

Esperion Therapeutics, Inc.
Form 10-K
February 22, 2017

Use these links to rapidly review the document

[TABLE OF CONTENTS](#)

[PART IV](#)

[Esperion Therapeutics, Inc. Index to the Financial Statements](#)

[Table of Contents](#)

**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, 2016

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

(State or Other Jurisdiction of
Incorporation or Organization)

26-1870780

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

**3891 Ranchero Drive, Suite 150
Ann Arbor, Michigan 48108**
(Address of Principal Executive Offices)

48108
(Zip Code)

(734) 887-3903

(Registrant's Telephone Number, Including Area Code)

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

Title of each class
Common Stock, \$0.001 par value

Name of each exchange on which registered
NASDAQ Stock Market LLC

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

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated
filer

Accelerated filer

Non-accelerated filer
(Do not check if a
smaller reporting
company)

Smaller reporting
company

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, 2016, based upon the closing price of \$9.88 of the registrant's common stock as reported on the NASDAQ Global Market, was \$222.7 million. Shares of the registrant's common stock held by each officer and director and each person known to the registrant to own 10% or more of the outstanding voting power of the registrant have been excluded in that such persons may be deemed affiliates. This determination of affiliate status is not a determination for other purposes.

As of February 1, 2017, there were 22,555,413 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 2017 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, 2016.

Table of Contents

TABLE OF CONTENTS

	Page	
<u>PART I</u>		
<u>Item 1.</u>	<u>Business</u>	4
<u>Item 1A.</u>	<u>Risk Factors</u>	27
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	57
<u>Item 2.</u>	<u>Properties</u>	57
<u>Item 3.</u>	<u>Legal Proceedings</u>	57
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	58
<u>PART II</u>		
<u>Item 5.</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	59
<u>Item 6.</u>	<u>Selected Financial Data</u>	61
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	62
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	73
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	73
<u>Item 9.</u>	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	73
<u>Item 9A.</u>	<u>Controls and Procedures</u>	73
<u>Item 9B.</u>	<u>Other Information</u>	75
<u>PART III</u>		
<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	76
<u>Item 11.</u>	<u>Executive Compensation</u>	76
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	76
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	76
<u>Item 14.</u>	<u>Principal Accounting Fees and Services</u>	76
<u>PART IV</u>		
<u>Item 15.</u>	<u>Exhibits and Financial Statement Schedules</u>	77
<u>Item 16.</u>	<u>Form 10-K Summary</u>	77
<u>Signatures</u>		78

Table of Contents

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 obtain regulatory approval for bempedoic acid, including statements related to specific clinical studies or clinical observations that will be required for such approval;

our ability to achieve clinical or regulatory milestones with our existing cash resources;

the design, timing or outcome of our Phase 3 clinical program of bempedoic acid;

the design, timing or outcome of our cardiovascular outcomes trial, or CVOT, of bempedoic acid;

the design, timing or outcome of our other clinical studies of bempedoic acid;

our ability to recruit and enroll patients, particularly "statin intolerant" patients, in any ongoing or future clinical study;

our ability to replicate positive results from a completed clinical study in a future clinical study;

our ability to fund our development programs with existing capital or our ability to raise additional capital in the future;

the potential benefits, effectiveness or safety of bempedoic acid, as compared to statins and other low-density lipoprotein cholesterol, or LDL-C, lowering therapies, either those currently available or those in development;

our ability to respond and adhere to changes in regulatory requirements, including any requirement to conduct additional, unplanned clinical studies in connection with our pursuit of bempedoic acid as an LDL-C lowering therapy;

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 government legislation, and their impact on our ability to market, distribute and obtain payment for bempedoic acid, if approved;

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

the accuracy of our estimates of the size and growth potential of the LDL-C lowering market and the rate and degree of bempedoic acid's market acceptance, if approved;

our ability to obtain and maintain intellectual property protection for bempedoic acid without infringing on the intellectual property rights of others;

the loss of any of our key scientific or management personnel;

Table of Contents

our intention to seek to establish strategic relationships or partnerships; and

our ability to compete with other companies that are, or may be, developing or selling products that may compete with bempedoic acid, if approved.

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.

Table of Contents

PART I

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

Item 1. Business

Overview

We are the lipid management company, a late-stage pharmaceutical company focused on developing and commercializing convenient, complementary, cost-effective, once-daily, oral therapies for the treatment of patients with elevated LDL-C. Through scientific and clinical excellence, and a deep understanding of cholesterol biology, the experienced lipid management team at Esperion is committed to developing new LDL-C lowering therapies that will make a substantial impact on reducing global cardiovascular disease, or CVD; the leading cause of death around the world. With a targeted mechanism of action, bempedoic acid, our lead product candidate, is a first-in-class, orally available, once-daily ATP-citrate lyase, or ACL, inhibitor that reduces cholesterol biosynthesis and lowers elevated levels of LDL-C by up-regulating the LDL receptor, but with reduced potential for muscle-related side effects. In addition to bempedoic acid as monotherapy, we are also developing bempedoic acid in a fixed dose combination with ezetimibe, an approved, non-statin, oral, LDL-C lowering therapy.

The clinical development program for bempedoic acid consists of two major components: 1) the global pivotal Phase 3 LDL-C lowering program in high CVD risk patients with hypercholesterolemia on optimized background lipid-modifying therapy, including maximally tolerated statins, and patients who are only able to tolerate less than the lowest approved daily starting dose of their statin and are considered "statin intolerant," and 2) the global CVOT known as **C**holesterol **L**owering via **B**empedoic Acid, an **A**CL-inhibiting **R**egimen (CLEAR) Outcomes, in patients with hypercholesterolemia and high CVD risk and who are considered "statin intolerant". We initiated our global Phase 3 clinical development program in January 2016, with the 52-week global pivotal Phase 3 long-term safety and tolerability study (Study 1), and initiated the three remaining global pivotal LDL-C lowering efficacy studies in December 2016. We expect to report top-line results from our global Phase 3 program in its entirety by mid-2018, and intend to use positive results from our Phase 3 program to support our submissions for an LDL-C lowering indication in the U.S. and Europe by the first half of 2019. We also initiated the CLEAR Outcomes CVOT in December 2016, and intend to use positive results from this CVOT to support our submissions for a CV risk reduction indication in the U.S. and Europe by 2022.

We believe that bempedoic acid, if approved, has the potential to become a convenient and complementary oral therapy to significantly reduce elevated levels of LDL-C in patients inadequately treated with current lipid-modifying therapies. It is estimated that 40 million patients in the U.S. are taking statins, with approximately 5-20 percent of these patients only able to tolerate less than the lowest approved daily starting dose of their statin and considered "statin intolerant".

We were founded in January 2008, by former executives of and investors in the original Esperion Therapeutics, Inc., a biopharmaceutical company which was primarily focused on the research and development of therapies to regulate high-density lipoprotein, or HDL. The original Esperion was acquired by Pfizer Inc. in 2004. Bempedoic acid was first discovered at the original Esperion and we subsequently acquired the rights to the product from Pfizer in 2008. We own the exclusive worldwide rights to bempedoic acid.

Table of Contents

Bempedoic Acid

With a targeted mechanism of action, bempedoic acid is a first-in-class, orally available, once-daily ACL inhibitor that reduces cholesterol biosynthesis and lowers elevated levels of LDL-C by up-regulating the LDL receptor, but with reduced potential for muscle-related side effects. Completed Phase 1 and 2 studies in more than 800 patients treated with bempedoic acid have produced clinically relevant LDL-C lowering results of up to 30 percent as monotherapy, approximately 50 percent in combination with ezetimibe, and an incremental 20+ percent when added to stable statin therapy.

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 Stephen L. Pinkosky, our Associate Director of Translational Research and Biology, et al., in *Nature Communications*. The paper systematically outlines the experiments and analyses undertaken by us and our collaborators to fully understand the mechanism of action for how bempedoic acid reduces LDL-C, including its specificity for the liver. Bempedoic acid is a prodrug that once activated, inhibits ACL, an enzyme upstream of HMG-CoA reductase (the molecular target of statins) in the cholesterol synthesis pathway. Like statins, bempedoic acid decreases cholesterol synthesis in the liver, which results in decreased intracellular cholesterol, up-regulation of LDL receptor activity and increased LDL-C clearance from the blood. Although bempedoic acid and statins both inhibit cholesterol synthesis in the liver, an important differentiating feature is that, unlike statins, bempedoic acid is inactive in skeletal muscle. Specifically, bempedoic acid is a prodrug which requires activation by a specific enzyme, very long-chain acyl-CoA synthetase, or ACSVL1, to convert bempedoic acid to its CoA activated form. This enzyme is present in the liver but not in skeletal muscle. Therefore, bempedoic acid does not inhibit the cholesterol biosynthesis pathway in skeletal muscle, thus providing a mechanistic basis for reduced potential for muscle-related adverse effects. Bempedoic acid has been shown to provide incremental lowering of LDL-C when used in combination with both ezetimibe and statins at all doses.

Fixed Dose Combination Bempedoic Acid and Ezetimibe (BA+EZ)

In the second quarter of 2016, the Food and Drug Administration, or FDA, accepted our submission of an Investigational New Drug, or IND, application for the fixed dose combination of bempedoic acid 180 mg and ezetimibe 10 mg, or BA+EZ, which is in development for the same indications as bempedoic acid monotherapy (LDL-C lowering and CV risk reduction). We recently completed a bioavailability study and a formulation of BA+EZ has been selected for manufacturing, development and, if approved, commercialization. We expect to announce clinical development and regulatory plans for BA+EZ in the first half of 2017.

Cardiovascular Disease and Elevated LDL-C

Cardiovascular disease, which results in heart attacks, strokes and other cardiovascular events, represents the number one cause of death and disability in western societies. The American Heart Association, or AHA, estimates that approximately 800,000 deaths in the United States were caused by cardiovascular disease in 2013.

Elevated LDL-C is well-accepted as a significant risk factor for cardiovascular disease and the CDC estimates that 78 million U.S. adults have elevated levels of LDL-C. A consequence of elevated LDL-C is atherosclerosis, which is a disease that is characterized by the deposition of excess cholesterol and other lipids in the walls of arteries as plaque. The development of atherosclerotic plaques often leads to cardiovascular disease. The risk relationship between elevated LDL-C and cardiovascular disease was first defined by the Framingham Heart Study, which commenced in 1948 to define the factors that contributed to the development of cardiovascular disease. The study enrolled participants

Table of Contents

who did not have any form of cardiovascular disease and followed them over a long period of time. Elevated LDL-C was identified early on as key risk factor for the eventual development of cardiovascular disease.

The hypothesis that lowering elevated levels of LDL-C would translate into reduced risk of cardiovascular disease was first proven in 1984 with the publication of the Lipid Research Clinics Coronary Primary Prevention Trial. In this study, treatment with cholestyramine, a bile acid sequestrant, showed a 20% reduction in LDL-C and, importantly, a 19% reduction in risk of cardiovascular disease death or nonfatal myocardial infarction, or heart attack. This was the first major clinical study to demonstrate a direct relationship between lowering LDL-C levels and reduced risk of major cardiovascular events.

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

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

Major completed clinical outcomes studies with statin therapies

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

In November 2014, the results of the IMPROVE-IT (IMProved Reduction of Outcomes: Vytorin Efficacy International Trial) study were presented at the Scientific Sessions of the AHA. 18,144 patients with acute coronary syndrome were enrolled in IMPROVE-IT and were randomized to receive either 40 mg of simvastatin or 10 mg of ezetimibe/40 mg of simvastatin, and were followed until > 5,250 events (cardiovascular death, heart attack, documented unstable angina requiring hospitalization, coronary revascularization or stroke) occurred. The addition of ezetimibe to simvastatin resulted in a 6.4% relative risk reduction (p=0.016) in the aggregate of the events described above. This was the first study to demonstrate incremental clinical benefit with a non-statin when added to a statin.

The direct relationship between lower LDL-C levels and reduced risk for major cardiovascular events has been consistently demonstrated in 18 clinical studies completed over the last 28 years involving more than 90,000 patients. As a result, physicians are highly focused on lowering LDL-C levels in their patients, and we believe there is a trend towards even more aggressive LDL-C lowering. For example, in the United States, increased attention has been placed on aggressive LDL-C management by organizations such as the National Cholesterol Education Program, or NCEP, the AHA

Table of Contents

and the American College of Cardiology, or ACC. Additionally, both the Canadian Cardiovascular Society and the Joint British Societies have supported even lower LDL-C treatment targets for high-risk patients. This has led to the combination of statins with other treatments, such as ezetimibe.

In July 2004, the NCEP issued an update to its Adult Treatment Panel III clinical practice guidelines on cholesterol management, advising physicians to consider new, more intensive treatment options for people at very high risk, high risk and moderately high risk for cardiovascular disease. The LDL-C goals in these updated clinical practice guidelines, which are presented below, contemplate initiating drug therapy at lower LDL-C thresholds, thus expanding the number of potential patients for LDL-C lowering therapy.

NCEP ATP III Clinical Practice Guidelines

Patient Cardiovascular Disease Risk	LDL-C Goal
Very High Risk	< 70 mg/dL
Cardiovascular Disease and Cardiovascular Disease Risk Equivalent	< 100 mg/dL
Multiple (2+) Risk Factors	< 130 mg/dL
0 - 1 Risk Factor	< 160 mg/dL

In November 2013, the American College of Cardiology, or ACC, and the AHA issued new guidelines for the treatment of elevated cholesterol. For the first time in more than 20 years, the new guidelines do not include specific, numerical LDL-C treatment goals for patients with elevated LDL-C. However, the guidelines strongly recommend the use of more potent statins and intensive statin therapy in patients with elevated LDL-C. The new guidelines also significantly expanded the number of patients eligible for statin therapy, including patients with a history of cardiovascular disease including stroke, patients with both Type 1 and Type 2 diabetes, all patients with LDL-C \geq 190 mg/dL and patients with a 10-year risk of > 7.5% of developing cardiovascular disease. Also for the first time, the guidelines acknowledge the existence of "statin intolerance", and incorporate "statin intolerance" into the consideration of treatment choices and into the evaluation of statin safety.

Other organizations continue to utilize goals of treatment in their guidelines. The National Lipid Association, or NLA, guidelines established < 100 mg/dL as the LDL-C goal of treatment for patients at low, moderate and high risk. Patients considered to be at very high risk have a goal of < 70 mg/dL of LDL-C. The International Atherosclerosis Society has recommended optimal LDL-C levels of < 100 mg/dL for patients who have not had a cardiovascular event, and < 70 mg/dl for patients who have had a cardiovascular event.

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

Table of Contents

Currently Approved Therapies

The following table illustrates common therapies used to treat elevated LDL-C:

Class of Therapy	Labeled Indication	Average LDL-C Change from Baseline	Key Issues/Side Effects
Statins	Reduction in LDL-C in patients with elevated LDL-C	Up to 63%	Skeletal muscle effects, elevated liver function tests
	Reduction in total mortality		
	Reduction in risk of major adverse cardiovascular events (MACE) in multiple populations that were tested		
Bile acid sequestrants	Reduction in LDL-C in patients with elevated LDL-C ⁽¹⁾	Up to 20%	Limited LDL-C lowering
	Retard the rate of progression and increase the rate of regression of coronary atherosclerosis		
Cholesterol absorption inhibitors	Reduction in LDL-C in patients with elevated LDL-C	Up to 18%	Elevation in triglycerides Limited LDL-C lowering; IMPROVE-IT study not in US prescribing information
Niacin	Reduction in LDL-C and triglycerides; increases in HDL-C, reduction in Lipoprotein (a)	Up to 17%	Flushing (i.e., warmth or redness) hepatic toxicity, skeletal muscle effects and gout
	Reduction in recurrent nonfatal myocardial infarction (MI) in patients with prior history of MI		
Fibrates	Reduction in triglycerides and LDL-C in patients with hypertriglyceridemia or mixed dyslipidemia	Up to 21%	Gallstones, skeletal muscle effects and liver disorders
	Reduction in risk of developing coronary heart disease (CHD) in patients with Type IIb Fredericksens hyperlipidemia and no prior history of CHD		
Proprotein convertase subtilisin kexin 9 (PCSK9) inhibitors	Reduction in LDL-C as adjunct to maximally tolerated statin therapy in patients with HeFH and/or	Up to 64%	High cost as biologic, injectable route of administration

ASCVD

No effect on hsCRP

Ongoing CVOTs

(1) Welchol®, a bile acid sequestrant, is also approved for improving glycemic control in adults with Type 2 diabetes.

Table of Contents

Other Approved Therapies for Specific Populations

A small subpopulation of patients with extremely elevated levels of LDL-C, estimated to be approximately 300 patients in the U.S., suffer from homozygous familial hypercholesterolemia, or HoFH. HoFH is a serious and rare genetic disease and patients with HoFH lack or have dysfunctional LDL-receptors and cannot remove LDL-particles and LDL-C from the blood. As a result, untreated HoFH patients typically have LDL-C levels in the range of 450 mg/dL to 1,000 mg/dL. Microsomal triglyceride transfer protein, or MTP inhibitors, a PCSK9 inhibitor and an ApoB antisense oligonucleotide are approved therapies to lower elevated LDL-C levels in patients with a clinical or laboratory diagnosis of HoFH. Given the serious safety concerns with the MTP inhibitor and ApoB antisense oligonucleotide, specifically hepatotoxicity, the FDA has restricted their usage to this narrow subpopulation.

Statin Therapy

Statins are the standard of care for patients with hypercholesterolemia today and are highly effective at lowering LDL-C. This class of drugs includes atorvastatin calcium, marketed as Lipitor®, the most prescribed LDL-C lowering drug in the world and the best-selling pharmaceutical drug in history. Approximately 25% of Americans over the age of 45 from 2005 to 2008 were treated for elevated LDL-C levels with statin therapy, according to a National Health and Nutrition Examination Survey.

Statins are selective, competitive inhibitors of HMG-CoA reductase, a rate-limiting enzyme in the cholesterol biosynthesis pathway, and work primarily 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 the potential to inhibit cholesterol synthesis in skeletal muscle. This inhibition could be linked to the myalgia associated with statin use as seen in 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 is a significant subset of patients who are unable to tolerate statins due to muscle pain or weakness, memory loss or increased glucose levels, or who are otherwise unable to reach their LDL-C goal on statin therapy alone. In rare but extreme cases, statins can lead to muscle breakdown, kidney failure and death. In addition, the FDA has recently warned that statins can cause hyperglycemia, an increase in blood sugar levels and create an increased risk of worsening of glycemic control and of new onset diabetes. There are approximately 36 million U.S. adults with elevated LDL-C levels who are not on an LDL-C lowering therapy. For these reasons, we believe there is a need for new therapies to treat patients with elevated LDL-C.

Patients with Heterozygous Familial Hypercholesterolemia (HeFH) and/or Atherosclerotic Cardiovascular Disease (ASCVD) who need additional lowering of LDL-C Market Opportunity for Bempedoic Acid and BA+EZ

We are pursuing the development of bempedoic acid and BA+EZ as an add-on to maximally tolerated statin therapy for patients with HeFH and/or ASCVD who require additional lowering of LDL-C. The severity of elevated LDL-C in these patients, their level of CVD risk and their therapeutic options, including those patients only able to tolerate less than the lowest approved daily starting dose of their statin and are considered to be "statin intolerant", all vary widely.

