe combination tablet, our CLEAR Outcomes CVOT or any future studies of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, do not 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, our partners 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. 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 over a significant period of time. 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 CLEAR Outcomes 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.

***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 next generation ACL inhibitors. 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.



***Inadequate funding for the FDA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for product applications to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, if the FDA is required to furlough review staff or necessary employees, or if the agency operations are otherwise impacted, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

### **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.

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 \$187.2 million in net 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 \$209.2 million and \$233.7 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of \$1.5 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 incur significant expenses and operating losses for the foreseeable future related to our commercialization of NEXLETOL and NEXLIZET and pursuing other research and development expenses, as well as other related personnel and activities. Our research and development expenses are expected to be reduced in the foreseeable future after having reported the full results of the CLEAR Outcomes CVOT and submitting regulatory filings to the FDA and EMA in 2023. 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 our selling, general and administrative expenses to increase in 2024 in anticipation of potential additional global regulatory approvals for new product indications, expanded commercialization initiatives for NEXLETOL and NEXLIZET, including marketing, and increases in our headcount for our sales team expansion. 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 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 clinical development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any other product candidate we pursue will consume substantial additional financial resources. We expect that our existing cash and cash equivalents, including the cash received in January 2024 in conjunction with the Settlement Agreement and the January 2024 Offering, 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 adequate reimbursement coverage, in the United States, and in Europe;
- the service and payment of potential debt maturities;
- 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 outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA and other comparable foreign regulatory authorities;
- 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 costs 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. We also could be required to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be acceptable or relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves. 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. In 2025, the percent of net revenue paid to Oberland could reset to a higher amount if certain revenue milestones are not met. This could result in substantially higher payments starting in 2025. 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.***

Holder 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, 2023, 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 37% 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.

***Our stock price may be volatile and an investment in our stock may decline. If we fail to comply with the continuing listing standards of Nasdaq, our securities could be delisted.***

Our common stock has experienced, and may continue to experience, substantial price volatility. The trading price of common stock may fluctuate significantly in response to a number of factors, many of which are beyond our control. For instance, if our financial results are below the expectations of securities analysts and investors, the market price of common stock could decrease, perhaps significantly. Other factors that may affect the market price of common stock, including announcements relating to significant corporate transactions, fluctuations in quarterly and annual financial results, operating and stock price performance of companies that investors deem comparable to us, changes in government regulation or related proposals and international conflict. In addition, the U.S. securities markets have experienced significant price and volume fluctuations, and these fluctuations often have been unrelated to the operating performance of companies in these markets. Any volatility of or a significant decrease in the market price of common stock could also limit our ability to raise capital by issuing additional equity. Further, if we were to be the object of securities class action litigation as a result of volatility in common stock price or for other reasons, it could result in substantial costs and diversion of management's attention and resources, which could negatively affect our financial results. The occurrence of any one or more of the factors noted in these risk factors could cause the market price of our common stock to be below the \$1.00 Nasdaq minimum price requirement.

#### **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, 2023, our patent estate, including patents we own, on a worldwide basis, included approximately 10 issued United States patents and 17 pending United States patent applications and over 25 issued patents and over 80 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. We have one granted European patent that has been validated in numerous European countries including France, Germany, Great Britain, Ireland, Italy, the Netherlands, Spain, Sweden and Switzerland. We obtained five year patent term extensions via supplementary protection certificates for 24 national patents validated from the granted European patent, which extends 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, U.S. Patent No. 11.613.511 directed to compositions of matter of high purity bempedoic acid, one pending U.S. patent application directed to the same, U.S. Patent No. 11,760,714 directed to pharmaceutical formulations containing the same, one pending U.S. patent application directed to methods of treatment using the same, and 15 pending patent applications outside of the United States. U.S. Patent Nos. 11,407,705, 11,613,511, and 11,760,714, 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 Nos. 10,912,751 and 11,744,816 that are scheduled to expire in March 2036. We also have one pending U.S. patent application, and 9 issued patents

and 14 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 7 issued patents and 23 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, i.e., U.S. Patent No. 11,116,739, one pending U.S. patent application, and 9 issued patents and 15 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. U.S. Patent No. 11,116,739 is scheduled to expire in March 2036.

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) came into force during 2023. The UPC is 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 obtained 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. On March 27, 2023, we filed a complaint in the United States District Court for the Southern District of New York seeking declaratory judgment against DSE regarding the Company's right to receive a \$300 million milestone payment upon inclusion of cardiovascular risk reduction in the EU label that correlates with a relative risk reduction rate of at least 20%, based on the results of the CLEAR Outcomes CVOT. On May 4, 2023, we filed an amended complaint against DSE in the Southern District of New York seeking a judicial declaration, on an expedited basis, that DSE is contractually required to make a \$300 million milestone payment to the Company upon applicable regulatory approval. On June 20, 2023, DSE filed a response to our amended complaint. On January 2, 2024, we entered into a settlement agreement with DSE to amicably resolve and dismiss the commercial dispute then pending in the Southern District of New York, or the Settlement Agreement. Under the Settlement Agreement, DSE agreed to pay us an aggregate of \$125 million, including (1) a \$100-million payment within 15 business days of the effective date of the Settlement Agreement and (2) a \$25-million payment in the calendar quarter immediately following the calendar quarter in which the EMA renders a decision on the application that was filed with the EMA for a Type II(a) variation for our oral non-statin products marketed as NILEMDO® (bempedoic acid) tablets and NUSTENDI® (bempedoic acid and ezetimibe) tablets in Europe. The application asks the EMA to approve both NILEMDO and NUSTENDI to reduce cardiovascular risk in patients with or at high risk for atherosclerotic cardiovascular disease. The legal action pending in the United States District Court for the Southern District of New York has now been dismissed.

Pursuant to the Settlement Agreement, also on January 2, 2024, we entered into a 3rd Amendment to the License and Collaboration Agreement dated January 2, 2019 with DSE, and a 1<sup>st</sup> Amendment to the License and Collaboration Agreement dated April 26, 2021 with DS. Each of these amendments grant each of DSE and DS exclusive rights for clinical development, regulatory activities, manufacture and commercialization of a bempedoic acid/ezetimibe/statin triple combination pill in their existing respective territories of the European Economic Area, UK, Switzerland and Turkey (the "DSE Territory") and South Korea, Taiwan, Hong Kong, Thailand, Vietnam, Brazil, Macao, Cambodia and Myanmar (the "DS Territory"). Further, after a transition period, DSE and DS will assume sole responsibility for the manufacture of NILEMDO and NUSTENDI for, respectively, the DSE Territory and DS Territory. As of January 2, 2024, DSE shall have sole authority and control of regulatory communications with the EMA regarding the pending marketing authorization applications for NILEMDO and NUSTENDI.

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.

Receipt of any milestone payment amounts is subject to risks and uncertainties, including our obtaining the relevant regulatory approvals and marketing authorizations, the absence of any material disagreements or disputes with regulators or our collaboration partners and the ultimate timing and payment of such milestone payment amounts by our collaboration partners. In addition, while we expect that we will be entitled to the foregoing milestone payments, our inability to receive some or all of our milestone payments and other royalty amounts from our collaboration partners may significantly impact our future capital needs.

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 future 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.

While we have monitoring measures and quality agreements in place with our suppliers, 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.

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.



## 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 any future public health epidemics, pandemics or outbreaks of infectious disease and any recession, depression or sustained market event resulting from such public health crises;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, political, 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 2023 and 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, 2023.

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.

***We are a “smaller reporting company” and have elected to comply with reduced public company reporting requirements, which could make our common stock less attractive to investors.***

Because our annual revenue was less than \$100.0 million during the most recently completed fiscal year and the market value of our voting and non-voting common stock held by non-affiliates was less than \$560.0 million measured on the last business day of our most recently completed second fiscal quarter, we qualify as a “smaller reporting company” as defined in the Exchange Act. Accordingly, we may provide less public disclosure than larger public companies, including the inclusion of only two years of audited financial statements and only two years of related selected financial data and management’s discussion and analysis of financial condition and results of operations disclosure. We are also no longer required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests. We cannot predict if investors will find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result of any choice we make to reduce disclosure, there may be a less active trading market for our common stock and the market price for our common stock may be more volatile.

***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.

***Increased attention to, and evolving expectations for, environmental, climate change, social, and governance (ESG) initiatives could increase our costs, harm our reputation, or otherwise adversely impact our business.***

Companies across industries are facing increasing scrutiny from a variety of stakeholders related to their ESG and sustainability practices, including practices associated with climate change. Expectations regarding voluntary ESG initiatives and disclosures may result in increased costs (including but not limited to increased costs related to compliance, stakeholder engagement, contracting and insurance), enhanced compliance or disclosure obligations, or other adverse impacts to our business, financial condition, or results of operations.

While we may at times engage in voluntary initiatives (such as voluntary disclosures, certifications, or goals, among others) to improve the ESG profile of the Company, such initiatives may be costly and may not have the desired effect. Moreover, we may not be able to successfully complete such initiatives due to factors that are within or outside of our control. Even if this is not the case, our actions may subsequently be determined to be insufficient by various stakeholders, and we may be subject to investor or regulator engagement on our ESG efforts, even if such initiatives are currently voluntary.

Certain market participants, including major institutional investors and capital providers, use third-party benchmarks and scores to assess companies' ESG profiles in making investment or voting decisions. Unfavorable ESG ratings could lead to increased negative investor sentiment towards us, which could negatively impact our share price as well as our access to and cost of capital. To the extent ESG matters negatively impact our reputation, it may also impede our ability to compete as effectively to attract and retain employees, which may adversely impact our operations.

In addition, we expect there will likely be increasing levels of regulation, disclosure-related and otherwise, with respect to ESG matters. For example, the SEC has published propose rules that would require companies to provide significantly expanded climate-related disclosures in their periodic reporting, which may require us to incur significant additional costs to comply, including the implementation of significant additional internal controls processes and procedures regarding matters that have not been subject to such controls in the past, and impose increased oversight obligations on our management and board of directors. These and other changes in stakeholder expectations will likely lead to increased costs as well as scrutiny that could heighten all of the risks identified in this risk factor. Additionally, our business partners may be subject to similar expectations, which may augment or create additional risks, including risks that may not be known to us.

***A decline in the federal budget, changes in spending or budgetary priorities of the U.S. government, a prolonged U.S. government shutdown or delays in contract awards may significantly and adversely affect our future revenues, cash flow and financial results.***

In recent years, U.S. government appropriations have been affected by larger U.S. government budgetary issues and related legislation. As a result, the Department of Defense funding levels have fluctuated and have been difficult to predict. Future spending levels are subject to a wide range of factors, including Congressional action. In addition, in recent years, the U.S. government has been unable to complete its budget process before the end of its fiscal year, resulting in both a government shutdown and continuing resolutions to extend sufficient funds only for U.S. government agencies to continue operating. Most recently, the federal government was shut down due to a lack of funding for over one month between late 2018 and early 2019. Additionally, the national debt has recently threatened to reach the statutory debt ceiling in 2023, and such an event in future years could result in the U.S. government defaulting on its debts.

As a result, government spending levels are difficult to predict beyond the near term due to numerous factors, including the external threat environment, future government priorities and the state of government finances. Significant changes in government spending or changes in U.S. government priorities, policies and requirements could have a material adverse effect on our results of operations, financial condition or liquidity.

*Unfavorable macroeconomic conditions or market volatility resulting from global economic conditions, including those affecting the financial services industry, could adversely affect our business, financial condition or results of operations.*

Adverse market or macroeconomic conditions or market volatility resulting from global economic developments, political unrest, high inflation, rising interest rates, changes in international trade relationships and military conflicts, such as the ongoing conflict between Russia and Ukraine and the conflict between Israel and Hamas, the post-COVID environment or other factors, could materially and adversely affect our business operations. For instance, actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. A severe or prolonged economic downturn or additional global financial crises could result in a variety of risks to our business, including weakened demand for any product candidates we develop or our ability to raise additional capital when needed on acceptable terms, if at all. In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our suppliers, which in turn, could have a material adverse effect on our current and/or planned business operations and our current or projected results of operations and financial condition. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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

None.

#### **Item 1C. Cybersecurity**

##### **Cyber Risk Management and Strategy**

We, under the oversight of the audit committee of our board of directors, have implemented and maintain a cybersecurity framework, informed by the Center of Internet Security, or CIS, cybersecurity framework. This includes policies, processes and technologies designed to minimize risks from cybersecurity threats. We maintain oversight of our third-party vendors with access to our information technology resources through the inclusion of contractual security requirements as appropriate.

Our cybersecurity approach is designed to minimize risks from cybersecurity threats identified by internal stakeholders, threat intelligence providers, vulnerability management programs, and security management programs. Our internal team manages and maintains remediation strategies for identified risks, and reports on them periodically to senior leadership.

As appropriate, we assess our internal controls, including controls around our information technology systems and their impact on our financial statements or systems, through either independent audits or internal assessments with the assistance of third party resources.

##### **Governance Related to Cybersecurity Risks**

Our cybersecurity program and related operations and processes are directed by our Executive Director of Information Technology, whom we refer to as the IT Director. Currently, the IT Director role is held by an individual who has over 15 years of cybersecurity, information technology, and systems engineering experience. The Director of IT reports to our management – currently the Chief Business Officer.

The IT Director meets with the Chief Financial Officer, the Chief Compliance Officer, and the General Counsel periodically to monitor and review the outcomes of our cybersecurity program and to discuss and decide matters related to cybersecurity treatment strategy (including mitigations). The IT Director and the Chief Financial Officer provide periodic reports to the audit committee on cybersecurity risk management, and, quarterly, the Chief Financial Officer updates the audit committee of any material changes in the Company's cybersecurity framework or cybersecurity activity. The audit committee is responsible for reviewing and overseeing our risk management process, including risks from cybersecurity threats, pursuant to the audit committee charter. Our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to confirm that the risk management processes designed and implemented by management are appropriate and functioning as designed.

#### **Item 2. Properties**

Our corporate headquarters are located in Ann Arbor, Michigan where we lease and occupy approximately 11,500 square feet of office space. We believe our current facilities will be sufficient to meet our needs until expiration.

### **Item 3. Legal Proceedings**

On March 27, 2023, we filed a complaint in the United States District Court for the Southern District of New York seeking declaratory judgment against DSE regarding the Company's right to receive a \$300 million milestone payment upon inclusion of cardiovascular risk reduction in the EU label that correlates with a relative risk reduction rate of at least 20%, based on the results of the CLEAR Outcomes CVOT. On May 4, 2023, we filed an amended complaint against DSE in the Southern District of New York seeking a judicial declaration, on an expedited basis, that DSE is contractually required to make a \$300 million milestone payment to the Company upon applicable regulatory approval. On June 20, 2023, DSE filed a response to our amended complaint.

On January 2, 2024, we entered into a settlement agreement with DSE to amicably resolve and dismiss the commercial dispute then pending in the Southern District of New York, or the Settlement Agreement. Under the Settlement Agreement, DSE agreed to pay us an aggregate of \$125 million, including (1) a \$100-million payment within 15 business days of the effective date of the Settlement Agreement and (2) a \$25-million payment in the calendar quarter immediately following the calendar quarter in which the EMA renders a decision on the application that was filed with the EMA for a Type II(a) variation for our oral non-statin products marketed as NILEMDO® (bempedoic acid) tablets and NUSTENDI® (bempedoic acid and ezetimibe) tablets in Europe. The application asks the EMA to approve both NILEMDO and NUSTENDI to reduce cardiovascular risk in patients with or at high risk for atherosclerotic cardiovascular disease. The legal action pending in the United States District Court for the Southern District of New York has now been dismissed.

Pursuant to the Settlement Agreement, also on January 2, 2024, we entered into a 3rd Amendment to the License and Collaboration Agreement dated January 2, 2019 with DSE, and a 1<sup>st</sup> Amendment to the License and Collaboration Agreement dated April 26, 2021 with DS. Each of these amendments grant each of DSE and DS exclusive rights for clinical development, regulatory activities, manufacture and commercialization of a bempedoic acid/ezetimibe/statin triple combination pill in their existing respective territories of the European Economic Area, UK, Switzerland and Turkey (the "DSE Territory") and South Korea, Taiwan, Hong Kong, Thailand, Vietnam, Brazil, Macao, Cambodia and Myanmar (the "DS Territory"). Further, after a transition period, DSE and DS will assume sole responsibility for the manufacture of NILEMDO and NUSTENDI for, respectively, the DSE Territory and DS Territory. As of January 2, 2024, DSE shall have sole authority and control of regulatory communications with the EMA regarding the pending marketing authorization applications for NILEMDO and NUSTENDI.

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”.

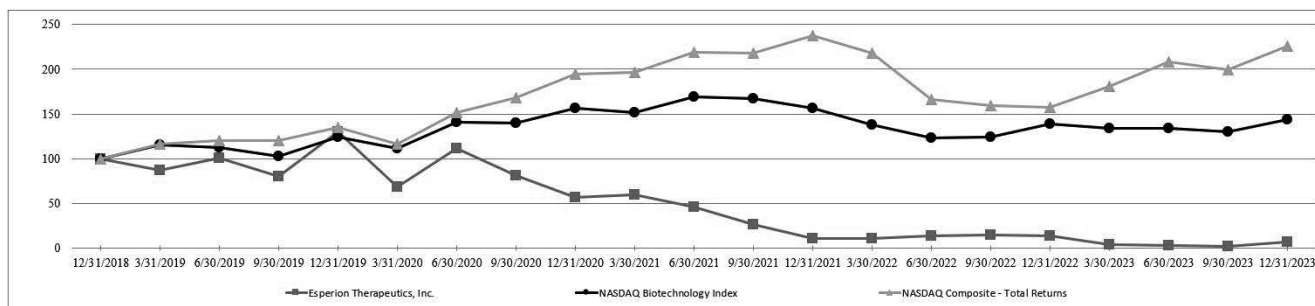
#### Stockholders

As of January 31, 2024, 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, 2018, 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, 2018 through December 31, 2023, 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, 2018 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 on Form 10-K.

### **Unregistered Securities Sold Within Last 3 Years**

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**

The Company has not made any repurchases of shares or other units of any class of the Company's equity securities during the fourth quarter of the fiscal year covered by this Annual Report on Form 10-K.

### **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 currently 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 biotech. Our team of experts are dedicated to lowering LDL-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. NEXLETOL® (bempedoic acid) and NEXLIZET® (bempedoic acid and ezetimibe) tablets are oral, once-daily, non-statin medicines for the treatment of primary hyperlipidemia in adults with heterozygous familial hypercholesterolemia, or HeFH or atherosclerotic cardiovascular disease, or ASCVD, who require additional lowering of LDL-C.

We 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 adult patients who are statin averse and who have cardiovascular disease, or CVD, or are at high risk for CVD. We initiated the CLEAR Outcomes CVOT in December 2016 and fully enrolled the study with nearly 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.

On March 4, 2023, we announced the full results from the CLEAR Outcomes trial. The study showed that bempedoic acid demonstrated significant cardiovascular risk reductions and significantly reduced the risk of heart attack and coronary revascularization 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 NEXLETOL and NEXLIZET (bempedoic acid and ezetimibe) tablets, became the first LDL-C lowering therapy since statins to demonstrate the ability 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.

On June 1, 2023, we announced that we submitted Supplemental New Drug Applications, or sNDAs, to the FDA seeking to add the use of both NEXLETOL and NEXLIZET for cardiovascular risk reduction and also seeking to remove the statin limitation in the LDL-C indication. Subsequently, the FDA accepted the sNDAs with an anticipated Prescription Drug User Fee Act date, or target action date, of March 31, 2024. On June 28, 2023, we announced that the application was filed for a Type II(a) variation with the EMA for our oral non-statin products marketed as NILEMDO® (bempedoic acid) tablets and NUSTENDI® (bempedoic acid and ezetimibe) tablets in Europe. The application asks EMA to approve both NILEMDO and NUSTENDI to reduce cardiovascular risk in patients with or at high risk for atherosclerotic cardiovascular disease. We anticipate EMA approval in the second quarter of 2024. On December 13, 2023, we announced that the FDA approved an updated LDL-cholesterol lowering indication for NEXLETOL and NEXLIZET to include the treatment of primary hyperlipidemia as a qualifier for existing approved populations. Additionally, the maximally tolerated qualifier for statin use has been removed, and the prior limitation of use stating “the effect of NEXLIZET or NEXLETOL on cardiovascular morbidity and mortality has not been determined” has also been removed.

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 \$209.2 million and \$233.7 million for the years ended December 31, 2023 and 2022, 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 and cardiovascular risk by reducing cholesterol biosynthesis and up-regulating the LDL receptors. Completed Phase 3 studies whose primary endpoint was LDL-C lowering were conducted in more than 3,000 patients, with over 2,000 patients treated with NEXLETOL, and demonstrated an average 18% placebo corrected LDL-C lowering when used in patients on moderate or high-intensity statins. The completed Phase 3 Cholesterol Lowering via Bempedoic acid, an ACL-Inhibiting Regimen (CLEAR) Outcomes trial in patients unwilling or unable to take statins and who had, or were at high risk for, cardiovascular disease demonstrated an average 21.1% placebo corrected LDL-C lowering, and a resulting 13% lower risk of major cardiovascular events versus placebo. NEXLETOL was approved by the FDA in February 2020 and is currently indicated as an adjunct to diet and statin therapy for the treatment of primary hyperlipidemia in adults with HeFH or 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% compared to placebo when added on to maximally tolerated statins. NEXLIZET was approved by the FDA in February 2020 and is currently indicated as an adjunct to diet and statin therapy for the treatment of primary hyperlipidemia in adults with HeFH or ASCVD who require additional lowering of LDL-C.