Patients with ASCVD and persistently elevated LDL-C despite maximally tolerated statin therapy represent a large population with important unmet medical needs. In a retrospective analysis of United States data, approximately one-third of high-risk patients treated with statin monotherapy for more

Table of Contents

than three months failed to achieve LDL-C target levels of < 100mg/dL, and more than three-quarters did not achieve the more stringent goal of < 70 mg/dL. Data from the TNT study showed that patients treated with 80 mg of atorvastatin daily demonstrated a major cardiovascular event rate of 8.7% despite having achieved mean LDL-C levels of 77 mg/dL. In this study, the higher-intensity atorvastatin 80 mg regimen lowered both LDL-C and cardiovascular events to a greater extent than the lower-intensity atorvastatin 10 mg regimen. These findings, among others, suggest that residual risk may be due to residual hyperlipidemia.

This has prompted the study of non-statin therapies as add-on treatment to statins for incremental reductions in LDL-C and CVD risk. The injectable PCSK9 inhibitors were recently granted approval in the United States as an adjunct to maximally tolerated statin therapy for patients in these populations that require additional lowering of LDL-C.

Within the ACVD and HeFH patient populations there are patients whose maximally tolerated dose of a statin may be no statin at all. These are patients who are considered to "statin intolerant".

Muscle pain or weakness is the most common side effect experienced by statin users and the most common cause for discontinuing therapy. Moreover, a significant proportion of patients remain on statin therapy despite experiencing muscle-related side effects. Accordingly, we believe that in the presence of a safe and effective complementary non-statin, oral, once-daily, small molecule LDL-C lowering therapy, the "statin intolerant" market could grow substantially.

Recently Approved Therapies

PCSK9 Inhibitors

A number of larger biopharmaceutical companies have developed, or are currently developing, a new class of biologic therapies that target proprotein convertase subtilisin kexin type 9, or PCSK9, an enzyme involved in the degradation of LDL receptors. These PCSK9 inhibitors are injectable, monoclonal antibodies that were evaluated as potential therapies to lower LDL-C. In 2015 the FDA approved two PCSK9 inhibitors: alirocumab, which was developed by Sanofi and Regeneron Pharmaceuticals and evolocumab, which was developed by Amgen, Inc. These therapies were approved as an adjunct to diet and maximally tolerated statin therapy for patients with HeFH 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 (Further Cardiovascular Outcomes Research with PCSK9 Inhibition in Subjects with Elevated Risk) CVOT where evolocumab significantly reduced the risk of cardiovascular events. Full results of FOURIER will be announced in March 2017, during the Scientific Sessions of the American College of Cardiology meeting.

As described in currently approved U.S. prescribing information, PCSK9 inhibitors have demonstrated reductions of LDL-C as adjunct 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%. 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 and their injectable route of administration.

Table of Contents

Additional Therapies in Development

CETP Inhibitors

A number of larger biopharmaceutical companies have tried to develop a class of therapies that target cholesteryl ester transfer protein, or CETP, which mediates the transfer of cholesteryl esters from HDL-particles to ApoB-containing particles. CETP inhibitors were initially designed to raise levels of HDL-C and are required by FDA to complete CVOTs in Phase 3 prior to approval. Pfizer brought the first drug in this class, torcetrapib, into clinical development but terminated development activities in December 2006, due to an increase in all-cause mortality and cardiovascular events in the ILLUMINATE (Investigation of Lipid Level Management to Understand its Impact in Atherosclerotic Events) study. Two other CETP inhibitors, dalcetrapib from Roche and evacetrapib from Lilly, were investigated in the dal-OUTCOMES and ACCELERATE studies, respectively. The development of dalcetrapib and evacetrapib were terminated in May 2012, and October 2015, respectively, due to lack of efficacy in their CVOTs, in spite of a 33% reduction in LDL-C in the case of evacetrapib. An additional CETP inhibitor, anacetrapib, from Merck, is being developed and is currently being investigated in the Phase 3 REVEAL (Randomized Evaluation of the Effects of Anacetrapib through Lipid-modification) study. Anacetrapib has been shown to significantly raise levels of HDL-C and to lower LDL-C. This Phase 3 CVOT is expected to complete and report top-line results in the middle of 2017.

PCSK9 Inhibitors

The Medicines Company/Alnylam are developing inclisiran, which is currently in Phase 2 clinical studies. Unlike the PCSK9 antibodies from Sanofi/Regeneron 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 3 or 6 months. Like the PCSK9 antibodies, inclisiran is an injectable therapy.

Clinical Experience

To date, bempedoic acid has been studied in over 800 patients across six patient populations: healthy volunteers; patients with elevated LDL-C levels; patients with Type 2 diabetes and elevated LDL-C levels; patients with elevated LDL-C levels and a history of "statin intolerance"; patients with elevated LDL-C levels taking low, moderate and high doses of the most commonly prescribed statins; and patients with both elevated LDL-C and hypertension. The individual design and results of each of the completed Phase 2 clinical studies of bempedoic acid are summarized below.

Table of Contents**Completed Clinical Studies**

To date, we have completed the following Phase 2 clinical studies of bempedoic acid:

Description	Title	Treatment Duration	Subjects	
			Total	Treated
1002-035	Phase 2 PK/PD clinical study in patients treated with high-dose statin therapy	4 weeks	68	45
	A randomized, double-blind, multi-center, placebo-controlled, parallel group clinical study that evaluated 180 mg of bempedoic acid versus placebo in patients already on stable 80 mg atorvastatin therapy			
1002-014	Phase 2 exploratory clinical safety study in patients with both elevated LDL-C and hypertension	6 weeks	143	71
	A randomized, double-blind, multi-center, placebo-controlled, parallel group exploratory study that evaluated 180 mg of bempedoic acid versus placebo in patients with both elevated LDL-C and hypertension			
1002-009	Phase 2 clinical study in patients with elevated LDL-C already receiving statin therapy	12 weeks	134	88
	A randomized, double-blind, multi-center placebo-controlled clinical study that evaluated 180 mg and 120 mg of bempedoic acid versus placebo in patients already on stable statin therapy			
1002-008	Phase 2 clinical study of safety and efficacy in patients with elevated LDL-C, with or without a history of "statin intolerance"	12 Weeks	349	249
	A randomized, double-blind, parallel-group, multicenter study to evaluate the efficacy and safety of bempedoic acid monotherapy, ezetimibe monotherapy, and the combination of bempedoic acid and ezetimibe in patients with elevated LDL-C, with or without "statin intolerance"			
1002-007	Phase 2 clinical study of safety and pharmacokinetic interaction in patients with elevated LDL-C on a background of atorvastatin 10 mg	8 Weeks	58	42
	Placebo-controlled, randomized, double-blind, drug interaction study to evaluate the safety, tolerability and effect on atorvastatin pharmacokinetics of bempedoic acid added to atorvastatin 10 mg/day in patients with elevated LDL-C			
1002-006	Phase 2 proof-of-concept clinical study in patients with elevated LDL-C and a history of "statin intolerance"	8 Weeks	56	37
	Placebo-controlled, randomized, double-blind, multicenter study to evaluate the efficacy and safety of bempedoic acid in patients with elevated LDL-C and a history of "statin intolerance"			

Table of Contents

Description	Title	Treatment Duration	Subjects	
			Total	Treated
1002-005	Phase 2 proof-of-concept clinical study in patients with elevated-LDL-C and Type 2 diabetes	4 Weeks	60	30
Placebo-controlled, randomized, double-blind, single site clinical study to evaluate the LDL-C lowering efficacy and safety of bempedoic acid in patients with Type 2 diabetes				

1002-003	Phase 2 proof-of-concept clinical study in patients with elevated LDL-C	12 Weeks	177	133
Placebo-controlled, randomized, double-blind, parallel group, multicenter clinical study to evaluate the LDL-C lowering efficacy and safety of bempedoic acid in patients with elevated LDL-C and either normal or elevated triglycerides				
Overall, bempedoic acid has been well-tolerated and associated with no dose-limiting adverse events, or AEs, in over 800 patients who received bempedoic acid.				

Phase 2 Clinical Studies Completed in 2016***1002-035 Phase 2 pharmacokinetics/pharmacodynamics clinical study in patients treated with high-dose statin therapy***

On October 13, 2016, we announced top-line results for our Phase 2 PK/PD (1002-035) clinical study. The eight-week, U.S.-based, multi-center, randomized, double-blind, parallel group study evaluated 68 patients on stable atorvastatin 80 mg per day. All patients in the study received atorvastatin 80 mg for four weeks. Patients were then randomized to receive either bempedoic acid 180 mg, or placebo, for four weeks. The primary objectives of the study were to assess the LDL-C lowering efficacy of bempedoic acid 180 mg versus placebo on a background of atorvastatin 80 mg, as well as multiple-dose plasma PK of atorvastatin 80 mg alone and in combination with bempedoic acid. Secondary objectives included assessment of the effect of bempedoic acid on lipid and cardiometabolic biomarkers, including high-sensitivity C-reactive protein, or hsCRP; and characterization of the tolerability and safety of bempedoic acid.

Patients treated with bempedoic acid 180 mg achieved 22 percent (p=0.0028) LDL-C lowering from baseline compared to placebo with all patients on a background of atorvastatin 80 mg. There was a 13 percent reduction in LDL-C in the bempedoic acid group and a nine percent increase in LDL-C in the placebo group when added to background atorvastatin 80 mg. Bempedoic acid also demonstrated an incremental reduction of 35 percent (p=0.0020) in hsCRP. Bempedoic acid added to atorvastatin 80 mg produced no clinically relevant effects on atorvastatin PK, and appeared to be safe and well-tolerated, with no serious adverse events reported.

Phase 1 Clinical Studies Completed in 2016***1002-037 Phase 1 clinical pharmacology study to assess the safety and tolerability of bempedoic acid added to maximally tolerated statin therapy***

On October 13, 2016, we announced top-line results from our Phase 1 PK (1002-037) clinical study. The open-label study assessed the PK levels in 48 healthy volunteers receiving single doses of the highest doses of the most commonly prescribed statins atorvastatin 80 mg, rosuvastatin 40 mg, simvastatin 40 mg and pravastatin 80 mg when added to steady-state bempedoic acid 180 mg. The PK profiles demonstrated in 1002-037 were consistent with those seen in previous studies conducted with

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

Table of Contents

bempedoic acid, and did not increase with the highest doses of the statins tested in combination with bempedoic acid.

1002-034 Phase 1 bioavailability study to assess the relative oral bioavailability of bempedoic acid 180 mg and ezetimibe 10 mg (BA+EZ)

1002-034 is a Phase 1, randomized, open-label, single-dose study which is designed to assess the relative oral bioavailability of bempedoic acid 180 mg and ezetimibe 10 mg co-administered as individual tablets versus as two different fixed dose combination formulation tablets in healthy human subjects. Based on the findings from this study, we have selected the formulation for BA+EZ which we intend to take forward into development. We expect to announce clinical development and regulatory plans for BA+EZ in the first half of 2017.

Overall Safety Observations

To date, in completed studies, over 800 patients have been treated with bempedoic acid for periods of up to 12 weeks at maximum repeated doses of 240 mg per day. Bempedoic acid has been safe and well-tolerated with no dose-limiting side effects identified to date in our ongoing or completed clinical studies. No clinical safety trends have emerged to date.

Study	Phase	Patient Population	Study Design	Duration	Patients (Treated)	Doses	LDL Lowering Efficacy (placebo corrected)
1002-035	Phase 2	Elevated LDL	Placebo controlled, 80 mg atorvastatin	4 weeks	68 (45)	180 mg	Up to 22%
1002-014	Phase 2	Elevated LDL; hypertension	Placebo controlled	6 weeks	143 (71)	180mg	Up to 24%
1002-009	Phase 2	Elevated LDL; statin add-on	Placebo controlled,	12 weeks	134 (89)	120mg, 180mg	Up to 20%
1002-008	Phase 2	Elevated LDL; "statin intolerant" and tolerant	Monotherapy and in combination with ezetimibe	12 weeks	349 (250)	120 mg, 180 mg	Up to 30% Up to 48%
1002-007	Phase 2	Elevated LDL; statin add-on	Placebo controlled, 10 mg atorvastatin	8 weeks	58 (42)	60, 120, 180, 240 mg	Up to 22%
1002-006	Phase 2	Elevated LDL; "statin intolerant"	Placebo controlled	8 weeks	56 (37)	60, 120, 180, 240 mg	Up to 29%
1002-005	Phase 2	Elevated LDL; T2DM	Placebo controlled	4 weeks	60 (30)	80, 120 mg	Up to 39%
1002-004	Phase 1	Healthy subjects	Multiple ascending dose, PK	2 weeks	24 (18)	40, 180, 220 mg	Up to 36%
1002-003	Phase 2	Elevated LDL	Placebo controlled	12 weeks	177 (133)	40, 80, 120 mg	Up to 25%
1002-002	Phase 1	Healthy subjects	Multiple ascending dose, PK/PD	2/4 weeks	53 (39)	20, 60, 100, 120 mg	Up to 17%
1002-001	Phase 1	Healthy subjects	Single dose, PK	Single dose	18 (18)	2.5, 10, 45, 125, 250 mg	Not applicable

Ongoing Clinical Studies

The clinical development program for bempedoic acid consists of two major components: 1) the global pivotal Phase 3 LDL-C lowering program in high CVD risk patients with hypercholesterolemia on optimized background lipid-modifying therapy, including maximally tolerated statins, and patients who are only able to tolerate less than the lowest approved daily starting dose of their statin and are considered "statin intolerant," and 2) the CLEAR Outcomes CVOT in patients with hypercholesterolemia and high CVD risk and who are considered "statin intolerant".

Global regulatory submissions for an LDL-C lowering indication are expected by the first half of 2019 for a New Drug Application, or NDA, to the FDA and a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA. The Company expects to submit a NDA for cardiovascular risk reduction to the FDA and a MAA to the EMA, on the basis of a successful completion of the CLEAR

Outcomes CVOT by 2022.

Table of Contents

Study 1 Global pivotal Phase 3 long-term safety and tolerability study in patients with hypercholesterolemia on maximally tolerated background lipid-modifying therapy

Study 1 is a 52-week global pivotal Phase 3 randomized, double-blind, placebo-controlled study evaluating the long-term safety and tolerability of 180 mg of bempedoic acid versus placebo in patients with ASCVD and/or HeFH at high CVD risk whose LDL-C is not adequately controlled with current lipid-modifying therapies. At initiation the study included 900 patients but was expanded to approximately 2,000 patients to further support our regulatory submissions for an LDL-C lowering indication expected in the first half of 2019. The study enrolled patients at approximately 100 sites in the U.S., Canada and Europe. The primary objective is to assess safety and tolerability of patients treated with bempedoic acid for 52 weeks. Secondary objectives include assessing the LDL-C lowering efficacy of bempedoic acid on top of maximally tolerated statin and other lipid altering therapies at 12, 24 and 52 weeks versus placebo. Effects on other risk markers, including non-high-density lipoprotein, or non-HDL-C, total cholesterol, apolipoprotein B, or apoB, and hsCRP, will also be evaluated. We initiated Study 1 in January 2016, and completed patient enrollment ahead of schedule in January 2017. We expect to report top-line results in the second quarter of 2018.

Additional safety data will be obtained from an open-label extension study which will enroll approximately 1,300 patients of the approximately 2,000 patients originally enrolled in Study 1. This open-label extension study will evaluate the long-term safety of 180 mg of bempedoic acid versus placebo in patients with hypercholesterolemia with ASCVD and/or HeFH on maximally tolerated background lipid-modifying therapies, including patients on any statin at any dose. This open-label extension study will be conducted at approximately 100 sites included in the parent study in the U.S., Canada and Europe. The primary objective is to assess the long-term safety in patients treated with bempedoic acid for up to 1.5 years. Secondary objectives include evaluating the 52- and 78-week effects of bempedoic acid on lipid and cardiometabolic risk markers, including LDL-C, non-HDL-C, total cholesterol, apoB and hsCRP.

Study 2 Global pivotal Phase 3 safety and efficacy study in patients with hypercholesterolemia not adequately controlled with current lipid-modifying therapy

Study 2 is a 52-week global pivotal Phase 3 randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of 180 mg of bempedoic acid versus placebo. This study is expected to enroll 750 patients with hypercholesterolemia (with ASCVD and/or HeFH) at high CVD risk and whose LDL-C is not adequately controlled with current lipid-modifying therapies. The study will be conducted at approximately 125 sites in the U.S., Canada and Europe. The primary objective is to assess the 12-week LDL-C lowering efficacy of patients treated with bempedoic acid versus placebo. Secondary objectives include evaluating the 24-week LDL-C lowering efficacy, and 52-week safety and tolerability of bempedoic acid versus placebo. Effects on other risk markers, including non-HDL-C, total cholesterol, apoB, and hsCRP, will also be evaluated. We initiated Study 2 in December 2016, and expect to report top-line results by mid-2018.

Study 3 Global pivotal Phase 3 safety and efficacy study in patients with hypercholesterolemia on optimized background lipid-modifying therapy, including patients considered "statin intolerant"

Study 3 is a 24-week global pivotal Phase 3 randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of 180 mg of bempedoic acid versus placebo. This study is expected to enroll 300 patients with hypercholesterolemia on optimized background lipid-modifying therapy, including patients considered "statin intolerant." The study will be conducted at approximately 70 sites in the U.S. and Canada. The primary objective is to assess the 12-week LDL-C lowering efficacy of patients treated with bempedoic acid versus placebo. Secondary objectives include evaluating the 24-week LDL-C lowering efficacy, safety and tolerability of bempedoic acid versus placebo and effects

Table of Contents

on other risk markers, including non-HDL-C, total cholesterol, apoB and hsCRP. We initiated Study 3 in December 2016, and expect to report top-line results by mid-2018.

Study 4 Global pivotal Phase 3 safety and efficacy study in patients with hypercholesterolemia on optimized background lipid-modifying therapy, including ezetimibe, and patients considered "statin intolerant"

Study 4 is a 12-week global pivotal Phase 3 randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of 180 mg of bempedoic acid versus placebo as an add-on to 10 mg of ezetimibe. This study is expected to enroll 225 patients with hypercholesterolemia on optimized background lipid-modifying therapy, including ezetimibe, and patients considered "statin intolerant." The study will be conducted at approximately 75 sites in the U.S., Canada and Europe. The primary objective is to assess the 12-week LDL-C lowering efficacy of patients treated with bempedoic acid versus placebo when added to ezetimibe. Secondary objectives include evaluating safety and tolerability of bempedoic acid when added to ezetimibe, and effects on other risk markers, including non-HDL-C, total cholesterol, apoB and hsCRP. We initiated Study 4 in December 2016, and expect to report top-line results by mid-2018.