NILEMDO is a first-in-class ACL inhibitor that lowers LDL-C and cardiovascular risk by reducing cholesterol biosynthesis and up-regulating the LDL receptors. NILEMDO was approved by the European Commission, or 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 years ended December 31, 2023 and December 31, 2022, we incurred \$46.2 million and \$83.5 million, respectively, in direct expenses related to our CLEAR Outcomes CVOT and other ongoing clinical studies.

## **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 years ended December 31, 2023 and December 31, 2022, was primarily related to 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 as they relate to other development programs or additional indications we choose to pursue such as the development of our next generation ACLY inhibitors. We expect research and development expenses to decrease substantially in 2024 after the completion of the CLEAR Outcomes CVOT and submitting regulatory filings to the FDA and EMA in 2023. 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 in 2024 in anticipation of potential additional global regulatory approvals for new product indications, expanded commercialization initiatives for NEXLETOL and NEXLIZET, and increases in our associated headcount to expand our sales team.

### ***Interest Expense***

Interest expense for the years ended December 31, 2023 and December 31, 2022 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.

### ***Other Income***

Other income, net, for the years ended December 31, 2023 and December 31, 2022 primarily relates to interest income and the accretion or amortization of premiums and discounts earned on our cash, cash equivalents and investment securities and also includes other income related to the sale of leased vehicles.

### **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. Our estimates give consideration for 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, 2023 net product sales would have an impact of approximately \$2.4 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. We impute 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. We evaluate the interest rate quarterly based on our 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 RIPA, 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. In 2025, the percent of net revenue paid to Oberland could reset to a higher amount if certain revenue milestones are not met. This could result in substantially higher payments starting in 2025. 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 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, 2023 and 2022*

The following table summarizes our results of operations for the years ended December 31, 2023 and 2022:

	Year Ended December 31,		
	2023	2022	Change
	(in thousands)		
<b>Revenues:</b>			
Product sales, net	\$ 78,335	\$ 55,863	\$ 22,472
Collaboration revenue	37,999	19,612	18,387
<b>Operating Expenses:</b>			
Cost of goods sold	43,267	26,967	16,300
Research and development	86,107	118,927	(32,820)
Selling, general and administrative	142,523	109,082	33,441
<b>Loss from operations</b>	<b>(155,563)</b>	<b>(179,501)</b>	<b>23,938</b>
Interest expense	(58,976)	(56,810)	(2,166)
Other income, net	5,291	2,652	2,639
<b>Net loss</b>	<b>\$ (209,248)</b>	<b>\$ (233,659)</b>	<b>\$ 24,411</b>

#### *Product sales, net*

Product sales, net for the year ended December 31, 2023 was \$78.3 million compared to \$55.9 million for the year ended December 31, 2022, an increase of approximately \$22.4 million. The increase is primarily due to prescription growth of NEXLETOL and NEXLIZET.

#### *Collaboration revenue*

Collaboration revenue recognized from our collaboration agreements for the year ended December 31, 2023 was \$38.0 million compared to \$19.6 million for the year ended December 31, 2022, an increase of \$18.4 million. The increase is primarily due to increased product sales to our collaboration partners from our supply agreements and royalty sales growth within our partner territories.

#### *Cost of goods sold*

Cost of goods sold for the year ended December 31, 2023, was \$43.3 million compared to \$27.0 million for the year ended December 31, 2022, an increase of \$16.3 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, 2023, were \$86.1 million compared to \$118.9 million for the year ended December 31, 2022, a decrease of \$32.8 million. The decrease in research and development expenses was primarily attributable to a decrease in costs related to CLEAR Outcomes study following the announcement and presentation of our CLEAR Outcomes study results in March 2023. Costs incurred in the year ended December 31, 2023 included the announcement and presentation of our CLEAR Outcomes study results, associated close-out activities and regulatory submissions.

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

Selling, general and administrative expenses for the year ended December 31, 2023, were \$142.5 million compared to \$109.1 million for the year ended December 31, 2022, an increase of \$33.4 million. The increase in selling, general and administrative expenses was primarily attributable to increases in legal costs, including legal costs associated with the settlement announced in early January 2024, increases in headcount, consulting and other promotional related expenses.

### ***Interest expense***

Interest expense for the year ended December 31, 2023, was \$59.0 million, compared to \$56.8 million for the year ended December 31, 2022, an increase of \$2.2 million. The increase in interest expense for the year ended December 31, 2023 was primarily due to additional interest expense attributable to our RIPA with Oberland.

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

Other income, net for the year ended December 31, 2023, was \$5.3 million compared to \$2.7 million for the year ended December 31, 2022, an increase of \$2.6 million. This increase was primarily due to higher interest income on our investments due to higher interest rates.

### **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.

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 us of up to \$70 million of shares of our 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 filed on February 21, 2023. During 2023, we issued 3,312,908 shares of common stock resulting in net proceeds of approximately \$4.4 million after deducting \$0.4 million of underwriting discounts and commissions and other expenses, pursuant to the 2023 ATM Program.

On March 19, 2023, we entered into a Securities Purchase Agreement, pursuant to which we agreed to issue and sell, in a registered direct offering, or the Registered Direct Offering, 12,205,000 shares of our common stock, pre-funded warrants pre-funded warrants to purchase up to an aggregate of 20,965,747 shares of our common stock, and warrants to purchase up to 33,170,747 shares of our common stock. The combined purchase price of each share of common stock and accompanying warrant was \$1.675 per share. The purchase price of each pre-funded warrant and the accompanying warrant was \$1.674 (equal to the combined purchase price per share of common stock and accompanying warrant, minus \$0.001). In connection with the Securities Purchase Agreement, we amended certain existing warrants to purchase up to an aggregate of 9,024,212 shares of our common stock that were previously issued in December 2021 at an exercise price of \$9.00 per share and had an expiration date of December 7, 2023, such that the amended warrants have a reduced exercise price of \$1.55 per share and expire three and one half years following the closing of the Registered Direct Offering, for additional consideration of \$0.125 per amended warrant. We received net proceeds of approximately \$51.3 million related to the Registered Direct Offering and approximately \$1.1 million in connection with the amended warrants.

On January 2, 2024, we entered into a settlement agreement with Daiichi Sankyo Europe GmbH, or DSE, to amicably resolve and dismiss the commercial dispute then pending in the Southern District of New York, or the Settlement Agreement. Under the Settlement Agreement, DSE agreed to pay us an aggregate of \$125 million, including (1) a \$100-million payment within 15 business days of the effective date of the Settlement Agreement and (2) a \$25-million payment in the calendar quarter immediately following the calendar quarter in which the EMA renders a decision on the application that was filed with the EMA for a Type II(a) variation for our oral non-statin products marketed as NILEMDO® (bempedoic acid) tablets and NUSTENDI® (bempedoic acid and ezetimibe) tablets in Europe. The application asks the EMA to approve both NILEMDO and NUSTENDI to reduce cardiovascular risk in patients with or at high risk for atherosclerotic cardiovascular disease. The legal action pending in the United States District Court for the Southern District of New York has now been dismissed.

On January 18, 2024, we entered into an underwriting agreement, or the Underwriting Agreement, with Jefferies LLC, or Jefferies, as representative of several underwriters, or the Underwriters, related to an underwritten public offering, or the January 2024 Offering, of 56,700,000 shares of our common stock, par value \$0.001 per share, at a purchase price to the public of \$1.50 per share. The Underwriters were also granted a 30-day option to purchase up to an additional 8,505,000 shares of our common stock, at the public offering price. On January 19, 2024, Jefferies gave us notice of its election to exercise the option to purchase additional shares, in full. Giving effect to the exercise of Underwriters' option, the offering proceeds to us were approximately \$90.8 million, after deducting the underwriting discount and estimated offering expenses. The January 2024 Offering closed on January 23, 2024.

We anticipate that we will incur operating 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, and investments, including the funds received in January 2024 from the Settlement Agreement and January 2024 Offering, 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, 2023, our primary sources of liquidity were our cash and cash equivalents which totaled \$82.2 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:

	<b>Year Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
	<b>(in thousands)</b>	
Net cash used in operating activities	(135,487)	(174,827)
Net cash provided by investing activities	42,500	8,104
Net cash provided by financing activities	50,460	32,606
<b>Net decrease in cash, cash equivalents and restricted cash</b>	<b>(42,527)</b>	<b>(134,117)</b>

### ***Operating Activities***

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

Net cash used in operating activities totaled \$135.5 million for the year ended December 31, 2023 and \$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 the amortization of issuance costs on our convertible notes, depreciation and amortization and changes in working capital. The decrease in cash used in operating activities for the year ended December 31, 2023 compared to the year ended December 31, 2022 was primarily related to a decrease in net loss from increases in net product sales and collaboration revenue and lower research and development costs from our CLEAR Outcomes CVOT following the public presentation of the results in 2023, partially offset by increase in selling, general, and administrative expenses due to increased legal costs and other promotional expenses, increases in inventory, and increases in cost of goods sold related to additional sales, adjusted for normal working capital and timing of cash outlays.

### ***Investing Activities***

Net cash provided by investing activities of \$42.5 million for the year ended December 31, 2023 and \$8.1 million for the year ended December 31, 2022 consisted primarily of net proceeds from the sales of highly liquid, interest bearing investment grade and government securities.

### ***Financing Activities***

Net cash provided by financing activities of \$50.5 million for the year ended December 31, 2023, related primarily to proceeds from our Registered Direct Offering, exercise of warrants, and net proceeds from our 2023 ATM Program, partially offset by payments on our revenue interest liability. Net cash provided by financing activities of \$32.6 million for the year ended December 31, 2022, related primarily proceeds from our 2022 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.

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 \$34.8 million in the next year to a maximum total payment of \$337.8 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. In 2025, the percent of net revenue paid to Oberland could reset to a higher amount if certain revenue milestones are not met. This could result in substantially higher payments starting in 2025. 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.

On April 15, 2022, we filed a new registration statement on Form S-3, which registered the offering, issuance and sale of up to \$239 million of common stock from time to time in "at-the-market" offerings, or the 2022 ATM Program. During the year ended December 31, 2022, we issued 13,043,797 shares of common stock, pursuant to the 2022 ATM Program for which Jefferies LLC served as sales agent, resulting in net proceeds of approximately \$90.8 million after deducting \$3.1 million of underwriting discounts and commissions and other expenses. 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 us of up to \$70 million of shares of our 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 filed on February 21, 2023. During the year ended December 31, 2023, we issued 3,312,908 shares of common stock resulting in net proceeds of approximately \$4.4 million after deducting \$0.4 million of underwriting discounts and commissions and other expenses, pursuant to the 2023 ATM Program. 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.