Global Cardiovascular Outcomes Trial CLEAR Outcomes

CLEAR Outcomes is an event driven, global, randomized, double-blind, placebo-controlled study to assess the effects of bempedoic acid in patients with hypercholesterolemia who are at high risk of CVD and who are only able to tolerate less than the lowest approved starting dose of a statin and can be considered "statin intolerant". The CLEAR Outcomes CVOT is expected to enroll approximately 12,600 patients with hypercholesterolemia and high CVD risk at more than 600 sites in approximately 30 countries. The study is expected to enroll over a 30-month period with a total estimated study duration of approximately 4.75 years. The expected average treatment duration will be 3.5 years with a minimum treatment duration of approximately 2.25 years. Patients enrolling in the study will be required to have a history of, or be at high-risk for, CVD with LDL-C levels between 100 mg/dL and 190 mg/dL despite background lipid-lowering therapy, resulting in an expected average baseline LDL-C level in all patients of approximately 135 mg/dL. The primary efficacy endpoint of the event-driven global study is the effect of bempedoic acid versus placebo on the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, hospitalization for unstable angina, or coronary revascularization; also referred to as "five-component MACE"). We initiated CLEAR Outcomes in December 2016, and the study is intended to support our submissions for a CV risk reduction indication in the U.S. and Europe by 2022.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2016, were \$57.9 million.

Sales and Marketing

Given our stage of development, we have not yet established a commercial organization or distribution capabilities, nor have we entered into any partnership or co-promotion arrangements with an established pharmaceutical company. To develop the appropriate commercial infrastructure to launch bempedoic acid in the United States, if approved, as a treatment for patients with elevated LDL-C, we would need to invest significant financial and managerial resources. We may engage in partnering discussions with third parties from time to time. If we elect to seek approval and launch commercial sales of bempedoic acid outside of the United States or for broader patient populations in the United States, including "statin intolerant" patients who are unable to reach their LDL-C goal with a statin therapy, we may either do so on our own or by establishing alliances with one or more

Table of Contents

pharmaceutical company collaborators, depending on, among other things, the applicable indications, the related development costs and our available resources.

Manufacturing and Supply

Bempedoic acid is a small molecule drug that is synthesized from readily available raw materials using conventional chemical processes. We currently have no manufacturing facilities and limited personnel with manufacturing experience. We rely on contract manufacturers to produce both drug substances and drug products required for our clinical studies. All lots of drug substance and drug product used in clinical studies are manufactured under current good manufacturing practices. We plan to continue to rely upon contract manufacturers and, potentially, collaboration partners to manufacture commercial quantities of bempedoic acid, if approved.

Licenses

In April 2008, we entered into an agreement with Pfizer pursuant to which we acquired a worldwide, exclusive, fully paid-up license from Pfizer to certain patent rights owned or controlled by Pfizer relating to bempedoic acid, 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, manufacture and commercialization of bempedoic acid. We may grant sublicenses under the license. Under the license agreement, Pfizer is restricted from making, using, developing or testing any of the compounds claimed under the same patents that claim or cover the composition of matter of bempedoic acid. Neither party is entitled to any royalties, milestones or any similar development or commercialization payments under the license agreement, and the licenses granted are irrevocable and may not be terminated for any cause, including intentional breaches or breaches caused by gross negligence.

Intellectual Property

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

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

As of December 31, 2016, our patent estate, including patents we own or license from third parties, on a worldwide basis, included approximately 25 issued United States patents and four pending United States patent applications and 23 issued patents and 15 pending patent applications in other foreign jurisdictions. Of our worldwide patents and pending applications, only a subset relates to our small molecule program which includes our lead product candidate, bempedoic acid. 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. U.S. Patent Nos. 9,000,041 and 8,497,301 claim methods of treatment using bempedoic acid. We also have a pending U.S. patent application directed to bempedoic acid. There are currently three issued patents and four pending application in countries outside the United States that relate to bempedoic acid.

Table of Contents

A subset of this portfolio relates to our planned fixed dose combination of bempedoic acid and ezetimibe and bempedoic acid and one or more statins. We have one pending application outside the United States claiming methods of treatment using a fixed dose combination of bempedoic acid and ezetimibe. We have one pending application outside the United States claiming methods of treatment using a fixed dose combination of bempedoic acid and one or more statins.

We hold an exclusive, worldwide, fully paid-up license from Pfizer to additional patents and patent applications.

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 the 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. 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 will expire on dates ranging from 2021 to 2030. 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 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.

As a result of the America Invents Act of 2011, the United States transitioned to a first-inventor-to-file system in March 2013, under which, assuming the other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent. This will require us to minimize the time from invention to the filing of a patent application.

Table of Contents

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, scientific advisors and contractors 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, contractors or collaborators 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 our future drugs 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 interference proceedings in the U.S. Patent and Trademark Office, or USPTO, to determine priority of 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, if approved, 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

Table of Contents

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 our Business and the Clinical Development and Commercialization of Bempedoic Acid 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, if approved, 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 other countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of products such as those we are developing. Our product candidates, including bempedoic acid, must be approved by the FDA through the NDA process before they may legally be marketed in the United States.

United States Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and 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, 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 nonclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices regulations;

submission to the FDA of an IND, which must become effective before human clinical studies may begin;

performance of adequate and well-controlled human clinical studies according to Good Clinical Practices, or GCP, to establish the safety and efficacy of the proposed drug for its intended use;

submission to the FDA of an NDA for a new drug;

satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP; and

FDA review and approval of the NDA.

The testing and approval process requires substantial time, effort and financial resources and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Table of Contents

Once a pharmaceutical product candidate is identified for development, it enters the nonclinical, also referred to as preclinical, testing stage. Nonclinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. An IND sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical study, 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. Protocols detail, among other things, the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety.

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 safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. 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

Table of Contents

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.

U.S. Review and Approval Processes

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.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, 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

Table of Contents

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.

If a product receives regulatory approval, the approval may be significantly limited to specific patient populations, therapeutic settings, risk categories of disease, and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require further Phase 3 and Phase 4 testing to be conducted, which involves clinical studies designed to further assess a drug's safety and effectiveness after NDA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply 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

Table of Contents

existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the nonclinical studies and adequate and well- controlled clinical studies necessary to demonstrate safety and effectiveness.

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

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

Post-Approval Requirements

Any drugs for which we receive FDA approval are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. Further, manufacturers of drugs must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Drug manufacturers and other entities involved in the manufacturing and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the drug. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory standards, and test each product batch or lot prior to its release. We rely, and expect to continue to rely, on third parties for the production of clinical quantities of our product candidates. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution or may require substantial resources to correct.

The FDA may withdraw a product approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, warning letters, holds on clinical studies, product recalls or seizures, product detention or refusal to permit the import or export

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

Table of Contents

of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, injunctions or civil or criminal penalties.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, the FDA regulations and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our product candidates. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

Foreign Regulation

In addition to regulations in the United States, we will be 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. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical studies or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical studies, product licensing, pricing and reimbursement vary greatly from country to country. As in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution would apply to any product that is approved outside the United States.

Employees

As of December 31, 2016, we had 44 full-time employees. Two of our employees have Ph.D. degrees and three have M.D. degrees. 28 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.

Facilities

Our corporate headquarters are located in Ann Arbor, Michigan where we lease and occupy approximately 7,900 square feet of office space. We lease and occupy an additional 5,500 square feet of office space in Ann Arbor, Michigan to support our clinical development operations. We believe our current facilities will be sufficient to meet our needs until expiration.

Legal Proceedings

On January 12, 2016, a purported stockholder of the Company filed a putative class action lawsuit in the United States District Court for the Eastern District of Michigan, against us and Tim Mayleben, captioned *Kevin L. Dougherty v. Esperion Therapeutics, Inc., et al.* (No. 16-cv-10089). The lawsuit alleges that we and Mr. Mayleben violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 by allegedly failing to disclose in an August 17, 2015, public statement that the FDA would require a cardiovascular outcomes trial before approving our lead product candidate. The lawsuit seeks, among other things, compensatory damages in connection with an allegedly inflated stock price between August 18, 2015, and September 28, 2015, as well as attorneys' fees and costs. On May 20, 2016, an amended complaint was filed in the lawsuit and on July 5, 2016, we filed a motion to dismiss the amended complaint. On December 27, 2016, the court granted our motion to dismiss with prejudice and entered judgment in our favor. On January 24, 2017, the plaintiffs in this lawsuit filed a motion to alter or amend the judgment.

On December 15, 2016, a purported stockholder of the Company filed a derivative lawsuit in the Court of Chancery of the State of Delaware against Tim Mayleben, Roger Newton, Mary McGowan,

Table of Contents

Nicole Vitullo, Dov Goldstein, Daniel Janney, Antonio Gotto Jr., Mark McGovern, Gilbert Omenn, Scott Braunstein, and Patrick Enright. The Company is named as a nominal defendant. The lawsuit alleges that the defendants breached their fiduciary duties to the Company when they made or approved improper statements on August 17, 2015, regarding our lead product candidate's path to FDA approval, and failed to ensure that reliable systems of internal controls were in place at the Company. The lawsuit seeks, among other things, any damages sustained by the Company as a result of the defendants' alleged breaches of fiduciary duties, including damages related to the above-referenced securities class action, an order directing the Company to take all necessary actions to reform and improve its corporate governance and internal procedures, restitution from the defendants, and attorneys' fees and costs. In light of, among other things, the early stage of the litigation, we are unable to predict the outcome of this matter and are unable to make a meaningful estimate of the amount or range of loss, if any, that could result from an unfavorable outcome.

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

Available Information

Our website address is www.esperion.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge through the investor relations page of our internet website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. Alternatively, these reports may be accessed at the SEC's website at www.sec.gov.

Table of Contents

Item 1A. Risk Factors

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

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

Risks Related to our Business and the Clinical Development and Commercialization of Bempedoic Acid

We depend almost entirely on the success of one product candidate, bempedoic acid, which only recently commenced Phase 3 clinical development. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, bempedoic acid.

Bempedoic acid and BA + EZ, the fixed dose combination of bempedoic acid and ezetimibe, are our only product candidates in clinical development, and our business depends almost entirely on bempedoic acid's successful clinical development, regulatory approvals and commercialization. We currently have no drug products for sale and may never be able to develop marketable drug products. Bempedoic acid, for which we recently launched our global pivotal Phase 3 clinical program in January 2016, will require substantial additional clinical development, testing, and regulatory approvals before we are permitted to commence its commercialization. The clinical studies of our product candidates are, and the manufacturing and marketing of our product candidates will be, 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 beyond the proceeds we have raised, and may include post-marketing studies and surveillance, including a Risk Evaluation and Mitigation Strategy, or REMS program. 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, even if we are able to obtain the requisite financing to continue to fund our development and clinical programs, we cannot assure you that bempedoic acid or any other of our product candidates will be successfully developed or commercialized.

We are not permitted to market bempedoic acid in the U.S. or Europe until we receive approval of a NDA from the FDA, a MAA from the EMA, or in any other foreign countries until we receive the requisite approval from such countries. As a condition to submitting an NDA to the FDA or an MAA to EMA for bempedoic acid to treat patients with elevated LDL-C, we have currently completed eight Phase 2 clinical studies and expect to complete the global pivotal Phase 3 LDL-C lowering efficacy and safety studies, and to potentially complete, the CLEAR Outcomes CVOT.

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

Table of Contents

Additionally, while we currently intend to submit our NDA for bempedoic acid for an LDL-C lowering indication in patients with hypercholesterolemia, the FDA has indicated its position regarding an LDL-C lowering indication could be impacted by potential future changes in their view of LDL-C lowering as a surrogate endpoint or the possibility of a shift in the future standard-of-care for "statin intolerant" patients with elevated LDL-C levels. In the event that FDA determines LDL-C lowering is no longer a surrogate endpoint for initial approval of bempedoic acid in the future, we would plan to submit our NDA with a proposed indication of CV risk reduction in "statin intolerant" patients on the basis of a completed and successful CLEAR Outcomes CVOT, which would include the results of the global pivotal Phase 3 LDL-C lowering efficacy and safety studies, by 2022. Obtaining approval of an NDA is a complex, lengthy, expensive and uncertain process, and the FDA may delay, limit or deny approval of bempedoic acid for many reasons, including, among others:

the FDA, EMA or any other regulatory authorities may change their approval policies or adopt new regulations, including with respect to whether LDL-C lowering is a surrogate endpoint for initial approval of bempedoic acid;

we may not be able to demonstrate that bempedoic acid is safe and effective in treating patients with elevated LDL-C to the satisfaction of the FDA, EMA or any other regulatory agency;

the results of our clinical studies may not meet the level of statistical or clinical significance required by the FDA or EMA for marketing approval;

the magnitude of the treatment effect must also be clinically meaningful along with the drug's safety for a favorable benefit/risk assessment by the FDA, EMA or any other regulatory agency;

the FDA, EMA or any other regulatory agency may disagree with the number, design, size, duration, 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;

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 bempedoic acid's clinical and other benefits outweigh its 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 NDA, if and when submitted, is 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 application 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;

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

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.

Table of Contents

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. Moreover, because our business is almost entirely dependent upon this one product candidate, any setback in our pursuit of its regulatory approval would have a material adverse effect on our business and prospects.

The development and approvals required for the approval of BA + EZ, which is in development for the same indications as bempedoic acid as monotherapy, are substantially identical to those for bempedoic acid as monotherapy, and the risks relating to the clinical development and approval of bempedoic acid monotherapy apply equally to BA + EZ. The FDA only recently accepted our submission of an IND application for BA + EZ in the second quarter of 2016 and we recently completed a bioavailability study. A formulation of BA + EZ has been selected for development and commercialization. We expect to announce clinical development and regulatory plans for BA + EZ in the first half of 2017. Any failure in our development of bempedoic acid monotherapy would materially and adversely affect our ability to develop, seek approval for and commercialize the BA + EZ combination therapy for the targeted indications. In addition, even if bempedoic acid monotherapy succeeds in its clinical development and is approved for one or more targeted indications, there can be no assurance that the BA + EZ combination therapy would be developed successfully and approved for the same indications or at all.

Failures or delays in the completion of our global pivotal Phase 3 efficacy and safety studies or our CLEAR Outcomes CVOT of bempedoic acid could result in increased costs to us and could delay, prevent or limit our ability to generate revenue and continue our business.

In January 2016, we commenced our global pivotal Phase 3 long-term safety study (Study 1). We do not know whether our ongoing clinical studies will be completed on schedule, if at all. We initiated our three remaining global pivotal Phase 3 LDL-C lowering efficacy studies and the CLEAR Outcomes CVOT in December 2016. We do not know whether these studies will be completed on schedule. Successful completion of such clinical studies and, if required by the FDA due to a change in regulatory policy, our CLEAR Outcomes CVOT, are likely prerequisites to submitting an initial NDA to the FDA, MAA to the EMA or a similar application to any other foreign regulatory authorities from whom we seek to obtain approval and, consequently, the ultimate approval and commercialization of bempedoic acid. The commencement and completion of 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;

challenges in recruiting and enrolling patients to participate in clinical studies or in our CLEAR Outcomes CVOT, including the size and nature of the patient population, the proximity of patients to clinical sites, eligibility criteria for the clinical study, the nature of the clinical study protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical study programs, including PCSK9 inhibitors, for similar indications;

Table of Contents

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 previously identified in our completed clinical studies;

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 board, or DSMB, 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 and Phase 2 clinical studies of bempedoic acid are not necessarily predictive of the results of our ongoing global pivotal Phase 3 program and CVOT of bempedoic acid, nor do they guarantee approval of bempedoic acid by the FDA, EMA or any other regulatory agency. If we cannot replicate the positive results from our completed Phase 1 and Phase 2 clinical studies of bempedoic acid in our ongoing clinical studies and CVOT, we may be unable to successfully develop, obtain regulatory approval for and commercialize bempedoic acid.

There is a high failure rate for drugs proceeding through clinical studies. Even if we are able to complete our ongoing global pivotal Phase 3 LDL-C studies, CVOT and any potential additional Phase 3 clinical studies of bempedoic acid according to our current development timeline, the positive results from our completed Phase 1 and Phase 2 clinical studies of bempedoic acid, including those of our Phase 2 PK/PD (1002-035) study completed in October 2016, may not be replicated in our ongoing global pivotal Phase 3 and CVOT or planned Phase 3 clinical study results, nor do they guarantee approval of bempedoic acid by the FDA, EMA or any other regulatory authorities in a timely manner or at all. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical studies after achieving positive results in early stage 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.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical studies nonetheless failed to obtain FDA and/or EMA approval. If we fail to obtain

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

Table of Contents

positive results in our ongoing global pivotal Phase 3, CVOT and planned Phase 3 clinical studies of bempedoic acid, the development timeline and regulatory approval and commercialization prospects for our leading product candidate, and, correspondingly, our business and financial prospects, would be materially adversely affected.

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

We reported top-line results from our Phase 2 (1002-008) clinical study in October 2014, our Phase 2 (1002-009) clinical study in March 2015, our Phase 2 (1002-014) exploratory clinical safety study in July 2015, and our Phase 2 PK/PD (1002-035) clinical study and Phase 1 PK (1002-037) study in October 2016. We held our End-of-Phase 2 meeting with the FDA in August 2015. In January 2016, we commenced our global pivotal Phase 3 long-term safety study (Study 1). We engaged in active dialogue in 2016 with the FDA and EMA to discuss our global pivotal Phase 3 clinical program for bempedoic acid in the "statin intolerant" patient population and, based on that dialogue, announced our clinical development and regulatory plans for bempedoic acid in June 2016. We initiated our global pivotal Phase 3 LDL-C lowering efficacy studies and our CLEAR Outcomes CVOT in December 2016.

In the event that FDA determines LDL-C lowering is no longer a surrogate endpoint for initial approval of bempedoic acid in the future, we would plan to submit our NDA for CV risk reduction indication on the basis of a completed and successful CVOT, which would include the results of the Phase 3 LDL-C lowering efficacy studies, by 2022. We expect that these clinical studies, plus any additional clinical studies that we undertake for the clinical development of BA + EZ, will consume substantial additional financial resources. We expect that our existing cash and cash equivalents only will be sufficient to fund our operations into early 2019. We will need to raise additional capital to continue to fund the further development and commercialization of bempedoic acid and our operations. Our future capital requirements may be substantial and will depend on many factors including:

the scope, size, rate of progress, results and costs of completing our CLEAR Outcomes CVOT of bempedoic acid;

the scope, size, rate of progress, results and costs of completing our global pivotal Phase 3 LDL-C lowering program of bempedoic acid, which currently includes multiple global pivotal Phase 3 clinical efficacy and safety studies;

the scope, size, rate of progress, results and costs of clinical development of BA + EZ for the same indications as bempedoic acid monotherapy;

the cost, timing and outcome of our efforts to obtain marketing approval for bempedoic acid, including to fund the preparation and filing of an NDA with the FDA and a MAA with the EMA for bempedoic acid and to satisfy related FDA and EMA requirements;

the number and characteristics of any additional product candidates we develop or acquire;

the costs associated with commercializing bempedoic acid 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 or any future product candidates;

the cost of manufacturing bempedoic acid or any future product candidates and any products we successfully commercialize; and

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

Table of Contents

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 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 or any future product candidate, or to commercialize bempedoic acid or any future product candidate, if approved, unless we find a partner.

We are an emerging pharmaceutical company and have not generated any revenue from product sales. We have incurred significant operating losses since our inception, and anticipate that we will incur continued losses for the foreseeable future.

We have a limited operating history on which to base your investment decision. Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We were incorporated in January 2008. Our operations to date have been limited primarily to organizing and staffing our company and conducting research and development activities for bempedoic acid. We have never generated any revenue from product sales. We have not obtained regulatory approvals for any of our product candidates. 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, which commenced Phase 3 clinical development in January 2016. We have funded our operations to date primarily through proceeds from sales of preferred stock, public offerings of common stock, convertible promissory notes and warrants and the incurrence of indebtedness, and we have incurred losses in each year since our inception. Our net losses were \$75.0 million, \$49.8 million and \$36.4 million for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, we had an accumulated deficit of \$229.2 million. Substantially all of our operating losses resulted from costs incurred in connection with our development program and from general and administrative costs associated with our operations. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect our research and development expenses to significantly increase in connection with our additional clinical studies of bempedoic acid, particularly our Phase 3 program and CLEAR Outcomes CVOT, as well as any clinical studies that we undertake to develop BA + EZ, and development of any other product candidates we may choose to pursue. In addition, if we obtain marketing approval for bempedoic acid, we will also incur significant sales, marketing and outsourced manufacturing expenses. As a public company, we have incurred and will continue to incur additional costs associated with operating as a public company, particularly now that we are no longer an "emerging growth company." As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

Table of Contents

Changes in regulatory requirements, FDA or EMA guidance or unanticipated events during our global pivotal Phase 3 clinical studies or our CVOT of bempedoic acid may occur, which may result in changes to clinical study protocols or additional clinical study requirements, which could result in increased costs to us and could delay our development timeline.

Changes in regulatory requirements, FDA or EMA guidance or unanticipated events during our clinical studies may force us to amend clinical study protocols or the FDA or EMA may impose additional clinical study requirements. Significant amendments to our clinical study protocols may require resubmission to the FDA and/or IRBs for review and approval, which may adversely impact the cost, timing and/or successful completion of these studies. If we experience substantial delays completing or if we terminate any of our global pivotal Phase 3 clinical studies or our CVOT, or if we are required to conduct additional clinical studies, the commercial prospects for bempedoic acid may be harmed and our ability to generate product revenue will be delayed.

Even though we completed enrollment of Study 1 ahead of schedule, we may not be able to identify and enroll the requisite number of patients in the remaining studies in our global pivotal Phase 3 LDL-C lowering program, our CLEAR Outcomes CVOT or any study that we undertake to support the development of BA+EZ. Even when we are successful in enrolling patients, we may not ultimately be able to demonstrate sufficient clinical benefits from bempedoic acid and our failure to do so may delay or hinder our ability to obtain FDA or EMA approval for bempedoic acid. While we currently plan to submit an NDA for bempedoic acid for an LDL-C lowering indication in patients with hypercholesterolemia after initiating our CLEAR Outcomes CVOT, the FDA has indicated its position regarding an LDL-C lowering indication could be impacted by potential future changes in their view of LDL-C lowering as a surrogate endpoint or the possibility of a shift in the future standard-of-care for "statin intolerant" patients with elevated LDL-C levels. Conducting our CLEAR Outcomes CVOT will be costly and time-consuming, and any requirement to complete the CVOT prior to approval of bempedoic acid would adversely affect our development timeline and financial condition.

Even if we receive marketing approval for bempedoic acid, we may still face future development and regulatory difficulties.

Even if we receive marketing approval for bempedoic acid, regulatory authorities may still impose significant restrictions on bempedoic acid's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies, such as a CVOT. Bempedoic acid 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. The FDA also has the authority to require, as part of an NDA or post-approval, the submission of a REMS. Any REMS required by the FDA may lead to increased costs to assure compliance with post-approval regulatory requirements and potential requirements or restrictions on the sale of approved products, all of which could lead to lower sales volume and revenue. The EMA and other foreign regulatory authorities may impose similar requirements on bempedoic acid as those described above with respect to the FDA.

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

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

Table of Contents

bempedoic acid 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.

Even if we receive marketing approval for bempedoic acid in the U.S., we may never receive regulatory approval to market bempedoic acid outside of the U.S., and vice versa.

In order to market any product outside of the U.S., 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 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., 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 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 if we receive marketing approval for bempedoic acid, it may not achieve broad market acceptance, which would limit the revenue that we generate from its sales.

The commercial success of bempedoic acid, if approved by the FDA or other regulatory authorities, will depend upon the awareness and acceptance of bempedoic acid among the medical community, including physicians, patients and healthcare payors. Market acceptance of bempedoic acid, if approved, will depend on a number of factors, including, among others:

bempedoic acid's demonstrated ability to treat "statin intolerant" patients for LDL-C lowering or CV risk reduction as an add-on for patients already on statin therapy, as compared with other available therapies;

the relative convenience and ease of administration of bempedoic acid, 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 by the FDA;

Table of Contents

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 sales and marketing strategies;

our ability to increase awareness of bempedoic acid 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 is approved but does not achieve an adequate level of acceptance by patients, physicians and payors, we may not generate sufficient revenue from bempedoic acid to become or remain profitable. Our efforts to educate the medical community and third-party payors about the benefits of bempedoic acid may require significant resources and may never be successful.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell bempedoic acid, we may not be able to generate any revenue.

We do not currently have an infrastructure for the sales, marketing and distribution of pharmaceutical products. In order to market bempedoic acid, if approved by the FDA or any other regulatory body, we must build our sales, marketing, managerial, and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, or if we are unable to do so on commercially reasonable terms, our business, results of operations, financial condition and prospects will be materially adversely affected.

Even if we obtain marketing approval for bempedoic acid, physicians and patients using other LDL-C lowering therapies may choose not to switch to our product.

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, if approved, our operating results and financial condition would be materially adversely affected.

The development and, if approved, commercialization of BA + EZ depends on the availability to and use of ezetimibe by the target patient of this combination therapy.

BA + EZ is dependent on the continued availability and use of ezetimibe in the marketplace, and there can be no assurance that the current availability and use of ezetimibe will continue. For example, changes in standard of care or use patterns of ezetimibe could make our BA + EZ combination therapy obsolete. In addition, ezetimibe could encounter unexpected results in the future and be associated with adverse outcomes during long-term use. Finally, 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 use in our planned clinical trials or impact the number of patients taking ezetimibe who are available to enroll in our clinical trials. For example, such producers may encounter manufacturing or other production issues and fail to produce enough ezetimibe for us to successfully complete our

Table of Contents

studies and clinical trials, and this could cause our BA + EZ development program or commercialization efforts, if BA + EZ is approved, to fail or be significantly delayed.

Guidelines and recommendations published by various organizations may adversely affect the FDA's review of bempedoic acid for LDL-C lowering in "statin intolerant" patients or the use or commercial viability of bempedoic acid, if approved for any indication or patient population.

Government agencies issue regulations and guidelines directly applicable to us and to bempedoic acid, including guidelines generally relating to therapeutically significant LDL-C levels. In addition, professional societies, practice management groups, private health or science foundations and other organizations involved in the research, treatment and prevention of various diseases from time to time publish guidelines or recommendations to the medical and patient communities. These various sorts of recommendations may relate to such matters as product usage and use of related or competing therapies. For example, organizations such as the AHA have made recommendations about therapies in the cardiovascular therapeutics market. We expect that the FDA's view of the standard of care for patients with elevated LDL-C at the time we submit an NDA for our LDL-C-lowering program in patients with elevated LDL-C will impact the evaluation of such NDA, including how this standard of care evolves in light of guidelines and recommendations in respect of the use of PCSK9 inhibitors. In addition, following any approval, we expect that changes to these existing recommendations or other guidelines advocating alternative therapies could result in decreased use of bempedoic acid, which would adversely affect our results of operations.

Even if approved, reimbursement policies could limit our ability to sell bempedoic acid.

Market acceptance and sales of bempedoic acid will depend on reimbursement policies and may be affected by healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels for those medications. 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. We cannot be sure that reimbursement will be available for bempedoic acid and, if reimbursement is available, the level of such reimbursement. Reimbursement may impact the demand for, or the price of, bempedoic acid. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize bempedoic acid.

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 with other available therapies. If reimbursement for bempedoic acid 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.

Our future product development programs for candidates other than bempedoic acid may require substantial financial resources and may ultimately be unsuccessful.

In addition to the development of bempedoic acid, we may in the future pursue the development of other early-stage development programs. Our potential product candidate has not commenced any clinical studies, and there are 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

Table of Contents

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 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.

Recent federal legislation will increase pressure to reduce prices of pharmaceutical products paid for by Medicare, which could materially adversely affect our revenue, if any, 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 than some other pharmaceutical products because a significant portion of the target patient population for bempedoic acid would likely be over 65 years of age and, therefore, many such patients will be covered by Medicare.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the PPACA, became law in the United States. The goal of the PPACA is to reduce the cost of healthcare and substantially change the way healthcare is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, the PPACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of bempedoic acid, if approved, or any of our future products. In 2012, members of the U.S. Congress and some state legislatures sought to overturn certain provisions of the PPACA including those concerning the mandatory purchase of insurance. However, on June 28, 2012, the United States Supreme Court upheld the constitutionality of these provisions. Members of the U.S. Congress have since proposed a number of legislative initiatives, including possible repeal of the PPACA. We cannot predict the outcome or impact of current proposals or whether new proposals will be made or adopted, when they may be adopted or what impact they may have on us if they are adopted. These challenges add to the uncertainty of the legislative changes as part of ACA.

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

Recent federal legislation and actions by state and local governments may permit reimportation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could materially adversely affect our operating results.

We may face competition for bempedoic acid, if approved, from cheaper LDL-C lowering therapies sourced from foreign countries that have placed price controls on pharmaceutical products. The MMA contains provisions that may change U.S. importation laws and expand pharmacists' and

Table of Contents

wholesalers' ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. These changes to U.S. importation laws will not take effect unless and until the Secretary of Health and Human Services certifies that the changes will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of products to consumers. The Secretary of Health and Human Services has so far declined to approve a reimportation plan. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop, including bempedoic acid, and adversely affect our future revenues and prospects for profitability.

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 if approved. 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. If we receive marketing approval for bempedoic acid as a therapy for lowering LDL-C levels in "statin intolerant" patients with elevated LDL-C, the first indication we intend to pursue, physicians may nevertheless prescribe bempedoic acid to their patients in a manner that is inconsistent with the approved label, potentially including as a therapy in addition to statins. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion 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, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

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, if approved, will be materially adversely affected.

The LDL-C lowering therapies market is highly competitive and dynamic and dominated by the sale of statin treatments, including the cheaper generic versions of statins. We estimate that the total statin monotherapy and fixed combination market, including generic drugs, accounted for 69% of U.S. sales in the LDL-C lowering market in 2012. Our success will depend, in part, on our ability to obtain a share of the market, initially, for patients who are "statin intolerant". Potential competitors in North America, Europe and elsewhere include major pharmaceutical companies, specialty pharmaceutical companies, biotechnology firms, universities and other research institutions and government agencies. Other pharmaceutical companies may develop LDL-C lowering therapies for "statin intolerant" patients that compete with bempedoic acid, if approved, 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. The FDA has also indicated to us that approval of other therapies that may be taken by "statin intolerant" patients could have an impact on their review of an NDA we submit for bempedoic acid for our LDL-C lowering program in these patients.

LDL-C lowering therapies currently on the market that would compete with bempedoic acid include the following:

Branded statins and their cheaper generic versions;

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

Table of Contents

Cholesterol absorption inhibitors, such as Zetia® (ezetimibe), a monotherapy marketed by Merck & Co., and the cheaper generic version;

PCSK9 inhibitors such as Praluent® (alirocumab) and Repatha® (evolocumab), marketed by Sanofi/Regeneron and Amgen Inc. respectively;

Bile acid sequestrants such as Welchol® (colesevelam), marketed by Daiichi Sankyo Inc.;

MTP inhibitors, such as JUXTAPID® (lomitapide), marketed by Novelion Therapeutics, Inc.;

Apo B Anti-Sense therapy, such as KYNAMRO® (mipomersen), marketed by Kastle Therapeutics LLC;

Combination therapies, such as Vytorin® (ezetimibe and simvastatin) and Liptruzet® (ezetimibe and atorvastatin), marketed by Merck & Co., Inc.; 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. Based on publicly available information, we believe the current therapies in development that would compete with bempedoic acid include:

PCSK9 inhibitors in development from Lilly, Roche, Kowa and The Medicines Company/Alnylam; and

CETP inhibitors, such as anacetrapib and dalcetrapib, therapies, in Phase 3 clinical testing being developed by Merck and DalCor, respectively.

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 FDA approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than bempedoic acid, if approved, and may render bempedoic acid obsolete or non-competitive before we can recover the expenses of developing and commercializing it. If approved, bempedoic acid 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.

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

The use of bempedoic acid in clinical studies and the sale of bempedoic acid, if approved, 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. 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

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

Table of Contents

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 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 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. 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. If and when we obtain marketing approval for bempedoic acid, we intend to expand our insurance coverage to include the sale of commercial products; however, we may not be able to obtain this product liability insurance on commercially reasonable terms. 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 are subject to 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 others will play a primary role in the recommendation and prescription of bempedoic acid, if approved. Our future arrangements with third-party payors will 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 bempedoic acid, if we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

The federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid.

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

The federal False Claims Act imposes criminal and civil penalties, including those from civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or

Table of Contents

fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government.

The federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

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.

The federal transparency requirements under the PPACA require manufacturers of drugs, devices, biologics, and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests.

Analogous state laws and regulations, such as state anti-kickback and false claims laws and transparency laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and drug pricing.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could be costly. It is possible that governmental authorities will conclude that our business practices do 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, including anticipated activities to be conducted by our sales team, were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines and exclusion from government funded healthcare programs, such as Medicare and Medicaid, any of which could substantially disrupt our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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

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

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

Table of Contents

Our credit facility imposes significant restrictions on our business, and if we default on our obligations, our lender would have a right to foreclose on substantially all our assets.

In June 2014, we entered into a loan and security agreement, or loan agreement, with Oxford Finance LLC, or Oxford, pursuant to which, subject to the conditions to borrowing thereunder, we borrowed an aggregate principal amount of \$5.0 million. The loans are secured by a lien on substantially all of our assets excluding intellectual property.

We could in the future incur additional indebtedness beyond amounts currently outstanding under our loan agreement with Oxford. Our debt combined with our other financial obligations and contractual commitments could have significant adverse consequences, including:

requiring us to dedicate a substantial portion of cash flow from operations to the payment of interest on, and principal of, our debt, which will reduce the amounts available to fund working capital, capital expenditures, product development efforts and other general corporate purposes;

increasing our vulnerability to adverse changes in general economic, industry and market conditions;

limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and

placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

Additionally, with certain exceptions, the loan agreement prohibits us from:

making any material dispositions of our assets, except for permitted dispositions;

making any changes in our business, management, ownership, or business locations;

entering into any merger or consolidation without Oxford's consent;

acquiring or making investments in any other person other than permitted investments;

incurring any indebtedness, other than permitted indebtedness;

granting or permitting liens against our assets, other than permitted liens;

declaring or paying any dividends or making any other distributions; or

entering into any material transaction with any affiliate, other than in the ordinary course of business.

We intend to satisfy our current and future debt service obligations with our cash and cash equivalents and short-term investments and funds from external sources. However, we may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt. Funds from external sources may not be available on acceptable terms, if at all. In addition, a failure to comply with the covenants under our debt instruments could result in an event of default under those instruments. In the event of an acceleration of amounts due under our debt instruments as a result of an event of default, we may not have sufficient funds and may be unable to arrange for additional financing to repay our indebtedness, and our lender could seek to enforce security interests in the collateral securing such indebtedness. In

addition, the covenants under our debt instruments and the pledge of our assets as collateral limit our ability to obtain additional debt financing.

Table of Contents

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, 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, 2016, our patent estate, including patents we own or license from third parties, on a worldwide basis, included approximately 25 issued United States patents and four pending United States patent applications and 23 issued patents and 15 pending patent applications in other foreign jurisdictions. Of our worldwide patents and pending applications, only a subset relates to our small molecule program which includes our lead product candidate, bempedoic acid. 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. U.S. Patent Nos. 9,000,041 and 8,497,301 claim methods of treatment using bempedoic acid. We also have a pending U.S. patent application directed to bempedoic acid. There are currently three issued patents and four pending application in countries outside the United States that relate to bempedoic acid.

A subset of this portfolio relates to our planned fixed dose combination of bempedoic acid and ezetimibe and bempedoic acid and one or more statins. We have one pending application outside the United States claiming methods of treatment using a fixed dose combination of bempedoic acid and ezetimibe. We have one pending application outside the United States claiming methods of treatment using a fixed dose combination of bempedoic acid and one or more statins.

We may not have identified all patents, published applications or published literature that affect our business either by blocking our ability to commercialize our drug candidates, by preventing the patentability of one or more aspects of our 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 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 U.S. PTO, 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 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 drug candidates. Any conflicts resulting from third-party patent applications and patents could affect our ability to obtain the necessary patent protection for our

Table of Contents

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 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 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 opposition or comparable proceedings lodged in various national and regional patent offices. These proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, re-examination, opposition, post-grant review, inter partes review, supplemental examination 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.

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.

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, our financial position and results of operations would be materially and adversely impacted. In addition, if a court found that valid, enforceable patents

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

Table of Contents

held by third parties covered bempedoic acid, our financial position and results of operations would also be materially and adversely impacted.

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

any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect bempedoic acid;

any of our pending patent applications will result in issued patents;

we will be able to successfully commercialize bempedoic acid, if approved, 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 to our lead product candidate 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

Table of Contents

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 to or independently developed by a competitor or other third-party, our competitive position would be harmed.

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, if approved.

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 use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. 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.

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;

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 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.

Table of Contents

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 and is currently implementing the America Invents Act of 2011, 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 U.S. PTO, 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 U.S. PTO 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 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) have or 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 or decide to terminate our license at will, and accordingly seek to terminate our license. 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 a product candidate or product, if approved, 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 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.

Table of Contents

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 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.

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, which would materially adversely affect our commercial development efforts.

Risks Related to our Dependence on Third Parties

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, and will continue to rely on CROs to conduct our ongoing Phase 3 clinical studies and CVOT for bempedoic acid, as well as any clinical studies we may undertake to develop BA + EZ. As a result, we will have less direct control over the conduct, timing and completion of these clinical studies and the management of data developed through the clinical studies than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

have staffing difficulties;

fail to comply with contractual obligations;

experience regulatory compliance issues;

undergo changes in priorities or become financially distressed; or

form relationships with other entities, some of which may be our competitors.

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

Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording, and reporting the results of clinical studies to assure that data and

Table of Contents

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 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 and preclude our ability to commercialize bempedoic acid, 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 we intend to rely on third parties to produce commercial supplies of bempedoic acid 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 clinical drug supply of bempedoic acid, or any future product candidates, for use in the conduct of our preclinical studies and clinical studies, and we lack the internal resources and the capability to manufacture any product candidates on a clinical or commercial scale. In addition, we have no control over the production of ezetimibe for our BA + EZ product candidate. 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 we submit our NDA or relevant foreign regulatory submission to the applicable regulatory agency.

We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers to comply with current Good Manufacturing Practices for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or applicable foreign regulatory agencies, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, all of our contract manufacturers are engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes our manufacturers to regulatory risks for the production of such materials and products. As a result, failure to satisfy the regulatory requirements for the production of those materials and products may affect the regulatory clearance of our contract manufacturers' facilities generally. If the FDA or a comparable foreign regulatory agency does not approve these facilities for the manufacture of our 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 develop, obtain regulatory approval for or market our product candidates.