As noted above, on March 22, 2023, we issued and sold, in a registered direct offering, or the Registered Direct Offering, 12,205,000 shares of our common stock, pre-funded warrants to purchase up to an aggregate of 20,965,747 shares of our common stock, and warrants to purchase up to 33,170,747 shares of our common stock. The combined purchase price of each share of common stock and accompanying warrant was \$1.675 per share. The purchase price of each pre-funded warrant and the accompanying warrant was \$1.674 (equal to the combined purchase price per share of common stock and accompanying warrant, minus \$0.001). In connection with the Registered Direct Offering, we amended certain existing warrants to purchase up to an aggregate of 9,024,212 shares of our common stock that were previously issued in December 2021 at an exercise price of \$9.00 per share and had an expiration date of December 7, 2023, such that the amended warrants have a reduced exercise price of \$1.55 per share. The warrants are immediately exercisable and will expire on September 22, 2026, which may provide



us with additional funding, if such warrants are exercised by their holders. Each pre-funded warrant is exercisable for one share of our common stock at an exercise price of \$0.001 per share. The pre-funded warrants were immediately exercisable and could be exercised at any time. As of December 31, 2023, no pre-funded warrants were outstanding. During the year ended December 31, 2023, we received net proceeds of approximately \$8.4 million from the exercise of warrants and pre-funded warrants. We received net proceeds of approximately \$51.3 million related to the Registered Direct Offering after deducting placement agent fees and related offering expenses of \$4.2 million, and we received approximately \$1.1 million in connection with the amended warrants after deducting placement fees of \$0.1 million. Refer to Note 12 to our audited financial statements appearing elsewhere in this Annual Report on Form 10-K for further information.

As noted above, subsequent to December 31, 2023, we received \$100 million from DSE in January 2024 under the Settlement Agreement and expect to receive \$25 million in the calendar quarter immediately following the calendar quarter in which the EMA renders a decision on the application that was filed with the EMA for a Type II(a) variation for our oral non-statin products marketed as NILEMDO tablets and NUSTENDI tablets in Europe. In addition, as noted above, we received approximately \$90.8 million, after deducting the underwriting discounts and estimated offering expenses, from our January 2024 Offering.

### ***Plan of Operations and Funding Requirements***

We expect to continue to incur significant expenses and operating losses for the foreseeable future in connection with our 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, including cash received in January 2024 in conjunction with Settlement Agreement with DSE and the January 2024 Offering, 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. 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 service and payment of potential debt maturities;
- 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 and regulatory approvals for cardiovascular risk reduction in 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 substantial U.S. 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 and cash equivalents of approximately \$82.2 million at December 31, 2023. 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, 2023.

Our outstanding warrants currently have an exercise price of \$1.55 per share and holders of such warrants may not exercise if the market price of our common stock is below \$1.55. 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 \$1.55 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, 2023.

#### **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, 2023, 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, 2023, 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, 2023, 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, 2023, based on those criteria.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm regarding our internal control over financial reporting. We are not required to have, nor have we engaged our independent registered public accounting firm to perform, an audit on our internal control over financial reporting pursuant to the rules of the SEC that permit us to provide only management's report in this Annual Report on Form 10-K.

### **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, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **Item 9B. Other Information**

We did not have any Rule 10b5-1 plans in place during the year ended December 31, 2023.

**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 2024 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 (excluding the information under the subheading “Pay Versus Performance”) is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2024 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 2024 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 2024 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 2024 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
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Amendment No. 2 to the Registration Statement on Form S-1, File No. 333-188595, filed on June 12, 2013)
3.2	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)
3.3	Certificate of Amendment No. 2 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 June 15, 2023)
3.4	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)
3.5	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)
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Amendment No. 2 to the Registration Statement on Form S-1, File No. 333-188595, filed on June 12, 2013)
4.2	Investor Rights Agreement by and between the Registrant and certain of its stockholders dated April 28, 2008 (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-1, File No. 333-188595, filed on May 14, 2013)
4.3	Amendment No. 1 to Investor Rights Agreement by and between the Registrant and certain of its stockholders dated April 11, 2013 (incorporated by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form S-1, File No. 333-188595, filed on May 14, 2013)
4.4**	Description of Registrant's Securities
4.5	Indenture, dated as of November 16, 2020, between Esperion Therapeutics, Inc. and U.S. Bank National Association (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on November 16, 2020)
4.6	Form of 4.00% Convertible Senior Subordinated Note due 2025 (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on November 16, 2020)
4.7	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).
4.8	Form of Warrant Amendment Agreement (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, File No. 001-35986, filed on May 9, 2023)
4.9	Securities Purchase Agreement by and among the Registrant and the Purchasers named therein, dated March 19, 2023 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, File No. 001-35986, filed on May 9, 2023)
10.1*	License Agreement between Pfizer Inc. and the Registrant dated April 28, 2008 and amended on November 17, 2010 (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1, File No. 333-188595, filed on May 14, 2013)
10.2	Valley Ranch Business Park Lease by and between the Registrant and McMullen SPE, LLC, dated February 4, 2014 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on February 7, 2014)
10.3	Form of Officer Indemnification Agreement entered into between the Registrant and its officers (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1, File No. 333-188595, filed on May 14, 2013)
10.4	Form of Director Indemnification Agreement entered into between the Registrant and its directors (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1, File No. 333-188595, filed on May 14, 2013)
10.5#	Amended and Restated 2013 Stock Option and Incentive Plan and forms of agreements thereunder (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q, File No. 001-35986, filed on November 3, 2016)
10.6#	Employment Agreement by and between the Registrant and Richard B. Bartram dated May 14, 2015 (incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K, File No. 001-35986 filed on February 28, 2019)

- 10.7# 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).
- 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 Registrant, 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 among the Registrant, 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 Registrant 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 Registrant 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 (incorporated by reference to Exhibit 10.24 to the Registrant's Annual Report on Form 10-K, File No. 001-35986, filed on February 21, 2023)
- 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)
10.29#	First Amendment to 2022 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-8, File No. 333-265247, filed on August 1, 2023)
10.30#	Second Amendment to 2017 Inducement Equity Plan (incorporated by reference to Exhibit 99.3 to the Registrant's Registration Statement on Form S-8, File No. 333-274183, filed on August 24, 2023)
97.1**	Esperion Therapeutics, Inc. Compensation Recovery Policy
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Registration Statement on Form S-1, File No. 333-188595, filed on May 14, 2013)
23.1**	Consent of Ernst & Young LLP
31.1**	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2**	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1***	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.SCH**	Inline XBRL Taxonomy Extension Schema Document
101.CAL**	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB**	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF**	Inline XBRL Taxonomy Extension Definition Linkbase Document
104**	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.)

(#) Management contract or compensatory plan or arrangement.

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

(\*\*) Filed herewith.

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

## SIGNATURES

Pursuant to the requirements of 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 27, 2024

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 27, 2024
<u>                                  /s/ BENJAMIN HALLADAY                                  </u> Benjamin Halladay	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 27, 2024
<u>                                  /s/ J. MARTIN CARROLL                                  </u> J. Martin Carroll	Director	February 27, 2024
<u>                                  /s/ SETH H.Z. FISCHER                                  </u> Seth H.Z. Fischer	Director	February 27, 2024
<u>                                  /s/ ALAN FUHRMAN                                  </u> Alan Fuhrman	Director	February 27, 2024
<u>                                  /s/ ANTONIO M. GOTTO, M.D., D. PHIL                                  </u> Antonio M. Gotto, M.D., D. Phil	Director	February 27, 2024
<u>                                  /s/ STEPHEN ROCAMBOLI                                  </u> Stephen Rocamboli	Director	February 27, 2024
<u>                                  /s/ JAY SHEPARD                                  </u> Jay Shepard	Director	February 27, 2024
<u>                                  /s/ NICOLE VITULLO                                  </u> Nicole Vitullo	Director	February 27, 2024
<u>                                  /s/ TRACY M. WOODY                                  </u> Tracy M. Woody	Director	February 27, 2024

**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, 2023 and 2022, 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, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, 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 Matter**

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 the 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, 2023. The carrying amount of the RIPA at December 31, 2023, was \$274.8 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 sales forecasts 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 evaluated the significant assumptions related to market penetration, market demand and sales price, used within the net sales forecasts by corroborating to observable industry, market and economic trends and external analyses. We also 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 27, 2024

**Esperion Therapeutics, Inc.**

**Balance Sheets**

(in thousands, except share data)

	December 31, 2023	December 31, 2022
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 82,248	\$ 124,775
Short-term investments	—	42,086
Accounts receivable	48,494	33,729
Inventories, net	65,623	35,201
Prepaid clinical development costs	193	1,026
Other prepaid and current assets	4,507	9,866
Total current assets	<u>201,065</u>	<u>246,683</u>
Property and equipment, net	—	164
Right of use operating lease assets	4,675	1,036
Intangible assets	56	56
Total assets	<u>\$ 205,796</u>	<u>\$ 247,939</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 31,718	\$ 23,040
Accrued clinical development costs	3,441	5,426
Accrued variable consideration	34,284	21,987
Other accrued liabilities	24,998	13,204
Revenue interest liability	34,828	24,760
Deferred revenue from collaborations	25,402	3,507
Operating lease liabilities	1,553	384
Total current liabilities	<u>156,224</u>	<u>92,308</u>
Convertible notes, net of issuance costs	261,596	259,899
Revenue interest liability	239,950	218,845
Operating lease liabilities	3,020	665
Total liabilities	<u>\$ 660,790</u>	<u>\$ 571,717</u>
Commitments and contingencies (Note 5)		
<b>Stockholders' (deficit) equity:</b>		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized and no shares issued or outstanding as of December 31, 2023 and December 31, 2022	\$ —	\$ —
Common stock, \$0.001 par value; 480,000,000 shares authorized as of December 31, 2023 and 240,000,000 shares authorized as of December 31, 2022; 120,204,513 shares issued at December 31, 2023 and 76,564,396 shares issued at December 31, 2022	118	75
Additional paid-in capital	1,149,170	1,071,183
Treasury stock, at cost; 1,994,198 shares at December 31, 2023 and December 31, 2022	(54,998)	(54,998)
Accumulated other comprehensive loss	—	(2)
Accumulated deficit	(1,549,284)	(1,340,036)
Total stockholders' deficit	<u>(454,994)</u>	<u>(323,778)</u>
Total liabilities and stockholders' deficit	<u>\$ 205,796</u>	<u>\$ 247,939</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,	
	2023	2022
<b>Revenues:</b>		
Product sales, net	\$ 78,335	\$ 55,863
Collaboration revenue	37,999	19,612
Total Revenues	116,334	75,475
<b>Operating expenses:</b>		
Cost of goods sold	43,267	26,967
Research and development	86,107	118,927
Selling, general and administrative	142,523	109,082
Total operating expenses	271,897	254,976
<b>Loss from operations</b>	(155,563)	(179,501)
Interest expense	(58,976)	(56,810)
Other income, net	5,291	2,652
<b>Net loss</b>	\$ (209,248)	\$ (233,659)
Net loss per common share (basic and diluted)	\$ (2.03)	\$ (3.52)
Weighted-average shares outstanding (basic and diluted)	103,106,616	66,407,242
<b>Other comprehensive (loss) gain:</b>		
Unrealized gain on investments	\$ 2	\$ 29
<b>Total comprehensive loss</b>	\$ (209,246)	\$ (233,630)

See accompanying notes to the financial statements.