Table of Contents

If we do not establish successful collaborations, we may have to alter our development and commercialization plans for bempedoic acid.

Our drug development programs and commercialization plans for bempedoic acid will require substantial additional cash to fund expenses. We may develop and initially commercialize bempedoic acid in the United States without a partner. However, in order to pursue the broader statin resistant 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 and we may enter into collaborative arrangements to develop and commercialize bempedoic acid outside of the United States. We will face significant competition in seeking appropriate collaborators and these collaboration agreements are complex and time-consuming to negotiate. We may not be able to negotiate collaborations on acceptable terms, or at all. If that were to occur, we may have to curtail the development or delay commercialization of bempedoic acid 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 on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all.

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

We are not currently party to any collaborative arrangements for the commercialization of bempedoic acid or similar arrangements, although we may pursue such arrangements before any commercialization of bempedoic acid outside of the United States or to further commercialize bempedoic acid in the broader statin resistant market in the United States, if approved. If we are successful in entering into collaborative arrangements for the commercialization of bempedoic acid or similar arrangements and any of our collaborative partners does not devote sufficient time and resources to a 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 any such future collaboration partner were to breach or terminate its arrangements with us, the commercialization of bempedoic acid could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue commercialization of bempedoic acid on our own in such locations.

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 develop, introduce, market and sell new products. In addition, collaborators may decide to enter into arrangements with third parties to commercialize products developed under collaborations using our technologies, which could reduce the milestone and royalty revenue that we may receive, if any. 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;

Table of Contents

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

cannot obtain the necessary marketing approvals.

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

Risks Related to General Business, Employee Matters and Managing Growth

We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

We expect that we will continue to increase our workforce and the scope of our operations. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure; or give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of bempedoic acid. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than anticipated, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize bempedoic acid, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

Our future success depends on our ability to retain members of our senior 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.

Table of Contents

Our company lacks experience commercializing products, which may have a material adverse effect on our business.

We will need to transition from a company with a development focus to a company capable of supporting commercial activities. We may be unsuccessful in making such a transition. Our company has never filed an NDA and has not yet demonstrated an ability to obtain marketing approval for or commercialize a product candidate. Therefore, our clinical development and regulatory approval process may involve more inherent risk, take longer, and cost more than it would if we were a company with a more significant operating history and had experience obtaining marketing approval for and commercializing a product candidate.

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.

In order to satisfy our obligations as a publicly traded company, we may need to hire qualified accounting and financial personnel with appropriate public company experience.

As a relatively new public company, we need to establish and maintain effective disclosure and financial controls and our corporate governance practices that we adopted in connection with our initial public offering. We may need to hire additional accounting and financial personnel with appropriate public company experience and technical accounting knowledge, and it may be difficult to recruit and maintain such personnel. Even if we are able to hire appropriate personnel, our existing operating expenses and operations will be impacted by the direct costs of their employment and the indirect consequences related to the diversion of management resources from product development efforts.

Risks Related to our Financial Position and Capital Requirements

We have not generated any revenue from bempedoic acid and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our lead product candidate, bempedoic acid, and we do not know when, or if, we will generate any revenue. We do not expect to generate significant revenue unless and

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

Table of Contents

until we obtain marketing approval of, and begin to sell, bempedoic acid. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

successfully complete our CLEAR Outcomes CVOT;

successfully complete our global pivotal Phase 3 LDL-C lowering program;

initiate and successfully complete all safety studies required to obtain U.S. and foreign marketing approval for bempedoic acid as a treatment for "statin intolerant" patients for LDL-C lowering or CV risk reduction;

commercialize bempedoic acid, if approved, by developing a sales force or entering into collaborations with third parties; and

achieve market acceptance of bempedoic acid in the medical community and with third-party payors.

Absent our entering into a collaboration or partnership agreement, we expect to incur significant sales and marketing costs as we prepare to commercialize bempedoic acid. Even if we initiate and successfully complete our clinical program of bempedoic acid and achieve all clinical endpoints and bempedoic acid is approved for commercial sale, and despite expending these costs, bempedoic acid may not be a commercially successful drug. We may not achieve profitability soon after generating product sales, if ever. If we are unable to generate product revenue, we will not become profitable and may be unable to continue operations without continued funding.

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

We may seek additional capital through a combination of private and public equity offerings, debt financings, royalty-based financings, collaborations and strategic and licensing arrangements. 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, 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, we may have to relinquish valuable rights to bempedoic acid, our intellectual property, future revenue streams or grant licenses on terms that are not favorable to us.

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

At December 31, 2016, we had United States federal net operating loss carryforwards of approximately \$196.4 million and state net operating loss carryforwards of approximately \$18.1 million. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. In general, an "ownership change" will occur if there is a cumulative change in our ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. As a result of prior equity issuances and other transactions in our stock, we have previously experienced "ownership changes" under section 382 of the Code and comparable state tax laws. 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

Table of Contents

pre-change tax attributes to offset United States federal and state taxable income is subject to limitations.

Complying with public company reporting and other obligations may strain our financial and managerial resources. Additionally, we are obligated to develop and maintain proper and effective internal control over financial reporting, but we may not complete our analysis of our internal control over financial reporting in a timely manner or these internal controls may not be determined to be effective, either of which may harm investor confidence in us and 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 initial and 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.

We are in the costly and challenging process of evaluating and testing our internal controls for the purpose of providing the reports required by these rules. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. 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.

Risks Related to the Securities Markets and Investment in our Common Stock

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

At December 31, 2016, our executive officers, directors and entities affiliated with certain of our directors beneficially owned approximately 32.2% of our outstanding voting common stock. These stockholders have the ability to influence us through their ownership position. These stockholders may be able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

Table of Contents

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.

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to decline.

At December 31, 2016, certain holders of shares of our common stock held approximately 7.3 million shares of our common stock. Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

Market volatility may affect our stock price and the value of your investment.

The market price of our common stock may fluctuate significantly in response to a number of factors, most of which we cannot control, including, among others:

plans for, progress of or results from clinical efficacy or safety studies of bempedoic acid;

guidance from or communications with the FDA regarding our ongoing or planned clinical studies of bempedoic acid;

the failure of or delay by of the FDA to approve bempedoic acid in our desired or expected target indications or at all;

announcements of new products, technologies, commercial relationships, acquisitions or other events by us or our competitors;

the success or failure of other LDL-C lowering therapies;

regulatory or legal developments in the United States and other countries;

failure of bempedoic acid, if approved, to achieve commercial success;

fluctuations in stock market prices and trading volumes of similar companies;

general market conditions and overall fluctuations in U.S. equity markets;

variations in our quarterly operating results;

changes in our financial guidance or securities analysts' estimates of our financial performance;

changes in accounting principles;

our ability to raise additional capital and the terms on which we can raise it;

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;

additions or departures of key personnel;

discussion of us or our stock price by the press and by online investor communities; and

other risks and uncertainties described in these risk factors.

As a result, you may not be able to sell your shares of common stock at or above the price at which you purchase them.

Table of Contents

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

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. For example, as described further in Part I, Item 3 Legal Proceedings, a purported securities class action lawsuit was filed in January 2016 naming us and certain of our officers as defendants. In December 2016, the court granted our motion to dismiss with prejudice and entered judgement in our favor. In January 2017, the plaintiffs in this lawsuit filed a motion to alter or amend the judgement. Additionally, in December 2016, a purported derivative action was filed in Delaware against certain of our directors and officers. 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. This proceeding and any others in which we may become involved could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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

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

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

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

Table of Contents

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. Additionally, our ability to pay dividends on our common stock is limited by restrictions under the terms of our Credit Facility with Oxford Finance LLC.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our corporate headquarters are located in Ann Arbor, Michigan where we lease and occupy approximately 7,900 square feet of office space. We lease and occupy an additional 5,500 square feet of office space in Ann Arbor, Michigan to support our clinical development operations. We believe our current facilities will be sufficient to meet our needs until expiration.

Item 3. Legal Proceedings

On January 12, 2016, a purported stockholder of the Company filed a putative class action lawsuit in the United States District Court for the Eastern District of Michigan, against us and Tim Mayleben, captioned *Kevin L. Dougherty v. Esperion Therapeutics, Inc., et al.* (No. 16-cv-10089). The lawsuit alleges that we and Mr. Mayleben violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 by allegedly failing to disclose in an August 17, 2015, public statement that the FDA would require a cardiovascular outcomes trial before approving our lead product candidate. The lawsuit seeks, among other things, compensatory damages in connection with an allegedly inflated stock price between August 18, 2015, and September 28, 2015, as well as attorneys' fees and costs. On May 20, 2016, an amended complaint was filed in the lawsuit. On July 5, 2016, we filed a motion to dismiss the amended complaint. On December 27, 2016, the court granted our motion to dismiss with prejudice and entered judgment in our favor. On January 24, 2017, the plaintiffs in this lawsuit filed a motion to alter or amend the judgment.

On December 15, 2016, a purported stockholder of the Company filed a derivative lawsuit in the Court of Chancery of the State of Delaware against Tim Mayleben, Roger Newton, Mary McGowan, Nicole Vitullo, Dov Goldstein, Daniel Janney, Antonio Gotto Jr., Mark McGovern, Gilbert Omenn, Scott Braunstein, and Patrick Enright. The Company is named as a nominal defendant. The lawsuit alleges that the defendants breached their fiduciary duties to the Company when they made or approved improper statements on August 17, 2015 regarding our lead product candidate's path to FDA approval, and failed to ensure that reliable systems of internal controls were in place at the Company. The lawsuit seeks, among other things, any damages sustained by the Company as a result of the defendants' alleged breaches of fiduciary duties, including damages related to the above-referenced securities class action, an order directing the Company to take all necessary actions to reform and improve its corporate governance and internal procedures, restitution from the defendants, and attorneys' fees and costs. In light of, among other things, the early stage of the litigation, we are unable to predict the outcome of this matter and are unable to make a meaningful estimate of the amount or range of loss, if any, that could result from an unfavorable outcome.

Table of Contents

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.

Table of Contents**PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities****Market Information**

Our common stock began trading on the NASDAQ Global Market on June 26, 2013, under the symbol "ESPR". Prior to that time there was no public market for our common stock. Shares sold in our initial public offering which closed on July 1, 2013, were priced at \$14.00 per share.

On December 31, 2016, the closing price for our common stock as reported on the NASDAQ Global Market was \$12.52. The following table sets forth the high and low sales prices per share of our common stock as reported on the NASDAQ Global Market for the period indicated:

Year Ended December 31, 2016	High	Low
First Quarter	\$ 22.43	\$ 12.61
Second Quarter	\$ 20.19	\$ 9.58
Third Quarter	\$ 14.85	\$ 9.75
Fourth Quarter	\$ 14.33	\$ 9.40

Year Ended December 31, 2015	High	Low
First Quarter	\$ 118.95	\$ 41.00
Second Quarter	\$ 120.96	\$ 72.05
Third Quarter	\$ 100.98	\$ 18.07
Fourth Quarter	\$ 30.41	\$ 21.14

Stockholders

As of February 1, 2017, there were 12 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 January 1, 2016, to two indices: the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes an initial investment of \$100 on January 1, 2016, in our common stock, the stocks comprising the NASDAQ Composite Index, and the stocks comprising the NASDAQ Biotechnology Index. Historical stockholder return is not necessarily indicative of the performance to be expected for any future periods.

Table of Contents

Comparison of 1 Year Cumulative Total Return*
Among Esperion Therapeutics, Inc., the NASDAQ Composite Index and
the NASDAQ Biotechnology Index

*
\$100 invested on January 1, 2016, in stock or index. Fiscal Year ending December 31.

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. Additionally, our ability to pay dividends on our common stock is limited by restrictions under the terms of our Credit Facility with Oxford Finance LLC.

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.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

Table of Contents

Item 6. Selected Financial Data

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

	Three Months Ended December 31,					Years Ended December 31,				
	2016	2015	2014	2013	2012	2016	2015	2014	2013	2012
(in thousands, except share and per share data)										
Operating expenses:										
Research and development	\$ 24,881	\$ 7,956	\$ 6,200	\$ 7,338	\$ 1,654	\$ 57,868	\$ 29,802	\$ 25,302	\$ 16,014	\$ 7,998
General and administrative	4,404	5,278	3,180	2,398	506	18,282	20,238	10,922	6,745	2,206
Total operating expenses	29,285	13,234	9,380	9,736	2,160	76,150	50,040	36,224	22,759	10,204
Loss from operations	(29,285)	(13,234)	(9,380)	(9,736)	(2,160)	(76,150)	(50,040)	(36,224)	(22,759)	(10,204)
Total other income (expense)	329	112	(77)	46	(615)	1,172	256	(151)	(3,329)	(1,538)
Net loss	\$ (28,956)	\$ (13,122)	\$ (9,457)	\$ (9,690)	\$ (2,775)	\$ (74,978)	\$ (49,784)	\$ (36,375)	\$ (26,088)	\$ (11,742)
Net loss per common share (basic and diluted)	\$ (1.29)	\$ (0.58)	\$ (0.49)	\$ (0.63)	\$ (8.12)	\$ (3.33)	\$ (2.26)	\$ (2.22)	\$ (3.31)	\$ (36.31)
Weighted average shares outstanding (basic and diluted)	22,554,418	22,515,136	19,276,639	15,340,713	341,935	22,544,475	22,019,818	16,374,102	7,885,921	323,382

The table below presents a summary of our balance sheet data as of December 31, 2016, 2015, 2014, 2013 and 2012:

	As of December 31,				
	2016	2015	2014	2013	2012
(in thousands)					
Balance Sheet Data:					
Cash and cash equivalents	\$ 38,165	\$ 77,336	\$ 85,038	\$ 56,537	\$ 6,512
Working capital (deficit)	197,988	208,769	101,208	56,417	(10,035)
Investments	204,324	215,240	56,544	21,062	
Total assets	245,213	295,572	143,276	78,294	7,312
Total long-term debt	1,022	2,688	4,231		7,529
Common stock	23	23	20	15	
Accumulated deficit	(229,200)	(154,222)	(104,438)	(68,063)	(41,975)

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

Total stockholders' equity (deficit)	228,602	287,259	133,554	74,091	(41,365)
--------------------------------------	---------	---------	---------	--------	----------

61

Table of Contents

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

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

Overview

Corporate Overview

We are the lipid management company, a late-stage pharmaceutical company focused on developing and commercializing convenient, complementary, cost-effective, once-daily, oral therapies for the treatment of patients with elevated LDL-C. Through scientific and clinical excellence, and a deep understanding of cholesterol biology, the experienced lipid management team at Esperion is committed to developing new LDL-C lowering therapies that will make a substantial impact on reducing global cardiovascular disease, or CVD; the leading cause of death around the world. With a targeted mechanism of action, bempedoic acid, our lead product candidate, is a first-in-class, orally available, once-daily ACL inhibitor that reduces cholesterol biosynthesis and lowers elevated levels of LDL-C by up-regulating the LDL receptor, but with reduced potential for muscle-related side effects. In addition to bempedoic acid as monotherapy, we are also developing bempedoic acid in a fixed dose combination with ezetimibe, an approved, non statin, oral, LDL-C lowering therapy.

The clinical development program for bempedoic acid consists of two major components: 1) the global pivotal Phase 3 LDL-C lowering program in high CVD risk patients with hypercholesterolemia on optimized background lipid-modifying therapy, including maximally tolerated statins, and patients who are only able to tolerate less than the lowest approved daily starting dose of their statin and are considered "statin intolerant," and 2) the global CVOT known as **C**holesterol **L**owering via **B**empedoic Acid, an **A**CL-inhibiting **R**egimen (CLEAR) Outcomes, in patients with hypercholesterolemia and high CVD risk and who are considered "statin intolerant". We initiated our global Phase 3 clinical development program in January 2016, with the 52-week global pivotal Phase 3 long-term safety study and tolerability (Study 1), and initiated the three remaining global pivotal LDL-C lowering efficacy studies in December 2016. We expect to report top-line results from our global Phase 3 program in its entirety by mid-2018, and intend to use positive results from our Phase 3 program to support our submissions for an LDL-C lowering indication in the U.S. and Europe by the first half of 2019. We also initiated the CLEAR Outcomes CVOT in December 2016, and intend to use positive results from this CVOT to support our submissions for a CV risk reduction indication in the U.S. and Europe by 2022.

We were incorporated in Delaware in January 2008, and commenced our operations in April 2008. Since our inception, we have focused substantially all of our efforts and financial resources on developing bempedoic acid, for which we recently initiated a global long-term safety study in January 2016. 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 the incurrence of indebtedness, and we have incurred losses in each year since our inception. We own the exclusive worldwide rights to bempedoic acid.

We have not commenced principal operations and do not have any products approved for sale. To date, we have not generated any revenue. We have never been profitable and our net losses were \$75.0 million, \$49.8 million, and \$36.4 million for the years ended December 31, 2016, 2015 and 2014,

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

Table of Contents

respectively. Substantially all of our net losses resulted from costs incurred in connection with research and development programs, general and administrative costs associated with our operations. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, including, among others:

completing the clinical development of bempedoic acid;

undertaking the clinical development activities for the fixed dose combination of bempedoic acid and ezetimibe, or BA+EZ;

completing the global pivotal Phase 3 LDL-C lowering program and the CLEAR Outcomes CVOT for bempedoic acid;

seeking regulatory approval for bempedoic acid;

commercializing bempedoic acid; and

operating as a public company.

Accordingly, we will need additional financing to support our continuing operations. We will seek to fund our operations through public or private equity or debt financings or through other sources, which may include collaborations with third parties. 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

With a targeted mechanism of action, bempedoic acid is a first-in-class, orally available, once-daily ACL inhibitor that reduces cholesterol biosynthesis and lowers elevated levels of LDL-C by up-regulating the LDL receptor, but with reduced potential for muscle-related side effects. Bempedoic acid is being developed for patients with hypercholesterolemia. We acquired the rights to bempedoic acid from Pfizer in 2008. We own the exclusive worldwide rights to bempedoic acid and we are not obligated to make any royalty or milestone payments to Pfizer.

During the year ended December 31, 2016, we incurred \$36.2 million in expenses related to the four studies in our global pivotal Phase 3 LDL-C lowering program in high CVD risk patients with hypercholesterolemia on optimized background lipid-modifying therapy, including maximally tolerated statins, and patients who are only able to tolerate less than the lowest approved daily starting dose of their statin and are considered "statin intolerant," our CLEAR Outcomes CVOT in patients with hypercholesterolemia and high CVD risk and who are considered "statin intolerant," our Phase 2 PK/PD (1002-035) study in patients treated with high-dose statin therapy, our Phase 1 PK (1002-037) study and other clinical pharmacology studies.

During the year ended December 31, 2015, we incurred \$12.0 million in expenses related to our Phase 2 clinical study in patients with elevated LDL-C already receiving statin therapy (1002-009), our Phase 2 exploratory clinical safety study in patients with both elevated LDL-C and hypertension (1002-014), our Phase 3 global long-term safety study in patients with hyperlipidemia whose LDL-C is not adequately controlled with low- and moderate-dose statins (1002-040) and other clinical pharmacology studies.

During the year ended December 31, 2014, we incurred \$14.5 million in expenses related to our Phase 2 clinical study in patients with elevated LDL-C with or without "statin intolerance" (1002-008), our Phase 2 clinical study in patients with elevated LDL-C already receiving statin therapy (1002-009),

Table of Contents

our Phase 2 exploratory clinical safety study in patients with both elevated LDL-C and hypertension (1002-014) and other clinical pharmacology studies.

Financial Operations Overview

Revenue

To date, we have not generated any revenue. In the future, we may never generate revenue from the sale of bempedoic acid or other product candidates. If we fail to complete the development of bempedoic acid or any other product candidates and secure approval from regulatory authorities, our ability to generate future revenue and our results of operations and financial position will be adversely affected.

Research and Development Expenses

Since our inception, we have focused our resources on our research and development activities, including conducting nonclinical, preclinical and clinical studies. Our research and development expenses consist primarily of costs incurred in connection with the development of bempedoic acid, 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;

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. 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.

Our research and development expenses are expected to increase in the foreseeable future. Costs associated with bempedoic acid will increase as we further its clinical development, including in connection with the commencement of our global pivotal Phase 3 LDL-C lowering program and our CLEAR Outcomes CVOT. We also expect to incur increased research and development costs as we pursue the clinical development of BA + EZ. We cannot determine with certainty the duration and completion costs associated with the ongoing or future clinical studies of bempedoic acid. Also, we cannot conclude with certainty if, or when, we will generate revenue from the commercialization and sale of bempedoic acid, if ever. We may never succeed in obtaining regulatory approval for bempedoic acid. The duration, costs and timing associated with the development and commercialization of bempedoic acid will depend on a variety of factors, including uncertainties associated with the results of our clinical studies and our ability to obtain regulatory approval. For example, if the FDA or another 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 if we experience significant delays in enrollment in any of our clinical

Table of Contents

studies, 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.

General and Administrative Expenses

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

We anticipate that our general and administrative expenses will increase in the future in connection with the continued research and development and commercialization of bempedoic acid, increases in our headcount, expansion of our information technology infrastructure, and increased expenses associated with being a public company and complying with exchange listing and Securities and Exchange Commission, or SEC, requirements, including the additional complexities and related costs of our transition away from being an "emerging growth company" under the rules of the SEC. These increases will likely include higher legal, compliance, accounting and investor and public relations expenses.

Interest Expense

Interest expense consists primarily of cash interest costs associated with our credit facility and non-cash interest costs associated with the amortization of the related debt discount, deferred issuance costs and final payment fee.

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 accrued expenses and stock-based compensation. 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.

Accrued Clinical Development Costs

As part of the process of preparing our financial statements we are required to estimate our accrued expenses. We base our accrued expenses related to clinical studies on estimates of patient enrollment and related expenses at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical studies on our behalf. We generally accrue expenses related to clinical studies based on contracted amounts applied to the level of patient enrollment and activity according to the protocol. If timelines or contracts are modified based upon changes in the clinical study protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a

Table of Contents

prospective basis. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. We do not anticipate the future settlement of existing accruals to differ materially from our estimates.

Stock-Based Compensation

We typically grant stock-based compensation to new employees in connection with their commencement of employment and to existing employees in connection with annual performance reviews. We account for all stock-based compensation payments issued to employees, consultants and directors using an option-pricing model for estimating fair value. Accordingly, stock-based compensation expense is measured based on the estimated fair value of the awards on the date of grant, net of estimated forfeitures. Compensation expense is recognized for the portion that is ultimately expected to vest over the period during which the recipient renders the required services to us using the straight-line method. In accordance with authoritative guidance, the fair value of non-employee stock-based awards is remeasured as the awards vest, and the resulting value, if any, is recognized as expense during the period the related services are rendered.

Significant Factors, Assumptions and Methodologies Used in Determining Fair Value

We estimate the fair value of our stock-based awards to employees, consultants and directors using the Black-Scholes option-pricing model. The Black-Scholes model requires the input of subjective assumptions, including (a) the per share fair value of our common stock, (b) the expected stock price volatility, (c) the calculation of the expected term of the award, (d) the risk free interest rate and (e) expected dividends. Due to our limited operating history and a lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies, which are publicly traded. When selecting these public companies on which we have based our expected stock price volatility, we selected companies with comparable characteristics to us, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of our stock-based awards. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of our stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. We have estimated the expected life of our employee stock options using the "simplified" method, whereby, the expected life equals the arithmetic average of the vesting term and the original contractual term of the option. The risk-free interest rates for periods within the expected life of the option are based on the U.S. Treasury yield curve in effect during the period the options were granted. We have never paid, and do not expect to pay, dividends in the foreseeable future.

We are also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from our estimates. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from our estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised.

Fair Value Estimate

We are required to estimate the fair value of the common stock underlying our stock-based awards when performing the fair value calculations with the Black-Scholes option-pricing model. All options to purchase shares of our common stock are intended to be granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant.

Table of Contents

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2014-15 which requires management of public companies to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued and, if so, to disclose that fact. Management will be required to make this evaluation for both annual and interim reporting periods, if applicable. Management is also required to evaluate and disclose whether its plans alleviate that doubt. The standard is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. The adoption of this standard did not have a material impact on our financial position, results of operations or related financial statement disclosures.

In February 2016, the FASB issued ASU 2016-02 which is intended to improve financial reporting about leasing transactions. The updated guidance will require a lessee to recognize assets and liabilities for leases with lease terms of more than twelve months. Consistent with current GAAP, the recognition, measurement and presentation of expenses and cash flows arising from a lease by a lessee primarily will depend on its classification as a capital or operating lease. Unlike current GAAP which requires only capital leases to be recognized on the balance sheet the updated guidance will require both types of leases to be recognized on the balance sheet. The standard is effective for public companies for fiscal years beginning after December 15, 2018, and interim periods within those years. Early adoption is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. We do not believe the adoption of this standard will have a material impact on our financial position, results of operations or related financial statement disclosures.

In March 2016, the FASB issued ASU 2016-09 which includes provisions intended to simplify the various aspects related to how share-based payments are accounted for and presented in the financial statements. The updated guidance will include income tax consequences on the income statement and the classification of the tax impact on the statement of cash flows. Additionally, under the updated guidance companies will have to elect whether to account for forfeitures of share-based payments by (1) recognizing forfeitures as they occur or (2) estimating the number of awards expected to be forfeited and adjusting the estimate when it is likely to change, as is currently required. The standard is effective for public business entities for fiscal years beginning after December 15, 2016, and interim periods within those years. Early adoption is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. We do not believe the adoption of this standard will have a material impact on our financial position, results of operations or related financial statement disclosures.

Table of Contents**Results of Operations***Comparison of the Years Ended December 31, 2016 and 2015*

The following table summarizes our results of operations for the years ended December 31, 2016 and 2015:

	Year Ended December 31,		
	2016	2015	Change
	(in thousands)		
Operating Expenses:			
Research and development	\$ 57,868	\$ 29,802	\$ 28,066
General and administrative	18,282	20,238	(1,956)
Loss from operations	(76,150)	(50,040)	(26,110)
Other income (expense):			
Interest expense	(376)	(520)	144
Other income, net	1,548	776	772
Net loss	\$ (74,978)	\$ (49,784)	\$ (25,194)

Research and development expenses

Research and development expenses for the year ended December 31, 2016, were \$57.9 million compared to \$29.8 million for the year ended December 31, 2015, an increase of \$28.1 million. The increase in research and development expenses was primarily related to the further clinical development of bempedoic acid, including costs to support the initiation of the three global pivotal Phase 3 studies and the CVOT, and further increases in our headcount and stock-based compensation expense.

General and administrative expenses

General and administrative expenses for the year ended December 31, 2016, were \$18.3 million compared to \$20.2 million for the year ended December 31, 2015, a decrease of approximately \$1.9 million. The decrease in general and administrative expenses was primarily related to a reduction in pre-commercialization activities, partially offset by increases in costs to support public company operations, increases in our headcount, and other costs to support our growth.

Interest expense

Interest expense for the year ended December 31, 2016, was \$0.4 million compared to \$0.5 million for the year ended December 31, 2015. Interest expense was related to our credit facility with Oxford Finance LLC.

Other income, net

Other income, net for the year ended December 31, 2016, was \$1.5 million compared to \$0.8 million for the year ended December 31, 2015. This increase was primarily related to an increase in interest income earned on our cash, cash equivalents and investment securities.

Table of Contents**Results of Operations***Comparison of the Years Ended December 31, 2015 and 2014*

The following table summarizes our results of operations for the years ended December 31, 2015 and 2014:

	Year Ended December 31,		Change
	2015	2014	
	(in thousands)		
Operating Expenses:			
Research and development	\$ 29,802	\$ 25,302	\$ 4,500
General and administrative	20,238	10,922	9,316
Loss from operations	(50,040)	(36,224)	(13,816)
Other income (expense):			
Interest expense	(520)	(270)	(250)
Other income, net	776	119	657
Net loss	\$ (49,784)	\$ (36,375)	\$ (13,409)

Research and development expenses

Research and development expenses for the year ended December 31, 2015, were \$29.8 million compared to \$25.3 million for the year ended December 31, 2014, an increase of \$4.5 million. Research and development expenses were primarily related to the further clinical development of bempedoic acid, including completing our Phase 2 clinical study in patients with elevated LDL-C already receiving statin therapy (1002-009), our Phase 2 exploratory clinical safety study in patients with elevated LDL-C and hypertension (1002-014) and our Phase 3 global long-term safety study in patients with hyperlipidemia whose LDL-C is not adequately controlled with low- and moderate-dose statins (1002-040).

General and administrative expenses

General and administrative expenses for the year ended December 31, 2015, were \$20.2 million compared to \$10.9 million for the year ended December 31, 2014, an increase of \$9.3 million. The increase in general and administrative expenses was primarily attributable to costs associated with pre-commercialization activities for bempedoic acid, increases in our headcount, which includes increased stock-based compensation expense for awards granted during the period, and other costs to support public company operations and our growth.

Interest expense

Interest expense for the year ended December 31, 2015, was \$0.5 million compared to \$0.3 million for the year ended December 31, 2014. Interest expense was related to our credit facility with Oxford Finance LLC.

Other income, net

Other income, net for the year ended December 31, 2015, was approximately \$0.8 million compared to approximately \$0.1 million for the year ended December 31, 2014. This increase was primarily related to an increase in interest income earned on our cash, cash equivalents and investment securities.

Table of Contents**Liquidity and Capital Resources**

We have funded our operations to date primarily through proceeds from sales of preferred stock, convertible promissory notes and warrants, public offerings of common stock and the incurrence of indebtedness. In June 2014, we entered into a loan and security agreement (the credit facility) with Oxford Finance LLC whereby we received net proceeds of \$4.9 million from the issuance of secured promissory notes under a term loan as part of the facility. In October 2014, we sold 4,887,500 shares of common stock at a price of \$20.00 per share, less underwriting discounts and commissions, for net proceeds of \$91.6 million. In March 2015, we sold 2,012,500 shares of common stock at a price of \$100.00 per share, less underwriting discounts and commissions, for net proceeds of \$190.0 million. To date, we have not generated any revenue and we anticipate that we will continue to incur losses for the foreseeable future.

As of December 31, 2016, our primary sources of liquidity were our cash and cash equivalents and available-for-sale investments, which totaled \$38.2 million and \$204.3 million, respectively. We invest our cash equivalents and investments in highly liquid, interest-bearing investment-grade and government securities to preserve principal.

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

	Year Ended December 31,	
	2016	2015
	(in thousands)	
Cash used in operating activities	\$ (47,730)	\$ (38,156)
Cash provided by (used) in investing activities	10,118	(160,068)
Cash (used in) provided by financing activities	(1,559)	190,522
Net decrease in cash and cash equivalents	\$ (39,171)	\$ (7,702)

Operating Activities

We have incurred, and expect to continue to incur, significant costs in the areas of research and development, regulatory and other clinical study costs, associated with our development of bempedoic acid and our operations.

Net cash used in operating activities totaled \$47.7 million and \$38.2 million for the years ended December 31, 2016 and 2015, respectively. The primary use of our cash was to fund the development of bempedoic acid, adjusted for non-cash expenses such as stock-based compensation expense, depreciation and amortization and changes in working capital.

Investing Activities

Net cash provided by investing activities of \$10.1 million for the year ended December 31, 2016, consisted primarily of proceeds from maturities of highly liquid, interest bearing investment-grade and government securities. Net cash used in investing activities of \$160.1 million for the year ended December 31, 2015, consisted primarily of purchases of highly liquid, interest bearing investment-grade and government securities.

Financing Activities

Net cash used in financing activities of \$1.6 million for the year ended December 31, 2016, related primarily to payments on our credit facility. Net cash provided by financing activities of \$190.5 million

Table of Contents

for the year ended December 31, 2015, related primarily to the proceeds of our underwritten public offering of common stock.

Plan of Operations and Funding Requirements

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future as we progress through the clinical development program for bempedoic acid. We estimate that current cash resources are sufficient to fund operations into early 2019 and through the announcement of top-line results from all global pivotal Phase 3 safety and efficacy studies. We will likely need to raise additional capital to continue to fund the further development and commercialization efforts for bempedoic acid and our operations, including to fund our initial submissions for an LDL-C lowering indication in the U.S. and Europe and to complete the CLEAR Outcomes CVOT. 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 commercialization of bempedoic acid and the extent to which we may enter into collaborations with pharmaceutical partners regarding the development and commercialization of bempedoic acid, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development and commercialization of bempedoic acid. Our future funding requirements will depend on many factors, including, but not limited to:

our ability to successfully develop and commercialize bempedoic acid or other product candidates;

the costs, timing and outcomes of our ongoing and planned clinical studies of bempedoic acid;

the time and cost necessary to obtain regulatory approvals for bempedoic acid, if at all;

our ability to establish a sales, marketing and distribution infrastructure to commercialize bempedoic acid or our ability to establish any future collaboration or commercialization arrangements on favorable terms, if at all;

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 product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. 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, 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, 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. If we are unable to raise additional funds through equity or debt financings or through collaborations, strategic alliances or licensing arrangements or 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 that we would otherwise prefer to develop and market ourselves.

Table of Contents**Contractual Obligations and Commitments**

We were originally party to a single lease that covered both office and laboratory space in Plymouth, Michigan. The Plymouth lease, as amended over time, was scheduled to expire in April 2014. In February 2014, we signed a new lease to move our principal executive offices to Ann Arbor, Michigan, while still maintaining our laboratory space in Plymouth. The Ann Arbor lease has a term of 63 months and provides for fixed monthly rent of approximately \$7,900, with monthly rent increasing every 12 months, and also provides for certain rent adjustments to be paid as determined by the landlord. In May 2014, we amended the Plymouth lease to (i) extend the expiration date from April 2014, to April 2017, (ii) adjust the rentable space to 3,045 square feet, (iii) adjust our proportionate share of the landlord's expenses and taxes to 7.40%, (iv) extend our option to renew for one term of three years through written notice to the landlord by February 2017, and (v) decrease the annual base rent to \$37,000, subject to certain increases and adjustments. In August 2015, we signed a new lease to increase our office space in Ann Arbor, Michigan to support our growing company and clinical development operations. The second Ann Arbor lease has a term of 49 months and provides for fixed monthly rent of approximately \$7,100, with monthly rent increasing every 12 months. In December 2015, we terminated our lease for our laboratory space in Plymouth, Michigan, effective retroactively on October 30, 2015, rather than April 30, 2017, as originally contemplated in the Plymouth lease.

In June 2014, we entered into a Credit Facility which provided for initial borrowings of \$5.0 million and additional borrowings of \$15.0 million until March 2015. We received proceeds of \$4.9 million, net of issuance costs, from the issuance of secured promissory notes under a term loan as part of the Credit Facility and we have not drawn upon any additional borrowings. Under the Credit Facility we are obligated to make monthly, interest-only payments on any term loans funded until July 1, 2015, and, thereafter, to pay 36 consecutive, equal monthly installments of principal and interest from August 1, 2015, through July 1, 2018. The term loan outstanding under the Credit Facility bears interest at an annual rate of 6.40%. In addition, a final payment equal to 8.0% of any amounts drawn under the Credit Facility is due upon the earlier of the maturity date or prepayment of the term loans.

The following table summarizes our future minimum contractual obligations as of December 31, 2016:

	Total	Less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
	(in thousands)				
Operating leases	\$ 520	\$ 191	\$ 329	\$	\$
Debt commitments ⁽¹⁾	3,307	1,836	1,471		
Total	\$ 3,827	\$ 2,027	\$ 1,800	\$	\$

(1) The amounts in the table reflect the contractually required principal and fixed interest payments in accordance with the payment schedule. The projected fixed interest payment obligations are based upon debt outstanding as of the balance sheet date and assume retirement at the scheduled maturity date of the loan.

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

Off-Balance Sheet Arrangements

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

Table of Contents

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We had cash and cash equivalents and available-for-sale investments of approximately \$38.2 million and \$204.3 million, respectively, at December 31, 2016. 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 do not believe that our cash, cash equivalents and available-for-sale investments have significant risk of default or illiquidity. While we believe our cash and cash equivalents do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

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, 2016.

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 principal financial officer, to allow timely decisions regarding required disclosure.

As of December 31, 2016, 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 has concluded based upon the evaluation described above that, as of December 31, 2016, our disclosure controls and procedures were effective at the reasonable assurance level.

Table of Contents

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 and principal financial officer and effected by the company's board of preparation of financial statements for external purposes in accordance with GAAP and directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the 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 and principal financial officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2016, 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, 2016, based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2016, has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included herein.

Changes in Internal Control over Financial Reporting

There were no changes to our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Esperion Therapeutics, Inc.

We have audited Esperion Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). Esperion Therapeutics, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

Table of Contents

Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

In our opinion, Esperion Therapeutics, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Esperion Therapeutics, Inc. as of December 31, 2016 and 2015, and the related statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2016 of Esperion Therapeutics, Inc. and our report dated February 22, 2017, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Detroit, Michigan
February 22, 2017

Item 9B. Other Information

None.

Table of Contents

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 2017 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

Item 11. Executive Compensation

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2017 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 2017 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 2017 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

Item 14. Principal Accounting Fees and Services

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2017 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.

Table of Contents

PART IV

Item 15. Exhibits and Financial Statement Schedules

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

(1) Financial Statements:

<u>Report of Independent Registered Public Accounting Firm</u>	<u>F-2</u>
<u>Balance Sheets</u>	<u>F-3</u>
<u>Statements of Operations and Comprehensive Loss</u>	<u>F-4</u>
<u>Statements of Stockholders' Equity</u>	<u>F-5</u>
<u>Statements of Cash Flows</u>	<u>F-6</u>
<u>Notes to Financial Statements</u>	<u>F-7</u>

(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 immediately following our consolidated financial statements. The Exhibit Index is incorporated herein by reference.

Item 16. Form 10-K Summary

Not applicable

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

Table of Contents

SIGNATURES

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

ESPERION THERAPEUTICS, INC.