**Esperion Therapeutics, Inc.**

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

(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Treasury Stock	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
	Shares	Amount					
Balance December 31, 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	74,570,198	\$ 75	\$ 1,071,183	\$ (1,340,036)	\$ (54,998)	\$ (2)	\$ (323,778)
Issuance of common stock, warrants, and pre- funded warrants, net of issuance costs	12,205,000	12	52,416	—	—	—	52,428
Issuance of common stock from ATM Program, net of issuance costs	3,312,908	3	4,445	—	—	—	4,448
Vesting of restricted stock units and performance- based restricted stock units	1,034,631	1	—	—	—	—	1
Vesting of ESPP Shares	271,084	—	740	—	—	—	740
Stock-based compensation	—	—	11,958	—	—	—	11,958
Exercise of pre-funded warrants	20,965,747	21	—	—	—	—	21
Exercise of warrants	5,850,747	6	8,428	—	—	—	8,434
Other comprehensive gain	—	—	—	—	—	2	2
Net loss	—	—	—	(209,248)	—	—	(209,248)
Balance December 31, 2023	118,210,315	\$ 118	\$ 1,149,170	\$ (1,549,284)	\$ (54,998)	\$ —	\$ (454,994)

See accompanying notes to the financial statements.



**Esperion Therapeutics, Inc.**

**Statements of Cash Flows**

(in thousands)

	Year Ended December 31,	
	2023	2022
<b>Operating activities</b>		
Net loss	\$ (209,248)	\$ (233,659)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	164	500
Amortization of premiums and discounts on investments	(412)	279
Amortization of discount and issuance costs on convertible notes	1,697	1,621
Non-cash interest expense related to the revenue interest liability	46,679	44,590
Stock-based compensation expense	11,958	15,215
Changes in assets and liabilities:		
Accounts receivable	(14,765)	(10,795)
Prepays and other assets	6,192	1,419
Deferred revenue	21,895	(2,810)
Inventories	(30,422)	(807)
Accounts payable	8,678	5,603
Other accrued liabilities	22,097	4,017
Net cash used in operating activities	(135,487)	(174,827)
<b>Investing activities</b>		
Purchases of investments	—	(59,897)
Proceeds from sales/maturities of investments	42,500	68,001
Net cash provided by investing activities	42,500	8,104
<b>Financing activities</b>		
Proceeds from issuance of common stock and warrants from offering, net of issuance costs	52,428	—
Proceeds from issuance of common stock from ATM Program, net of issuance costs	4,448	90,849
Proceeds from exercise of warrants	9,069	—
Proceeds from exercise of pre-funded warrants	21	—
Payments on revenue interest liability	(15,506)	(8,024)
Repayment of principal on revenue interest liability	—	(50,000)
Payment for other issuance costs	—	(219)
Net cash provided by financing activities	50,460	32,606
Net decrease in cash, cash equivalents and restricted cash	(42,527)	(134,117)
Cash, cash equivalents and restricted cash at beginning of period	124,775	258,892
Cash and cash equivalents at end of period	<u>\$ 82,248</u>	<u>\$ 124,775</u>
Supplemental disclosure of cash flow information:		
Issuance costs not yet paid	\$ 635	\$ 1
Non-cash right of use asset	115	5

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 currently 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 biotech. The Esperion team of experts are dedicated to lowering LDL-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. NEXLETOL® (bempedoic acid) and NEXLIZET® (bempedoic acid and ezetimibe) tablets are oral, once-daily, non-statin medicines for the treatment of primary hyperlipidemia in adults with heterozygous familial hypercholesterolemia ("HeFH") or atherosclerotic cardiovascular disease ("ASCVD"), who require additional lowering of LDL-C.

The Company completed a global cardiovascular outcomes trial ("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 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 nearly 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.

On March 4, 2023, the Company announced the full results from the CLEAR Outcomes trial. The study showed that bempedoic acid demonstrated significant cardiovascular risk reductions and significantly reduced the risk of heart attack and coronary revascularization 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 NEXLETOL (bempedoic acid) tablets and NEXLIZET (bempedoic acid and ezetimibe) tablets, became the first LDL-C lowering therapy since statins to demonstrate the ability 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.

On March 19, 2023, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain purchasers named therein (the "Purchasers"), pursuant to which the Company agreed to issue and sell, in a registered direct offering (the "Registered Direct Offering"), 12,205,000 shares of its common stock, par value \$0.001 per share (the "Common Stock"), pre-funded warrants to purchase up to an aggregate of 20,965,747 shares of Common Stock (the "Pre-Funded Warrants") in lieu of shares of Common Stock, and warrants to purchase up to 33,170,747 shares of Common Stock (the "Warrants"). The combined purchase price of each share of Common Stock and accompanying Warrant is \$1.675 per share. The purchase price of each Pre-Funded Warrant and the accompanying Warrant is \$1.674 (equal to the combined purchase price per share of Common Stock and accompanying Warrant, minus \$0.001). The Purchase Agreement contains customary representations, warranties, covenants and indemnification rights and obligations of the Company and the Purchasers. The Registered Direct Offering closed on March 22, 2023. In connection with the Registered Direct Offering, the Company amended, pursuant to Warrant Amendment Agreements (the "Warrant Amendment Agreements"), certain existing warrants to purchase up to an aggregate of 9,024,212 shares of the Company's common stock that were previously issued in December 2021 at an exercise price of \$9.00 per share and had an expiration date of December 7, 2023, effective upon the closing of the Registered Direct Offering, such that the amended warrants have a reduced exercise price of \$1.55 per share and expire three and one half years following the closing of the Registered Direct Offering, for additional consideration of \$0.125 per amended warrant. The Company received gross proceeds of approximately \$55.5 million from the Registered Direct Offering, before deducting placement agent fees and related offering expenses. The net proceeds to the Company from the Registered Direct Offering, after deducting the placement agent fees and expenses and the Company's estimated offering expenses, are approximately \$51.3 million. In addition, the Company received approximately \$1.2 million as the gross consideration in connection with the Warrant Amendment Agreements. The net proceeds of the Warrant Amendment Agreements after deducting placement fees were approximately \$1.1 million. Refer to Note 12 "Stockholders' Deficit" for further information.

## Esperion Therapeutics, Inc.

### Notes to Financial Statements (Continued)

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

On June 1, 2023, the Company announced that it submitted Supplemental New Drug Applications ("sNDAs") to the FDA seeking to add the use of both NEXLETOL and NEXLIZET for cardiovascular risk reduction and also seeking to remove the statin limitation in the LDL-C indication. Subsequently, the FDA accepted the sNDAs with an anticipated Prescription Drug User Fee Act date, or target action date, of March 31, 2024. On June 28, 2023, the Company announced that the application was filed for a Type II(a) variation with the EMA for the Company's oral non-statin products marketed as NILEMDO® (bempedoic acid) tablets and NUSTENDI® (bempedoic acid and ezetimibe) tablets in Europe. The application asks EMA to approve both NILEMDO and NUSTENDI to reduce cardiovascular risk in patients with or at high risk for atherosclerotic cardiovascular disease. The Company anticipates EMA approval in the second quarter of 2024.

On January 2, 2024, the Company entered into a settlement agreement with Daiichi Sankyo Europe GmbH ("DSE") to amicably resolve and dismiss the commercial dispute then pending in the Southern District of New York ("Settlement Agreement"). Under the Settlement Agreement, DSE agreed to pay the Company an aggregate of \$125 million, including (1) a \$100-million payment within 15 business days of the effective date of the Settlement Agreement and (2) a \$25-million payment in the calendar quarter immediately following the calendar quarter in which the EMA renders a decision on the application that was filed with the EMA for a Type II(a) variation for the Company's oral non-statin products marketed as NILEMDO® (bempedoic acid) tablets and NUSTENDI® (bempedoic acid and ezetimibe) tablets in Europe. The application asks the EMA to approve both NILEMDO and NUSTENDI to reduce cardiovascular risk in patients with or at high risk for atherosclerotic cardiovascular disease. The legal action pending in the United States District Court for the Southern District of New York has now been dismissed. Refer to Note 3 "Collaborations with Third Parties," Note 5 "Commitments and Contingencies," and Note 18 "Subsequent Events" for further information.

On January 18, 2024, the Company entered into an Underwriting Agreement (the "Underwriting Agreement") with Jefferies LLC ("Jefferies"), as representative of several underwriters (the "Underwriters"), related to an underwritten public offering (the "January 2024 Offering") of 56,700,000 shares of common stock of the Company, par value \$0.001 per share ("Common Stock"), at a purchase price to the public of \$1.50 per share. The Underwriters were also granted a 30-day option to purchase up to an additional 8,505,000 shares of Common Stock, at the public offering price. On January 19, 2024, Jefferies gave notice to the Company of its election to exercise the option to purchase additional shares, in full. Giving effect to the exercise of Underwriters' option, the offering proceeds to the Company were approximately \$90.8 million, after deducting the underwriting discount and estimated offering expenses. The January 2024 Offering closed on January 23, 2024.

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. While management believes current cash resources, including the cash received in January 2024 as disclosed in Note 18 "Subsequent Events," and future cash received from the Company's net product sales and collaboration agreements with 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.

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").

## Esperion Therapeutics, Inc.

### Notes to Financial Statements (Continued)

## 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 Eiger III SA LLC, or Oberland, an affiliate of Oberland Capital LLC. 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 Revenue Interest Purchase Agreement ("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 \$15.6 million and \$11.3 million for the years ended December 31, 2023 and December 31, 2022, respectively.

### 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, 2023, eleven customers accounted for all of the Company's net trade receivables and as of December 31, 2022 eleven customers accounted for all the Company's net trade receivables. As of December 31, 2023, three customers hold approximately 96% of the Company's trade receivables associated with net product sales and accounted for approximately 95% of gross sales of NEXLETOL and NEXLIZET in 2023.

Notes to Financial Statements (Continued)

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

**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, 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, 2023.

**Leases**

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

**Convertible Notes**

The convertible notes are reported as a single liability at their amortized costs on the balance sheets, net of unamortized issuance costs. Issuance costs are amortized to interest expense over the life of the convertible debt. The Company uses the if-converted method when calculating diluted earnings per share.

Notes to Financial Statements (Continued)

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

**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.

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

## Esperion Therapeutics, Inc.

### Notes to Financial Statements (Continued)

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

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 \$78.3 million and \$55.9 million for the years ended December 31, 2023 and December 31, 2022, 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 "Accrued variable consideration" 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.

##### *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.

## Esperion Therapeutics, Inc.

### Notes to Financial Statements (Continued)

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

*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.

#### 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.



Notes to Financial Statements (Continued)

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

**Recent Accounting Pronouncements**

In December 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, *Segment Reporting (Topic 280): Improvements to Segment Reporting Disclosures*. This standard requires an entity to provide more detailed information about its reportable segment expenses that are included within management's measurement of profit and loss and will require certain annual disclosures to be provided on an interim basis. The amendments in this ASU are effective for the Company in 2025 for annual reporting and in 2026 for interim reporting, with early adoption permitted beginning in 2024, and is required to be applied using the full retrospective method of transition. The Company is evaluating the timing and effects of adoption of this ASU on the Company's segment disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires disaggregated information about a reporting entity's effective tax rate reconciliation, as well as information related to income taxes paid to enhance the transparency and decision usefulness of income tax disclosures. This ASU will be effective for the annual period ending December 31, 2025. The Company is currently evaluating the timing and impacts of adoption of this ASU.

The Company does not expect adoption of any remaining 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. 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.

On January 2, 2024, the Company entered into a Settlement Agreement with DSE to amicably resolve and dismiss their commercial dispute in the Southern District of New York. Under the Settlement Agreement, DSE has agreed to pay the Company an aggregate of \$125 million, including (1) a \$100-million payment within 15 business days of the effective date of the Settlement Agreement and (2) a \$25-million payment in the calendar quarter immediately following the calendar quarter in which the EMA renders a decision on the application that was filed with the EMA for a Type II(a) variation for the Company's oral non-statin products marketed as NILEMDO (bempedoic acid) tablets and NUSTENDI (bempedoic acid and ezetimibe) tablets in Europe. The DSE Amendment grants DSE the exclusive rights for clinical development, regulatory activities, manufacture and commercialization of a bempedoic acid/ezetimibe/statin triple combination pill in the DSE Territory. Further, after a transition period, DSE will assume sole responsibility for the manufacture of NILEMDO and NUSTENDI for the DSE Territory. As of January 2, 2024, DSE shall have sole authority and control of regulatory communications with the EMA regarding the pending marketing authorization applications for NILEMDO and NUSTENDI. Pursuant to the DSE Amendment, the Company is entitled to receive one-time cash payments of up to \$300 million upon the achievement of certain commercial

## Esperion Therapeutics, Inc.

### Notes to Financial Statements (Continued)

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

milestones related to total net sales achievements in the DSE Territory. The Company is also entitled to receive tiered 15% to 25% royalties on net DSE Territory sales.

##### *Collaboration Revenue*

During the years ended December 31, 2023 and December 31, 2022, the Company recognized collaboration revenue of \$37.2 million and \$18.2 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.

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 years ended December 31, 2023, and December 31, 2022, the Company recognized collaboration revenue of \$0.1 million and \$0.6 million, respectively, related to sales of bulk tablets to Otsuka pursuant to the supply agreement that was executed with Otsuka.

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.

Notes to Financial Statements (Continued)

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

**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.

Pursuant to the Settlement Agreement, on January 2, 2024, the Company entered a 1st Amendment (the "DS Amendment") to the License and Collaboration Agreement with DS. The DS Amendment grants DS exclusive rights for clinical development, regulatory activities, manufacture and commercialization of a bempedoic acid/ezetimibe/statin triple combination pill in the DS Territory. Further, after a transition period, DS will assume sole responsibility for the manufacture of NILEMDO and NUSTENDI for 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 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. During the years ended December 31, 2023 and December 31, 2022, the Company recognized \$0.7 million and \$0.8 million, respectively, of collaboration revenue related to the ongoing regulatory and development 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. The agreement allowed 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. On July 6, 2023, the Company provided notice to Serometrix of its intent to terminate the licensing agreement between the Company and Serometrix dated December 3, 2020. The agreement terminated as of August 5, 2023. The Company expects to continue to advance its internal pipeline assets, including next-generation ACLY inhibitors.

## Notes to Financial Statements (Continued)

## 4. Inventories, net

Inventories, net consist of the following:

	December 31,	
	2023	2022
	(in thousands)	
Raw materials	\$ 61,890	\$ 26,558
Work in process	1,728	6,548
Finished goods	2,005	2,095
	<u>\$ 65,623</u>	<u>\$ 35,201</u>

## 5. Commitments and Contingencies

## Legal Proceedings

On March 27, 2023, the Company filed a complaint in the United States District Court for the Southern District of New York seeking declaratory judgment against DSE regarding the Company's right to receive a \$300 million milestone payment upon inclusion of cardiovascular risk reduction in the EU label that correlates with a relative risk reduction rate of at least 20%, based on the results of the CLEAR Outcomes CVOT. On May 4, 2023, the Company filed an amended complaint against DSE in the Southern District of New York seeking a judicial declaration, on an expedited basis, that DSE is contractually required to make a \$300 million milestone payment to the Company upon applicable regulatory approval. On June 20, 2023, DSE filed a response to the amended complaint.

On January 2, 2024, the Company entered into a settlement agreement with DSE to amicably resolve and dismiss the commercial dispute then pending in the Southern District of New York, or the Settlement Agreement. Under the Settlement Agreement, DSE agreed to pay the Company an aggregate of \$125 million, including (1) a \$100-million payment within 15 business days of the effective date of the Settlement Agreement and (2) a \$25-million payment in the calendar quarter immediately following the calendar quarter in which the EMA renders a decision on the application that was filed with the EMA for a Type II(a) variation for the Company's oral non-statin products marketed as NILEMDO® (bempedoic acid) tablets and NUSTENDI® (bempedoic acid and ezetimibe) tablets in Europe. The application asks the EMA to approve both NILEMDO and NUSTENDI to reduce cardiovascular risk in patients with or at high risk for atherosclerotic cardiovascular disease. The legal action pending in the United States District Court for the Southern District of New York has now been dismissed.

Pursuant to the Settlement Agreement, also on January 2, 2024, the Company entered into a 3rd Amendment to the License and Collaboration Agreement dated January 2, 2019 with DSE, and a 1<sup>st</sup> Amendment to the License and Collaboration Agreement dated April 26, 2021 with DS. Each of these amendments grant each of DSE and DS exclusive rights for clinical development, regulatory activities, manufacture and commercialization of a bempedoic acid/ezetimibe/statin triple combination pill in their existing respective territories of the European Economic Area, UK, Switzerland and Turkey (the "DSE Territory") and South Korea, Taiwan, Hong Kong, Thailand, Vietnam, Brazil, Macao, Cambodia and Myanmar (the "DS Territory"). Further, after a transition period, DSE and DS will assume sole responsibility for the manufacture of NILEMDO and NUSTENDI for, respectively, the DSE Territory and DS Territory. As of January 2, 2024, DSE shall have sole authority and control of regulatory communications with the EMA regarding the pending marketing authorization applications for NILEMDO and NUSTENDI.

**Esperion Therapeutics, Inc.**

**Notes to Financial Statements (Continued)**

**6. Property and Equipment, net**

Property and equipment, net, consist of the following:

	December 31,	
	2023	2022
	(in thousands)	
Computer equipment	\$ 249	\$ 278
Software	968	968
Furniture, fixtures and other	606	1,170
Leasehold improvements	189	299
Subtotal	2,012	2,715
Less accumulated depreciation and amortization	2,012	2,551
Property and equipment, net	\$ —	\$ 164

Depreciation expense was \$0.2 million and \$0.5 million for the years ended December 31, 2023 and 2022, respectively.

**7. Other Accrued Liabilities**

Other accrued liabilities consist of the following:

	December 31,	
	2023	2022
	(in thousands)	
Accrued compensation	\$ 10,769	\$ 9,053
Accrued legal fees	9,202	186
Accrued professional fees	2,712	2,361
Accrued interest on convertible notes	1,325	1,325
Accrued other	990	279
Total other accrued liabilities	\$ 24,998	\$ 13,204

**8. Investments**

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

	December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
<b>Cash equivalents:</b>				
Money market funds	\$ 68,445	\$ —	\$ —	\$ 68,445
Certificates of deposit	402	—	—	402
Total	\$ 68,847	\$ —	\$ —	\$ 68,847

**Esperion Therapeutics, Inc.**

**Notes to Financial Statements (Continued)**

**8. Investments (Continued)**

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

During the years ended December 31, 2023 and 2022, other income, net in the statements of operations includes interest income on available-for-sale investments of \$4.4 million and \$2.4 million, respectively. Other income, net in the statements of operations includes amortization of premiums and discounts on investments of \$0.4 million and \$0.2 million during the years ended December 31, 2023 and 2022, respectively.

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, 2023 and 2022.

**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.

**Esperion Therapeutics, Inc.**

**Notes to Financial Statements (Continued)**

**9. Fair Value Measurements (Continued)**

The following table presents the Company’s financial assets that have been measured at fair value on a recurring basis:

Description	Total	Level 1	Level 2	Level 3
<b>December 31, 2023</b>				
Assets:				
Money market funds	\$ 68,445	\$ 68,445	\$ —	\$ —
Certificates of deposit	402	402	—	—
<b>Total assets at fair value</b>	<b>\$ 68,847</b>	<b>\$ 68,847</b>	<b>\$ —</b>	<b>\$ —</b>
<b>December 31, 2022</b>				
Assets:				
Money market funds	\$ 105,078	\$ 105,078	\$ —	\$ —
Certificates of deposit	401	401	—	—
U.S. treasury notes	47,081	47,081	—	—
<b>Total assets at fair value</b>	<b>\$ 152,560</b>	<b>\$ 152,560</b>	<b>\$ —</b>	<b>\$ —</b>

There were no transfers between Levels 1, 2 or 3 during the years ended December 31, 2023 or December 31, 2022.

**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 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.

Notes to Financial Statements (Continued)

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

*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.

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 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 Wavier 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



Notes to Financial Statements (Continued)

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

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, 2023, the Company has recorded a liability, referred to as the “Revenue interest liability” on the balance sheet, of \$274.8 million, net of \$0.2 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. At December 31, 2023, the remaining redemption amount is \$372.6 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 \$46.7 million and \$44.6 million in interest expense related to this arrangement for the years ended December 31, 2023 and 2022, 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, 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. In 2025, the percent of net revenue paid to Oberland could reset to a higher amount if certain revenue milestones are not met. This could result in substantially higher payments starting in 2025. 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 \$34.8 million in the next twelve months.