Date: February 22, 2017

By: /s/ TIM M. MAYLEBEN

Tim M. Mayleben
President and Chief Executive Officer
(Principal Executive Officer and
Principal Financial 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:

Signature	Title	Date
<u> /s/ TIM M. MAYLEBEN</u> Tim M. Mayleben	President, Chief Executive Officer and Director (Principal Executive Officer and Principal Financial Officer)	February 22, 2017
<u> /s/ RICHARD B. BARTRAM</u> Richard B. Bartram	Vice President, Finance (Principal Accounting Officer)	February 22, 2017
<u> /s/ SCOTT BRAUNSTEIN, M.D.</u> Scott Braunstein, M.D.	Director	February 22, 2017
<u> /s/ DOV A. GOLDSTEIN, M.D.</u> Dov A. Goldstein, M.D.	Director	February 22, 2017
<u> /s/ ANTONIO M. GOTTO, M.D., D. PHIL</u> Antonio M. Gotto, M.D., D. Phil	Director	February 22, 2017
<u> /s/ DANIEL JANNEY</u> Daniel Janney	Director	February 22, 2017

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

Table of Contents

Signature	Title	Date
<hr/> <i>/s/ MARK E. MCGOVERN, M.D.</i> Mark E. McGovern, M.D.	Director	February 22, 2017
<hr/> <i>/s/ ROGER S. NEWTON, PH.D., FAHA, FACN</i> Roger S. Newton, Ph.D., FAHA, FACN	Director	February 22, 2017
<hr/> <i>/s/ GILBERT S. OMENN, M.D., PH.D.</i> Gilbert S. Omenn, M.D., Ph.D.	Director	February 22, 2017
<hr/> <i>/s/ NICOLE VITULLO</i> Nicole Vitullo	Director	February 22, 2017
	79	

Table of Contents

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

Contents

<u>Report of Independent Registered Public Accounting Firm</u>	<u>F-2</u>
Financial Statements	
<u>Balance Sheets</u>	<u>F-3</u>
<u>Statements of Operations and Comprehensive Loss</u>	<u>F-4</u>
<u>Statements of Stockholders' Equity</u>	<u>F-5</u>
<u>Statements of Cash Flows</u>	<u>F-6</u>
<u>Notes to Financial Statements</u>	<u>F-7</u>
	F-1

Table of Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Esperion Therapeutics, Inc.

We have audited the accompanying balance sheets of Esperion Therapeutics, Inc. as of December 31, 2016 and 2015, and the related statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Esperion Therapeutics, Inc. at December 31, 2016 and 2015, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Esperion Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 22, 2017, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Detroit, Michigan
February 22, 2017

Table of Contents**Esperion Therapeutics, Inc.****Balance Sheets**

(in thousands, except share data)

	December 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 38,165	\$ 77,336
Short-term investments	173,418	134,925
Prepaid clinical development costs	560	888
Other prepaid and current assets	1,434	1,245
Total current assets	213,577	214,394
Property and equipment, net	674	807
Intangible assets	56	56
Long-term investments	30,906	80,315
Total assets	\$ 245,213	\$ 295,572
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,595	\$ 707
Current portion of long-term debt	1,709	1,604
Accrued clinical development costs	8,138	2,191
Other accrued liabilities	1,147	1,123
Total current liabilities	15,589	5,625
Long-term debt, net of discount	1,022	2,688
Total liabilities	16,611	8,313
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized and no shares issued or outstanding as of December 31, 2016 and December 31, 2015		
Common stock, \$0.001 par value; 120,000,000 shares authorized as of December 31, 2016 and December 31, 2015; 22,555,413 shares issued and outstanding at December 31, 2016; 22,518,907 shares issued and 22,516,508 outstanding at December 31, 2015		
	23	23
Additional paid-in capital	457,951	441,940
Accumulated other comprehensive loss	(172)	(482)
Accumulated deficit	(229,200)	(154,222)
Total stockholders' equity	228,602	287,259
Total liabilities and stockholders' equity	\$ 245,213	\$ 295,572

See accompanying notes to the financial statements.

F-3

Table of Contents

Esperion Therapeutics, Inc.

Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

	Year Ended December 31,		
	2016	2015	2014
Operating expenses:			
Research and development	\$ 57,868	\$ 29,802	\$ 25,302
General and administrative	18,282	20,238	10,922
Total operating expenses	76,150	50,040	36,224
Loss from operations	(76,150)	(50,040)	(36,224)
Interest expense	(376)	(520)	(270)
Other income, net	1,548	776	119
Net loss	\$ (74,978)	\$ (49,784)	\$ (36,375)
Net loss per common share (basic and diluted)	\$ (3.33)	\$ (2.26)	\$ (2.22)
Weighted-average shares outstanding (basic and diluted)	22,544,475	22,019,818	16,374,102
Other comprehensive loss:			
Unrealized gain (loss) on investments	\$ 310	\$ (423)	\$ (56)
Total comprehensive loss	\$ (74,668)	\$ (50,207)	\$ (36,431)

See accompanying notes to the financial statements.

Table of Contents**Esperion Therapeutics, Inc.****Statements of Stockholders' Equity****(in thousands, except share data)**

	Common Stock		Additional	Deficit	Accumulated	Accumulated	Total
	Shares	Amount	Paid-In	During the	Other	Comprehensive	Stockholders'
			Capital	Development	Loss	Loss	Equity
				Stage			
Balance December 31, 2013	15,357,413	\$ 15	\$ 142,142	\$ (68,063)	\$ (3)		\$ 74,091
Issuance of common stock from public offering, net of issuance costs (\$260)	4,887,500	5	91,620				91,625
Issuance of warrants in connection with issuance of notes			78				78
Early exercise of stock options and vesting of restricted stock			39				39
Exercise of stock options	107,963		473				473
Stock-based compensation			3,679				3,679
Other comprehensive loss						(56)	(56)
Net loss				(36,375)			(36,375)
Balance December 31, 2014	20,352,876	20	238,031	(104,438)	(59)		133,554
Issuance of common stock from public offering, net of issuance costs (\$199)	2,012,500	3	189,980				189,983
Early exercise of stock options and vesting of restricted stock			26				26
Exercise of stock options	128,086		1,177				1,177
Exercise of warrants	25,445						
Stock-based compensation			12,726				12,726
Other comprehensive loss						(423)	(423)
Net loss				(49,784)			(49,784)
Balance December 31, 2015	22,518,907	23	441,940	(154,222)	(482)		287,259
Early exercise of stock options and vesting of restricted stock			9				9
Exercise of stock options	27,757		45				45
Vesting of restricted stock units	8,749						
Stock-based compensation			15,957				15,957
Other comprehensive gain						310	310
Net loss				(74,978)			(74,978)
Balance December 31, 2016	22,555,413	\$ 23	\$ 457,951	\$ (229,200)	\$ (172)		\$ 228,602

See accompanying notes to the financial statements.

Table of Contents**Esperion Therapeutics, Inc.****Statements of Cash Flows****(in thousands)**

	Year Ended December 31,		
	2016	2015	2014
Operating activities			
Net loss	\$ (74,978)	\$ (49,784)	\$ (36,375)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation expense	252	236	160
Amortization of debt discount	21	29	15
Amortization of debt issuance costs	23	32	16
Amortization of premiums and discounts on investments	1,014	647	202
Stock-based compensation expense	15,957	12,726	3,679
Loss related to assets held for sale			29
Loss on sale of assets		47	2
Changes in assets and liabilities:			
Prepays and other assets	139	(1,275)	(264)
Accounts payable	3,888	(1,333)	(299)
Other accrued liabilities	5,954	519	814
Net cash used in operating activities	(47,730)	(38,156)	(32,021)
Investing activities			
Purchases of investments	(197,230)	(280,559)	(48,088)
Proceeds from sales/maturities of investments	207,442	120,792	12,351
Proceeds from sale of assets		24	12
Purchase of property and equipment	(94)	(325)	(873)
Net cash provided by (used in) investing activities	10,118	(160,068)	(36,598)
Financing activities			
Proceeds from issuance of common stock, net of issuance costs		189,983	91,731
Proceeds from exercise of common stock options	45	1,177	473
Proceeds from warrant issuance			78
Proceeds from debt issuance, net of issuance costs			4,838
Payments on long-term debt	(1,604)	(638)	
Net cash (used in) provided by financing activities	(1,559)	190,522	97,120
Net (decrease) increase in cash and cash equivalents	(39,171)	(7,702)	28,501
Cash and cash equivalents at beginning of period	77,336	85,038	56,537
Cash and cash equivalents at end of period	\$ 38,165	\$ 77,336	\$ 85,038

See accompanying notes to the financial statements.

Table of Contents

Esperion Therapeutics, Inc.

Notes to the Financial Statements

1. The Company and Basis of Presentation

The Company is the lipid management company, a late-stage pharmaceutical company focused on developing and commercializing convenient, complementary, cost-effective, once-daily oral therapies for the treatment of patients with elevated LDL-C. Through scientific and clinical excellence, and a deep understanding of cholesterol biology, the experienced lipid management team at Esperion is committed to developing new LDL-C lowering therapies that will make a substantial impact on reducing global cardiovascular disease ("CVD"); the leading cause of death around the world. With a targeted mechanism of action, bempedoic acid, the Company's lead product candidate, is a first-in-class, orally available, once-daily ATP-citrate lyase ("ACL") inhibitor that reduces cholesterol biosynthesis and lowers elevated levels of LDL-C by up-regulating the LDL receptor, but with reduced potential for muscle-related side effects. In addition to bempedoic acid as monotherapy, the Company is also developing bempedoic acid in a fixed dose combination with ezetimibe, an approved, non statin, oral, LDL-C lowering therapy.

The clinical development program for bempedoic acid consists of two major components: 1) the global pivotal Phase 3 LDL-C lowering program in high CVD risk patients with hypercholesterolemia on optimized background lipid-modifying therapy, including maximally tolerated statins, and patients who are only able to tolerate less than the lowest approved daily starting dose of their statin and are considered "statin intolerant," and 2) the global CVOT known as **C**holesterol **L**owering via **B**empedoic Acid, an **A**CL-inhibiting **R**egimen (CLEAR) Outcomes, in patients with hypercholesterolemia and high CVD risk and who are considered "statin intolerant". The Company initiated the global Phase 3 clinical development program in January 2016, with the 52-week global pivotal Phase 3 long-term safety study (Study 1), and initiated the three remaining global pivotal LDL-C lowering efficacy studies in December 2016. The Company expects to report top-line results from the global Phase 3 program in its entirety by mid-2018, and intends to use the Phase 3 program to support the submission for an LDL-C lowering indication in the U.S. and Europe by the first half of 2019. The Company also initiated the CLEAR Outcomes CVOT in December 2016, and intends to use positive results from this CVOT to support the submissions for a CV risk reduction indication in the U.S. and Europe by 2022.

The Company's primary activities since incorporation have been conducting research and development activities, including nonclinical, preclinical and clinical testing, performing business and financial planning, recruiting personnel, and raising capital. Accordingly, the Company has not commenced principal operations and is subject to risks and uncertainties which include the need to research, develop, and clinically test potential therapeutic products; obtain regulatory approvals for its products and commercialize them, if approved; expand its management and scientific staff; and finance its operations with an ultimate goal of achieving profitable operations.

The Company has sustained operating losses since inception and expects such losses to continue over the foreseeable future. Management plans to continue to fund operations through public or private equity or debt financings or through other sources, which may include collaborations with third parties. If adequate funds are not available, the Company may not be able to continue the development of its current or future product candidates, or to commercialize its current or future product candidates, if approved.

Table of Contents

Esperion Therapeutics, Inc.

Notes to the Financial Statements (Continued)

1. The Company and Basis of Presentation (Continued)

Follow On Offerings

On October 21, 2014, the Company completed an underwritten public offering of 4,887,500 shares of common stock, including 637,500 shares sold pursuant to the full exercise of an over-allotment option granted to the underwriters. All the shares were offered by the Company at a price to the public of \$20.00 per share. The aggregate net proceeds received by the Company from the offering were \$91.6 million, net of underwriting discounts and commissions and expenses payable by the Company.

On March 24, 2015, the Company completed an underwritten public offering of 2,012,500 shares of common stock, including 262,500 shares sold pursuant to the full exercise of an over-allotment option granted to the underwriters. All the shares were offered by the Company at a price to the public of \$100.00 per share. The aggregate net proceeds received by the Company from the offering were \$190.0 million, net of underwriting discounts and commissions and expenses payable by the Company.

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, 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.

Investments

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

Concentration of Credit Risk

Cash, cash equivalents, and marketable securities consist of financial instruments that potentially subject the Company to concentrations of credit risk. The Company has established guidelines for investment of its excess cash and believes the guidelines maintain safety and liquidity through diversification of counterparties and maturities.

Table of Contents

Esperion Therapeutics, Inc.

Notes to the Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

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 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, 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, 2016.

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, research-related overhead expenses 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.

Table of Contents

Esperion Therapeutics, Inc.

Notes to the Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

Income Taxes

The Company utilizes the liability method of accounting for income taxes as required by ASC 740, Income Taxes. Under this method, 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 operating losses since inception. Accordingly, it is not more likely than not that the Company will realize deferred tax assets and as such, it has recorded a full valuation allowance.

Warrants

The Company accounts for its warrants issued in connection with its various financing transactions based upon the characteristics and provisions of the instrument. Warrants classified as liabilities are recorded on the Company's balance sheet at their fair value on the date of issuance and are marked-to-market on each subsequent reporting period, with the fair value changes recognized in the statement of operations. Warrants classified as additional-paid-in-capital are recorded on the Company's balance sheet at their fair value on the date of issuance. The warrants are measured using the Black-Scholes option-pricing model subsequent to the pricing of the Company's IPO and a Monte Carlo valuation model for previous periods which are based, in part, upon inputs where there is little or no market data, requiring the Company to develop its own independent assumptions (see Note 4).

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with the provisions of ASC 718, Compensation - Stock Compensation. Accordingly, compensation costs related to equity instruments granted are recognized over the requisite service periods of the awards on a straight-line basis at the grant-date fair value calculated using a Black-Scholes option-pricing model. Additionally, under the provisions of ASC 718, the Company is required to include an estimate of the number of awards that will be forfeited in calculating compensation costs. Any changes to the estimated forfeiture rates are accounted for prospectively. Stock-based compensation arrangements with non-employees are recognized at the grant-date fair value and then re-measured at each reporting period. Expense is recognized during the period the related services are rendered.

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-15 which requires management of public companies to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued and, if so, to disclose that fact. Management will be required to make this evaluation for both annual and interim reporting periods, if applicable. Management is also required to evaluate and disclose whether its plans alleviate that doubt. The standard is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. The adoption of this standard did not have a material impact on the financial position, results of operations or related financial statement disclosures.

In February 2016, the FASB issued ASU 2016-02 which is intended to improve financial reporting about leasing transactions. The updated guidance will require a lessee to recognize assets and liabilities

Table of Contents

Esperion Therapeutics, Inc.

Notes to the Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

for leases with lease terms of more than twelve months. Consistent with current GAAP, the recognition, measurement and presentation of expenses and cash flows arising from a lease by a lessee primarily will depend on its classification as a capital or operating lease. Unlike current GAAP which requires only capital leases to be recognized on the balance sheet the updated guidance will require both types of leases to be recognized on the balance sheet. The standard is effective for public companies for fiscal years beginning after December 15, 2018, and interim periods within those years. Early adoption is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. The Company does not believe the adoption of this standard will have a material impact on its financial position, results of operations or related financial statement disclosures.

In March 2016, the FASB issued ASU 2016-09 which includes provisions intended to simplify the various aspects related to how share-based payments are accounted for and presented in the financial statements. The updated guidance will include income tax consequences on the income statement and the classification of the tax impact on the statement of cash flows. Additionally, under the updated guidance companies will have to elect whether to account for forfeitures of share-based payments by (1) recognizing forfeitures as they occur or (2) estimating the number of awards expected to be forfeited and adjusting the estimate when it is likely to change, as is currently required. The standard is effective for public business entities for fiscal years beginning after December 15, 2016, and interim periods within those years. Early adoption is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. The Company does not believe the adoption of this standard will have a material impact on its financial position, results of operations or related financial statement disclosures.

3. Debt

Credit Facility

In June 2014, the Company entered into a loan and security agreement (the "Credit Facility") with Oxford Finance LLC which provided for initial borrowings of \$5.0 million under the term loan (the "Term A Loan") and additional borrowings of \$15.0 million (the "Term B Loan") at the Company's option, for a maximum of \$20.0 million. On June 30, 2014, the Company received proceeds of \$5.0 million from the issuance of secured promissory notes under the Term A Loan. Upon achieving positive clinical development results in March 2015, the remaining \$15.0 million under the Term B Loan became available to be drawn down, at the Company's sole discretion, until March 31, 2015. The Company did not elect to draw down the Term B Loan as of March 31, 2015. The secured promissory notes issued under the Credit Facility are due on July 1, 2018, and are collateralized by substantially all of the Company's personal property, other than its intellectual property.

The Company is obligated to make monthly, interest-only payments on the Term A Loan until July 1, 2015, and, thereafter, to pay 36 consecutive, equal monthly installments of principal and interest from August 1, 2015, through July 1, 2018. The Term A Loan bears interest at an annual rate of 6.40%. In addition, a final payment equal to 8.0% of the Term A Loan is due upon the earlier of the maturity date or prepayment of the term loan. The Company is recognizing the final payment as interest expense using the effective interest method over the life of the Credit Facility.

There are no financial covenants associated to the Credit Facility. However, so long as the Credit Facility is outstanding, there are negative covenants that limit or restrict the Company's activities, which include limitations on incurring indebtedness, granting liens, mergers or acquisitions, dispositions of

Table of Contents**Esperion Therapeutics, Inc.****Notes to the Financial Statements (Continued)****3. Debt (Continued)**

assets, making certain investments, entering into certain transactions with affiliates, paying dividends or distributions, encumbering or pledging interest in its intellectual property and certain other business transactions. Additionally, the Credit Facility includes events of default, the occurrence and continuation of any of which provides the lenders the right to exercise remedies against the Company and the collateral securing the loans under the Credit Facility, which includes cash. These events of default include, among other things, non-payment of any amounts due under the Credit Facility, insolvency, the occurrence of a material adverse event, inaccuracy of representations and warranties, cross default to material indebtedness and a material judgment against the Company. Upon the occurrence of an event of default, all obligations under the Credit Facility shall accrue interest at a rate equal to the fixed annual rate plus five percentage points.

In connection with the borrowing of the Term A Loan, the Company issued a warrant to purchase 8,230 shares of common stock at an exercise price of \$15.19 (see Note 4). The warrant resulted in a debt discount of \$0.1 million which is amortized into interest expense using the effective interest method over the life of the Term A Loan. In addition, the Company incurred debt issuance costs of \$0.1 million in connection with the borrowing of the Term A Loan. The debt issuance costs were capitalized and included in long-term debt on the condensed balance sheet at the inception of the Term A Loan, and are amortized to interest expense using the effective interest method over the same term. As of December 31, 2016, the remaining unamortized discount and debt issuance costs associated with the debt were less than \$0.1 million and less than \$0.1 million, respectively.

Estimated future principal payments due under the Credit Facility are as follows:

Years Ending December 31,	(in thousands)
2017	\$ 1,709
2018	1,049
Total	\$ 2,758

During the years ended December 31, 2016 and 2015, the Company recognized \$0.4 million and \$0.5 million of interest expense and made cash interest payments of \$0.2 million and \$0.3 million related to the Credit Facility, respectively.