The effective annual imputed interest rate is 17.6% as of December 31, 2023. Payments made to Oberland as a result of the Company’s net sales will reduce the revenue interest liability.

## Esperion Therapeutics, Inc.

### Notes to Financial Statements (Continued)

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

The following table summarizes the revenue interest liability activity during the years ended December 31, 2023 and 2022:

	(in thousands)
Revenue interest liability at December 31, 2021	\$ 257,039
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>
Interest expense recognized	46,679
Revenue interest payments	(15,506)
Revenue interest liability at December 31, 2023	<u>\$ 274,778</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 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.

Notes to Financial Statements (Continued)

**11. Convertible Notes (Continued)**

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.

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.

As of December 31, 2023, the principal amount of convertible notes was \$265.0 million, and the unamortized debt discount and issuance costs were \$3.4 million, for a net carrying amount of \$261.6 million. 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.

The Company recorded \$12.3 million and \$12.2 million of interest expense during the years ended December 31, 2023 and 2022, respectively, relating to the cash interest on the convertible notes due semi-annually and amortization of the debt issuance costs.

As of December 31, 2023, no Convertible Notes were convertible pursuant to their terms. The estimated fair value of the Convertible Notes was \$155.9 million as of December 31, 2023 and \$145.9 million as of December 31, 2022. The estimated fair value of the Convertible Notes was determined through consideration of quoted market prices. As of December 31, 2023, 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.

Notes to Financial Statements (Continued)

**11. Convertible Notes (Continued)**

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, 2023, 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, 2023, 448,698 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.

**12. Stockholders' Deficit**

*ATM Offering*

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 registered 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, the Company 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 shares of the Company's common stock from time to time in "at-the-market" offerings (the "2023 ATM Program"), pursuant to its 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. During the year ended December 31, 2023, the Company issued 3,312,908 shares of common stock resulting in net proceeds of approximately \$4.4 million after deducting \$0.4 million of underwriting discounts and commissions and other expenses, pursuant to the 2023 ATM Program.

*Warrants*

In connection with an underwriting agreement with H.C. Wainwright & Co., LLC ("Wainwright") on December 2, 2021, the Company issued warrants to purchase 36,964,286 shares of common stock at an exercise price of \$9.00 and an expiration date of 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 December 2021 Offering and the warrants. On December 7, 2023, 27,940,074 of these warrants expired. The remaining 9,024,212 warrants were amended as described below.

*Registered Direct Offering and Warrant Amendment*

On March 19, 2023, the Company entered into a Purchase Agreement with the Purchasers pursuant to which the Company agreed to issue and sell, in a Registered Direct Offering, 12,205,000 shares of its Common Stock, par value \$0.001 per share, Pre-Funded Warrants to purchase up to an aggregate of 20,965,747 shares of Common Stock in lieu of shares of Common Stock, and Warrants to purchase up to 33,170,747 shares of Common Stock. The combined purchase price of each share of Common Stock and accompanying Warrant is \$1.675 per share. The Warrants expire on September 22, 2026 and have an

## Esperion Therapeutics, Inc.

### Notes to Financial Statements (Continued)

#### 12. Stockholders' Deficit (Continued)

exercise price of \$1.55. The purchase price of each Pre-Funded Warrant is \$1.674 (equal to the combined purchase price per share of Common Stock and accompanying Warrant, minus \$0.001). The Purchase Agreement contains customary representations, warranties, covenants and indemnification rights and obligations of the Company and the Purchasers. The Registered Direct Offering closed on March 22, 2023. The warrants and pre-funded warrants were recorded at fair value of \$22.8 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 Registered Direct Offering and the warrants and pre-funded 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. The Company estimated the fair value of the pre-funded warrants based on the market price of the Company's common stock at issuance.

In connection with the Registered Direct Offering, the Company amended, pursuant to Warrant Amendment Agreements certain existing warrants to purchase up to an aggregate of 9,024,212 shares of the Company's common stock that were previously issued in December 2021 at an exercise price of \$9.00 per share and had an expiration date of December 7, 2023, effective upon the closing of the Registered Direct Offering, such that the amended warrants have a reduced exercise price of \$1.55 per share and expire three and one half years following the closing of the Registered Direct Offering, or September 22, 2026, for additional consideration of \$0.125 per amended warrant. Based on the change in the fair value of the amended warrants, the Company recorded issuance costs to additional paid-in capital of \$2.9 million.

The Company received gross proceeds of approximately \$55.5 million from the Registered Direct Offering, before deducting placement agent fees and related offering expenses. The net proceeds to the Company from the Registered Direct Offering, after deducting the placement agent fees and expenses and the Company's estimated offering expenses of \$4.2 million, were approximately \$51.3 million. In addition, the Company received approximately \$1.2 million as the gross consideration in connection with the Warrant Amendment Agreements. The net proceeds of the Warrant Amendment Agreements after deducting placement fees of \$0.1 million were approximately \$1.1 million.

During the year ended December 31, 2023, 20,965,747 shares of pre-funded warrants were exercised and 5,850,747 shares of warrants were exercised. As of December 31, 2023, no pre-funded warrants were outstanding. The following table summarizes the warrants outstanding for the Company as of December 31, 2023 and 2022:

	December 31, 2023	December 31, 2022	Weighted average exercise price
Warrants outstanding from 2021 agreement, expiring December 7, 2023	—	36,964,286	\$ 9.00
Warrants outstanding from Warrant Amendment Agreements, expiring September 22, 2026	9,024,212	—	\$ 1.55
Warrants outstanding from Purchase Agreement, expiring September 22, 2026	27,320,000	—	\$ 1.55
Total warrants outstanding	<u>36,344,212</u>	<u>36,964,286</u>	

#### 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 or 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.

Notes to Financial Statements (Continued)

**13. Stock Compensation (Continued)**

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"). In June 2023, the Company's stockholders approved an amendment to the 2022 Plan, which increased the number of shares of common stock reserved for awards under the 2022 Plan to 10,650,000.

**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, 2023 and 2022, the Company recognized \$0.3 million and \$0.4 million of stock compensation expense related to the ESPP, respectively. As of December 31, 2023, there have been 610,506 shares issued and 214,494 shares reserved for future issuance under the ESPP. The Company paused the ESPP effective as of September 1, 2023, such that the offering period which would otherwise have begun on September 1, 2023 did not commence. The administrator will determine the next offering period, pursuant to the ESPP.

**2017 Inducement Equity Plan**

In May 2017, the Company's board of directors approved the Esperion Therapeutics, Inc. 2017 Inducement Equity Plan (as amended in November 2019 and August 2023, the "2017 Plan"). The number of shares of common stock available for awards under the 2017 Plan is 2,650,000, 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 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.

**Esperion Therapeutics, Inc.**

**Notes to Financial Statements (Continued)**

**13. Stock Compensation (Continued)**

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% 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, 2023:

	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	3,842,737	\$ 27.75	4.86	\$ 1,658
Granted	1,550,200	\$ 3.53		
Forfeited or cancelled (vested and unvested)	<u>(1,706,746)</u>	\$ 35.69		
Outstanding at December 31, 2023	<u>3,686,191</u>	\$ 13.88	7.47	\$ 584
Vested and expected to vest at December 31, 2023	<u>3,686,191</u>	\$ 13.88	7.47	\$ 584
Exercisable at December 31, 2023	<u><u>1,706,622</u></u>	\$ 23.99	5.84	\$ 20

No stock options were exercised during the years ended December 31, 2023 or December 31, 2022.

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, 2023, using the Black-Scholes option-pricing model:

	Year ended December 31,	
	2023	2022
Risk-free interest rate	3.83%	2.26%
Dividend yield	—	—
Weighted-average expected life of options (years)	6.17	6.16
Volatility	79%	81%

The risk-free interest rate assumption was based on the United States Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. The weighted-average expected life of the options was calculated using the simplified method as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin No. 107 ("SAB No. 107"). This decision was based on the lack of relevant historical data due to the Company's limited historical experience. 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, 2023 and 2022, were \$2.51 and \$3.38, respectively. During the years ended December 31, 2023 and 2022, the Company recognized stock-based compensation expense related to stock options of \$3.8 million and \$5.6 million, including \$0.2 million and \$0.6 million that was capitalized into inventory, respectively.

**Esperion Therapeutics, Inc.**

**Notes to Financial Statements (Continued)**

**13. Stock Compensation (Continued)**

As of December 31, 2023, there was approximately \$6.7 million of unrecognized compensation cost related to unvested options, which will be recognized over a weighted-average period of approximately 2.3 years.

*Restricted Stock Units*

The following table summarizes the activity relating to the Company's RSUs for the year ended December 31, 2023:

	<u>Number of RSUs</u>	<u>Weighted-Average Fair Value Per Share</u>
Outstanding and unvested at December 31, 2022	1,768,185	\$ 8.80
Granted	2,456,485	\$ 3.22
Forfeited or expired	(342,876)	\$ 7.14
Vested	(833,906)	\$ 8.07
Outstanding and unvested at December 31, 2023	<u>3,047,888</u>	<u>\$ 4.69</u>

During the years ended December 31, 2023 and 2022, the Company recognized stock-based compensation expense related to RSUs of \$6.6 million, including \$0.4 million that was capitalized into inventory, and \$6.6 million, including \$0.7 million that was capitalized into inventory, respectively. As of December 31, 2023, there was approximately \$13.2 million of unrecognized stock-based compensation expense related to unvested RSUs, which will be recognized over a weighted-average period of approximately 2.5 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.

The following table summarizes the activity relating to the Company's PBRsUs for the year ended December 31, 2023:

	<u>Numbers of PBRsUs</u>	<u>Weighted-Average Fair Value Per Share</u>
Outstanding and unvested at December 31, 2022	461,250	\$ 9.50
Granted	—	\$ —
Forfeited	(100,250)	\$ 11.50
Vested	(200,725)	\$ 8.94
Outstanding and unvested at December 31, 2023	<u>160,275</u>	<u>\$ 8.94</u>

Stock-based compensation related to the PBRsUs was approximately \$0.4 million, including less than \$0.1 million that was capitalized into inventory, for the year ended December 31, 2023. Stock-based compensation related to PBRsUs was approximately \$1.8 million, including \$0.2 million that was capitalized into inventory, for the year ended December 31, 2022. As of December 31, 2023, there was approximately \$0.2 million of unrecognized stock-based compensation expense related to unvested PBRsUs, which will be recognized over a weighted-average period of approximately 0.2 years.



## Esperion Therapeutics, Inc.

### Notes to Financial Statements (Continued)

#### 13. Stock Compensation (Continued)

##### *Performance-based stock options ("PBSOs")*

In 2021, 2022, and 2023 the Company granted PBSOs from the 2013 Plan and the 2022 Plan, 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 PBSOs based on the expected performance period to achieve the performance milestone. The fair value of the PBSOs 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 PBSOs granted during the years ended December 31, 2023 and December 31, 2022 was \$1.14 and \$4.36, respectively.

The following table summarizes the activity relating to the Company's performance-based stock options for the year ended December 31, 2023:

	Number of PBSOs	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	499,200	\$ 6.73	9.32	\$ 12
Granted	227,900	\$ 1.62		
Forfeited	(65,250)	\$ 6.76		
Outstanding at December 31, 2023	661,850	\$ 4.97	8.63	\$ 312
Vested and expected to vest at December 31, 2023	661,850	\$ 4.97	8.63	\$ 312
Exercisable at December 31, 2023	48,100	\$ 8.94	5.87	\$ —

Stock-based compensation related to the PBSOs was approximately \$0.9 million and \$0.8 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, there was approximately \$0.5 million of unrecognized stock-based compensation expense related to unvested PBSOs, which will be recognized over a weighted-average period of approximately 0.2 years.

#### 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, 2023 and 2022, were \$1.3 million and \$0.7 million, respectively.

#### 15. Leases

The Company has operating leases primarily related to the Company's principal executive office, automobile leases and other IT related equipment. The lease for the principal executive office has a lease term of 5 years 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, 2023 and December 31, 2022, the Company recognized \$1.0 million and \$1.3 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 \$1.0 million and \$1.2 million, respectively, which were included in operating cash flows on the statements of cash flows. At December 31, 2023 and December 31, 2022, the weighted-average remaining lease term of operating leases was 2.9 years and 4.7 years, respectively, and the weighted average discount rate was 7.5% and 7.7%, respectively. There was \$4.5 million and \$0.6 million in right-of-use assets obtained in exchange for lease obligations for the twelve months ended

## Esperion Therapeutics, Inc.

### Notes to Financial Statements (Continued)

#### 14. Leases (Continued)

December 31, 2023 and December 31, 2022, respectively. The Company had 45 additional operating and finance leases that had not yet commenced as of December 31, 2023, mainly associated with increased headcount for the Company's sales force.

The following table summarizes the Company's future maturities of operating lease liabilities as of December 31, 2023:

	(in thousands)
2024	\$ 1,838
2025	1,811
2026	1,140
2027	169
2028	144
Total lease payments	5,102
Less imputed interest	(529)
Total	<u>\$ 4,573</u>

The following table summarizes supplemental balance sheet information related to leases as of December 31, 2023:

Operating Leases	(in thousands)
<b>Total right of use operating lease assets</b>	<b>\$ 4,675</b>
Operating lease liabilities (short-term)	\$ (1,553)
Operating lease liabilities (long-term)	(3,020)
<b>Total lease obligations under operating leases</b>	<b><u>\$ (4,573)</u></b>

#### 16. Income Taxes

There was no provision for income taxes for the years ended December 31, 2023 and 2022 because the Company has incurred operating losses since inception. At December 31, 2023, 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.

As of December 31, 2023 and 2022, the Company had net deferred tax assets, before valuation allowance, of approximately \$395.6 million and \$352.1 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, 2023 and 2022, the Company had federal net operating loss ("NOL") carryforwards of approximately \$1,027.5 million and \$950.8 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, 2023 and 2022, the Company had state NOL carryforwards of approximately \$696.1 million and \$698.4 million, respectively. In 2022, state NOL carryforwards began to expire as they were not able to be fully utilized. State NOL carryforwards will continue to expire in 2023 onward at various dates, 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 2017.

**Esperion Therapeutics, Inc.**

**Notes to Financial Statements (Continued)**

**16. Income Taxes (Continued)**

A reconciliation of the U.S. statutory income tax rate to the Company's effective tax rate is as follows:

	December 31,	
	2023	2022
Federal income tax (benefit) at statutory rate	(21.0)%	(21.0)%
Change in state tax rate	0.2 %	(0.5)%
Permanent items	0.2 %	0.1 %
Prior period adjustments	0.9 %	(3.6)%
Change in valuation allowance	19.7 %	25.0 %
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 experienced an ownership change in 2017, 2021 and 2023.

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, 2023, 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, 2023, 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.

	December 31,	
	2023	2022
	(in thousands)	
Balance at January 1	\$ 2,099	\$ 2,099
Reductions for tax positions of prior year	—	—
Balance at December 31	<u>2,099</u>	<u>2,099</u>

**Esperion Therapeutics, Inc.**

**Notes to Financial Statements (Continued)**

**16. Income Taxes (Continued)**

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

	December 31,	
	2023	2022
(in thousands)		
Deferred tax assets:		
Federal and state operating loss carryforwards	\$ 258,836	\$ 242,584
Equity compensation	25,413	26,243
Capitalized research and development	37,998	26,480
R&D tax credits, net of reserves	18,887	18,887
Disallowed interest	43,239	29,979
Temporary differences	12,362	8,340
Total deferred tax assets	396,735	352,513
Deferred tax liabilities:		
Other	(1,154)	(400)
Total deferred tax liabilities	(1,154)	(400)
Valuation allowance	(395,581)	(352,113)
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. Pre-Funded Warrants are included in the weighted-average number of common shares outstanding during the periods. 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, 2023	December 31, 2022
Common shares under option	3,686,191	3,842,737
Unvested RSUs	3,047,888	1,768,185
Shares issuable related to the ESPP	—	27,558
Unvested PBRsUs	160,275	461,250
Common shares under PBSOs	661,850	499,200
Shares issuable upon conversion of convertible notes	8,007,010	8,007,010
Warrants for common stock	36,344,212	36,964,286
Total potential dilutive shares	51,907,426	51,570,226

**18. Subsequent Events**

As discussed in Note 5 "Commitments and Contingencies," on March 27, 2023, the Company filed a complaint in the United States District Court for the Southern District of New York seeking declaratory judgment against DSE regarding the Company's right to receive a \$300 million milestone payment upon inclusion of cardiovascular risk reduction in the EU label that correlates with a relative risk reduction rate of at least 20%, based on the results of the CLEAR Outcomes CVOT. On May

Notes to Financial Statements (Continued)

**18. Subsequent Events (Continued)**

4, 2023, the Company filed an amended complaint against DSE in the Southern District of New York seeking a judicial declaration, on an expedited basis, that DSE is contractually required to make a \$300 million milestone payment to the Company upon applicable regulatory approval. On June 20, 2023, DSE filed a response to the amended complaint. On January 2, 2024, the Company entered into a settlement agreement with DSE to amicably resolve and dismiss the commercial dispute then pending in the Southern District of New York, or the Settlement Agreement. Under the Settlement Agreement, DSE agreed to pay the Company an aggregate of \$125 million, including (1) a \$100-million payment within 15 business days of the effective date of the Settlement Agreement and (2) a \$25-million payment in the calendar quarter immediately following the calendar quarter in which the EMA renders a decision on the application that was filed with the EMA for a Type II(a) variation for the Company's oral non-statin products marketed as NILEMDO (bempedoic acid) tablets and NUSTENDI (bempedoic acid and ezetimibe) tablets in Europe. The application asks the EMA to approve both NILEMDO and NUSTENDI to reduce cardiovascular risk in patients with or at high risk for atherosclerotic cardiovascular disease. The legal action pending in the United States District Court for the Southern District of New York has now been dismissed.

Pursuant to the Settlement Agreement, also on January 2, 2024, the Company entered into a 3rd Amendment to the License and Collaboration Agreement dated January 2, 2019 with DSE, and a 1<sup>st</sup> Amendment to the License and Collaboration Agreement dated April 26, 2021 with DS. Each of these amendments grant each of DSE and DS exclusive rights for clinical development, regulatory activities, manufacture and commercialization of a bempedoic acid/ezetimibe/statin triple combination pill in their existing respective territories of the European Economic Area, UK, Switzerland and Turkey (the “DSE Territory”) and South Korea, Taiwan, Hong Kong, Thailand, Vietnam, Brazil, Macao, Cambodia and Myanmar (the “DS Territory”). Further, after a transition period, DSE and DS will assume sole responsibility for the manufacture of NILEMDO and NUSTENDI for, respectively, the DSE Territory and DS Territory. As of January 2, 2024, DSE shall have sole authority and control of regulatory communications with the EMA regarding the pending marketing authorization applications for NILEMDO and NUSTENDI.

On January 18, 2024, the Company entered into an Underwriting Agreement with Jefferies, as representative of several Underwriters, related to an underwritten public offering (the “January 2024 Offering”) of 56,700,000 shares of Common Stock of the Company, par value \$0.001 per share, at a purchase price to the public of \$1.50 per share. The Underwriters were also granted a 30-day option to purchase up to an additional 8,505,000 shares of Common Stock, at the public offering price. On January 19, 2024, Jefferies gave notice to the Company of its election to exercise the option to purchase additional shares, in full. Giving effect to the exercise of Underwriters' option, the offering proceeds to the Company were approximately \$90.8 million, after deducting the underwriting discount and estimated offering expenses. The January 2024 Offering closed on January 23, 2024.

**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) of Esperion Therapeutics, Inc.
- Registration Statement (Form S-8 No. 333-274183) pertaining to the Amended 2017 Inducement Equity Plan of Esperion Therapeutics, Inc.
- Registration Statement (Form S-8 No. 333-273555) pertaining to the 2022 Stock Option and Incentive Plan of Esperion Therapeutics, Inc.
- 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.

of our report dated February 27, 2024, with respect to the financial statements of Esperion Therapeutics, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2023.

/s/ Ernst & Young LLP

Detroit, Michigan  
February 27, 2024

## 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 27, 2024

/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 27, 2024

/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, 2023 (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 27, 2024

/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 Business Officer

### Eric Warren, R.Ph.

Chief Commercial Officer

## Esperion Board of Directors

### J. Martin Carroll

Chairman of the Board

### Sheldon Koenig

### Seth H.Z. Fischer

### Alan Fuhrman

### Antonio M. Gotto, Jr., MD, DPhil

### Stephen Rocamboli

### Jay Shepard

### Nicole Vitullo

### Tracy M. Woody



# ESPERION<sup>®</sup> | 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](https://esperion.com) and [esperionscience.com](https://esperionscience.com) and follow us on X at [twitter.com/EsperionInc](https://twitter.com/EsperionInc).

### Investor Relations

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[investorrelations@esperion.com](mailto:investorrelations@esperion.com)

### Independent Registered Public Accounting Firm **Ernst & Young**

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777 Woodward Avenue  
Detroit, MI 48226  
Phone: (313) 628-7100

### General Counsel

**Benjamin O. Looker**  
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[blooker@esperion.com](mailto:blooker@esperion.com)

### Outside Counsel

**Goodwin Procter LLP**  
100 Northern Ave  
Boston, MA 02210  
Phone: (617) 570-1000

### Register and Transfer Agent

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