4. Warrants

In connection with the Credit Facility entered into in June 2014, the Company issued a warrant to purchase 8,230 shares of common stock at an exercise price of \$15.19. The warrant will terminate on the earlier of June 30, 2019, and the closing of a merger or consolidation transaction in which the Company is not the surviving entity. The warrant was recorded at fair value of \$0.1 million to additional-paid-in-capital in accordance with ASC 815-10 based upon the allocation of the debt proceeds. The Company estimated the fair value of the warrant 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 of its stock based on public company peer group historical volatility that is in line with the expected remaining life of the warrant. The risk-free interest rate is based on the U.S. Treasury zero-coupon bond for a maturity similar to the

Table of Contents

Esperion Therapeutics, Inc.

Notes to the Financial Statements (Continued)

4. Warrants (Continued)

expected remaining life of the warrant. The expected remaining life of the warrant is assumed to be equivalent to its remaining contractual term.

Upon the closing of the Company's IPO, all warrants exercisable for 1,940,000 shares of Series A preferred stock, at an exercise price of \$1.00 per share (unadjusted for stock splits), were automatically converted into warrants exercisable for 277,690 shares of common stock, at an exercise price of \$6.99 per share. As a result, the Company concluded the warrants outstanding no longer met the criteria to be classified as liabilities and were reclassified to additional paid-in capital at fair value on the date of reclassification. During the year ended December 31, 2015, 29,330 warrants were net exercised for 25,445 shares of the Company's common stock. The remaining 248,360 warrants outstanding as of December 31, 2016, expire in February 2018.

As of December 31, 2016, the Company had warrants outstanding that were exercisable for a total of 256,590 shares of common stock at a weighted-average exercise price of \$7.25 per share.

5. Commitments and Contingencies

In February 2014, the Company entered into an operating lease agreement for its principal executive offices located in Ann Arbor, Michigan commencing in April 2014, with a term of 63 months. The Company's lease provides for fixed monthly rent for the term of the lease, with monthly rent increasing every 12 months subsequent to the first three months of the lease, and also provides for certain rent adjustments to be paid as determined by the landlord.

In May 2014, the Company entered into the third amendment to the operating lease agreement for its laboratory facility in Plymouth, Michigan. The amendment provides in part that (i) the expiration date of the term of the lease is extended from April 2014 to April 2017, (ii) the rentable laboratory space is adjusted to 3,045 square feet, (iii) the Company's proportionate share of the landlord's expenses and taxes is adjusted to 7.40%, (iv) the Company may exercise its option to renew the lease for one term of three years through written notice to the landlord by February 2017, and (v) the annual base rent under the lease is decreased to \$37,000, subject to increases and adjustments provided in the lease. In December 2015, the Company entered into a termination agreement for its laboratory facility. Pursuant to the termination, the Plymouth lease was terminated, effective retroactively on October 30, 2015 (the "Termination Date"), rather than April 30, 2017, as contemplated by the Plymouth lease, with the Company having no further rent obligations to the Landlord pursuant to the Plymouth lease after the Termination Date.

In August 2015, the Company entered into an operating lease agreement to increase its office space and support its clinical development operations located in Ann Arbor, Michigan, commencing September 2015, with a term of 49 months. The Company's lease provides for fixed monthly rent for the term of the lease, with monthly rent increasing every 12 months subsequent to the first month of the lease.

Table of Contents**Esperion Therapeutics, Inc.****Notes to the Financial Statements (Continued)****5. Commitments and Contingencies (Continued)**

The total rent expense for the years ended December 31, 2016, 2015 and 2014, was approximately \$0.2 million, \$0.2 million and \$0.3 million, respectively. The following table summarizes the Company's future minimum lease payments as of December 31, 2016:

	Total	Less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
	(in thousands)				
Operating lease	\$ 520	\$ 191	\$ 329	\$	\$
Total	\$ 520	\$ 191	\$ 329	\$	\$

Legal Proceedings

On January 12, 2016, a purported stockholder of the Company filed a putative class action lawsuit in the United States District Court for the Eastern District of Michigan, against the Company and Tim Mayleben, captioned *Kevin L. Dougherty v. Esperion Therapeutics, Inc., et al.* (No. 16-cv-10089). The lawsuit alleges that the Company and Mr. Mayleben violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 by allegedly failing to disclose in an August 17, 2015, public statement that the FDA would require a cardiovascular outcomes trial before approving our lead product candidate. The lawsuit seeks, among other things, compensatory damages in connection with an allegedly inflated stock price between August 18, 2015, and September 28, 2015, as well as attorneys' fees and costs. On May 20, 2016, an amended complaint was filed in the lawsuit and on July 5, 2016, the Company filed a motion to dismiss the amended complaint. On December 27, 2016, the court granted the Company's motion to dismiss with prejudice and entered judgment in the Company's favor. On January 24, 2017, the plaintiffs in this lawsuit filed a motion to alter or amend the judgment.

On December 15, 2016, a purported stockholder of the Company filed a derivative lawsuit in the Court of Chancery of the State of Delaware against Tim Mayleben, Roger Newton, Mary McGowan, Nicole Vitullo, Dov Goldstein, Daniel Janney, Antonio Gotto Jr., Mark McGovern, Gilbert Omenn, Scott Braunstein, and Patrick Enright. The Company is named as a nominal defendant. The lawsuit alleges that the defendants breached their fiduciary duties to the Company when they made or approved improper statements on August 17, 2015, regarding the Company's lead product candidate's path to FDA approval, and failed to ensure that reliable systems of internal controls were in place at the Company. The lawsuit seeks, among other things, any damages sustained by the Company as a result of the defendants' alleged breaches of fiduciary duties, including damages related to the above-referenced securities class action, an order directing the Company to take all necessary actions to reform and improve its corporate governance and internal procedures, restitution from the defendants, and attorneys' fees and costs. In light of, among other things, the early stage of the litigation, the Company is unable to predict the outcome of this matter and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from an unfavorable outcome.

Table of Contents**Esperion Therapeutics, Inc.****Notes to the Financial Statements (Continued)****6. Property and Equipment**

Property and equipment consist of the following:

	December 31,	
	2016	2015
	(in thousands)	
Lab equipment	\$ 232	\$ 232
Computer equipment	135	130
Software	73	73
Furniture and fixtures	568	568
Leasehold improvements	159	159
Assets in Progress	114	
Subtotal	1,281	1,162
Less accumulated depreciation and amortization	607	355
Property and equipment, net	\$ 674	\$ 807

Depreciation expense was \$0.3 million, \$0.2 million and \$0.2 million for the years ended December 31, 2016, 2015 and 2014, respectively.

7. Other Accrued Liabilities

Other accrued liabilities consist of the following:

	December 31,	
	2016	2015
	(in thousands)	
Accrued compensation	\$ 456	\$ 571
Accrued professional fees	158	140
Accrued franchise and property taxes	40	37
Accrued interest	350	250
Accrued other	143	125
Total other accrued liabilities	\$ 1,147	\$ 1,123

Table of Contents

Esperion Therapeutics, Inc.

Notes to the Financial Statements (Continued)

8. Investments

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

	Amortized Cost	December 31, 2016		Estimated Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
(in thousands)				
Cash equivalents:				
Money market funds	\$ 33,661	\$	\$	\$ 33,661
Short-term investments:				
Certificates of deposit	25,586	1	(20)	25,567
U.S. treasury notes	47,547	2	(30)	47,519
U.S. government agency securities	100,356	13	(37)	100,332
Long-term investments:				
Certificates of deposit	3,432		(15)	3,417
U.S. treasury notes	22,575		(72)	22,503
U.S. government agency securities	5,000		(14)	4,986
Total	\$ 238,157	\$ 16	\$ (188)	\$ 237,985

	Amortized Cost	December 31, 2015		Estimated Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
(in thousands)				
Cash equivalents:				
Money market funds	\$ 31,761	\$	\$	\$ 31,761
Short-term investments:				
Certificates of deposit	19,774		(28)	19,746
U.S. treasury notes	12,620		(14)	12,606
U.S. government agency securities	102,683		(110)	102,573
Long-term investments:				
Certificates of deposit	12,299		(42)	12,257
U.S. treasury notes	22,553		(105)	22,448
U.S. government agency securities	45,793		(183)	45,610
Total	\$ 247,483	\$	\$ (482)	\$ 247,001

At December 31, 2016, remaining contractual maturities of available-for-sale investments classified as current on the balance sheet were less than 12 months, and remaining contractual maturities of available-for-sale investments classified as long-term were less than two years.

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

During the years ended December 31, 2016, 2015 and 2014, other income, net in the statements of operations includes interest income on available-for-sale investments of \$2.6 million, \$1.5 million and \$0.4 million, and expense for the amortization of premiums and discounts on investments of \$1.0 million, \$0.6 million and \$0.2 million, respectively.

F-16

Table of Contents**Esperion Therapeutics, Inc.****Notes to the Financial Statements (Continued)****8. Investments (Continued)**

There were no unrealized gains or losses on investments reclassified from accumulated other comprehensive loss to other income, net in the statements of operations during the year ended December 31, 2016.

9. Fair Value Measurements

The Company follows accounting guidance that emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Fair value is defined as "the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date." Fair value measurements are defined on a three level hierarchy:

Level 1 inputs: Quoted prices for identical assets or liabilities in active markets;

Level 2 inputs: Observable inputs other than Level 1 prices, such as quoted market prices for similar assets or liabilities or other inputs that are observable or can be corroborated by market data; and

Level 3 inputs: Unobservable inputs that are supported by little or no market activity and require the reporting entity to develop assumptions that market participants would use when pricing the asset or liability.

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

Description	Total	Level 1	Level 2	Level 3
	(in thousands)			
December 31, 2016				
Assets:				
Money market funds	\$ 33,661	\$ 33,661	\$	\$
Available-for-sale securities:				
Certificates of deposit	28,984	28,984		
U.S. treasury notes	70,022	70,022		
U.S. government agency securities	105,318		105,318	
Total assets at fair value	\$ 237,985	\$ 132,667	\$ 105,318	\$

Description	Total	Level 1	Level 2	Level 3
	(in thousands)			
December 31, 2015				
Assets:				
Money market funds	\$ 31,761	\$ 31,761	\$	\$
Available-for-sale securities:				
Certificates of deposit	32,003	32,003		
U.S. treasury notes	35,054	35,054		
U.S. government agency securities	148,183		148,183	
Total assets at fair value	\$ 247,001	\$ 98,818	\$ 148,183	\$

Table of Contents

Esperion Therapeutics, Inc.

Notes to the Financial Statements (Continued)

9. Fair Value Measurements (Continued)

There were no transfers between Levels 1, 2 or 3 during the years ended December 31, 2016 or December 31, 2015.

Fair Value Measurements on a Nonrecurring Basis

In addition to items that are measured at fair value on a recurring basis, the Company also measures assets held for sale at the lower of its carrying amount or fair value on a nonrecurring basis. The Company did not recognize impairment expense and other losses relating to assets held for sale during the years ended December 31, 2016, 2015, and 2014. There are no assets held for sale as of December 31, 2016.

10. Stock Compensation

2013 Stock Option and Incentive Plan

In May 2015, the Company's stockholders approved the amended and restated 2013 Stock Option and Incentive Plan (as amended, the "2013 Plan") which, among other things, increased the number of shares of common stock reserved for issuance 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, restricted stock units ("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 and RSUs. The fair value of RSUs is determined by the closing market price of the Company's common stock on the date of grant. The fair value of stock options is calculated using a Black-Scholes option-pricing model. 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, taking into account estimated forfeitures.

2008 Stock Option and Restricted Stock Plan

In April 2008, the Company adopted the 2008 Plan, administered by the Board of Directors or a committee appointed by the Board of Directors. The 2008 Plan provides for the granting of stock options and restricted stock to employees and nonemployees of the Company. Options granted under the 2008 Plan may either be incentive stock options, restricted stock awards or nonqualified stock

Table of Contents**Esperion Therapeutics, Inc.****Notes to the Financial Statements (Continued)****10. Stock Compensation (Continued)**

options. Stock options and restricted stock grants may be granted to employees, directors and consultants.

Stock awards under the 2008 Plan may be granted for up to ten years from the adoption of the 2008 Plan at prices no less than 100 percent of the fair value of the shares on the date of the grant as determined by (i) the closing price of the Company's common stock on any national exchange, (ii) the National Association of Securities Dealers Inc. Automated Quotation System ("NASDAQ"), if so authorized for quotation as a NASDAQ security, or (iii) by reasonable application of a reasonable valuation method. The valuation methods utilized by the Company are consistent with the AICPA Technical Practice Aid.

Under the 2013 Plan and the 2008 Plan the vesting of options granted or restricted awards given will be determined individually with each option grant. Generally, 25 percent of the granted amount will vest upon the first anniversary of the option grant with the remainder vesting ratably on the first day of each calendar quarter for the following three years. Stock options have a 10-year life and expire if not exercised within that period, or if not exercised within 90 days of cessation of providing service to the Company.

The following table summarizes the activity relating to the Company's options to purchase common stock for the year ended December 31, 2016:

	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2015	2,662,862	\$ 32.42	8.36	\$ 16,433
Granted	786,250	\$ 15.31		
Forfeited or expired (vested and unvested)	(165,368)	\$ 32.86		
Exercised	(27,757)	\$ 1.61		
Outstanding at December 31, 2016	3,255,987	\$ 28.53	7.73	\$ 5,214

The following table summarizes information about the Company's stock option plan as of December 31, 2016:

	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Vested and expected to vest at December 31, 2016	3,161,251	\$ 28.46	7.70	\$ 5,171
Exercisable at December 31, 2016	1,692,914	\$ 25.70	6.88	\$ 4,579

The total intrinsic value of stock options exercised during the years ended December 31, 2016, 2015 and 2014, was \$0.4 million, \$7.4 million, and \$1.4 million, respectively.

Table of Contents**Esperion Therapeutics, Inc.****Notes to the Financial Statements (Continued)****10. Stock Compensation (Continued)**

The following table shows the weighted-average assumptions used to compute the stock-based compensation costs for the stock options granted to employees and non-employees during the period from December 31, 2016, to December 31, 2014, using the Black-Scholes option-pricing model:

	Year ended December 31,		
	2016	2015	2014
Risk-free interest rate	1.47%	1.65%	1.81%
Dividend yield			
Weighted-average expected life of options (years)	6.22	6.11	6.32
Volatility	71%	70%	75%

The risk-free interest rate assumption was based on the United States Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. The weighted-average expected life of the options was calculated using the simplified method as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin No. 107 ("SAB No. 107"). This decision was based on the lack of relevant historical data due to the Company's limited historical experience. In addition, due to the Company's limited historical data, the estimated volatility also reflects the application of SAB No. 107, incorporating the historical volatility of comparable companies whose share prices are publicly available.

The weighted-average grant-date fair values of stock options granted during the years ended December 31, 2016, 2015 and 2014, were \$9.78, \$38.44 and \$10.15, respectively. During the years ended December 31, 2016, 2015 and 2014, the Company recognized stock-based compensation expense related to stock options of \$15.6 million, \$12.6 million and \$3.7 million, respectively.

As of December 31, 2016, there was approximately \$27.3 million of unrecognized compensation cost related to unvested options, adjusted for forfeitures, which will be recognized over a weighted-average period of approximately 2.4 years.

The following table summarizes the activity relating to the Company's RSUs for the year ended December 31, 2016:

	Number of RSUs	Weighted-Average Fair Value Per Share
Outstanding and unvested at December 31, 2015	25,000	\$ 57.54
Granted	3,000	\$ 15.97
Forfeited or expired	(3,000)	\$ 15.97
Vested	(8,749)	\$ 57.54
Outstanding and unvested at December 31, 2016	16,251	\$ 57.54

During the years ended December 31, 2016, 2015 and 2014, the Company recognized approximately \$0.4 million, \$0.1 million and \$0, respectively, of stock-based compensation expense recognized related to RSUs. As of December 31, 2016, there was approximately \$0.8 million of

Table of Contents**Esperion Therapeutics, Inc.****Notes to the Financial Statements (Continued)****10. Stock Compensation (Continued)**

unrecognized stock-based compensation expense related to unvested RSUs, adjusted for forfeitures, which will be recognized over a weighted-average period of approximately 2.5 years.

11. 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, 2016, 2015 and 2014, were \$0.2 million, \$0.1 million, and \$0, respectively.

12. Income Taxes

There was no provision for income taxes for the years ended December 31, 2016, 2015 and 2014, because the Company has incurred operating losses since inception. At December 31, 2016, 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, 2016, 2015 and 2014, the Company had deferred tax assets, before valuation allowance, of approximately \$75.3 million, \$50.6 million and \$34.2 million, respectively. Realization of the deferred assets is dependent upon future taxable income, if any, the amount and timing of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance.

As of December 31, 2016, 2015 and 2014, the Company had federal net operating loss ("NOL") carryforwards of approximately \$196.4 million, \$137.4 million and \$95.1 million, respectively. The federal NOL carryforwards will expire at various dates beginning in 2028, if not utilized. As of December 31, 2016, 2015 and 2014, the Company had state NOL carryforwards of approximately \$18.1 million, \$15.4 million and \$16.6 million, respectively. The state NOL carryforwards will expire at various dates beginning in 2022, if not utilized. The Company has \$4.5 million of NOLs related to excess tax benefits generated upon the settlement of stock awards that increased NOL. The Company cannot record the benefit of these losses in the financial statements until the losses are utilized to reduce its income taxes payable at which time it will recognize the tax benefit in equity.

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

	December 31,		
	2016	2015	2014
Federal income tax (benefit) at statutory rate	(34.0)%	(34.0)%	(34.0)%
Change in tax rate	0.1%	0.3%	2.1%
Permanent items	0.9%	1.3%	1.0%
Other	0.2%	0.0%	0.1%
Change in valuation allowance	32.8%	32.4%	30.8%
Effective income tax rate	0.0%	0.0%	0.0%

Table of Contents**Esperion Therapeutics, Inc.****Notes to the Financial Statements (Continued)****12. Income Taxes (Continued)**

If the Company experiences a greater than 50 percentage point aggregate change in ownership of certain significant stockholders over a three-year period, a Section 382 ownership change could be deemed to have occurred. If a section 382 change occurs, the Company's future utilization of the net operating loss carryforwards and credits as of the ownership change will be subject to an annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended, and similar state provisions. Such an annual limitation may result in the expiration of net operating losses before utilization.

The Company's reserves related to taxes are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized following resolution of any potential contingencies present related to the tax benefit. The Company recognized no material adjustment for unrecognized income tax benefits. Through December 31, 2016, the Company had no unrecognized tax benefits or related interest and penalties accrued.

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

	December 31,	
	2016	2015
	(in thousands)	
Deferred tax assets:		
Federal and state operating loss carryforwards	\$ 65,972	\$ 45,848
Equity compensation	9,067	4,387
Temporary differences	226	341
Total deferred tax assets	75,265	50,576
Valuation allowance	(75,265)	(50,576)
Net deferred tax assets	\$	\$

13. Net Loss Per Common Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common stock equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, warrants for common stock, stock options and unvested restricted stock and RSUs 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.

Table of Contents

Esperion Therapeutics, Inc.

Notes to the Financial Statements (Continued)

13. Net Loss Per Common Share (Continued)

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,		
	2016	2015	2014
Warrants for common stock	256,590	256,590	285,920
Common shares under option	3,255,987	2,662,862	1,729,586
Unvested restricted stock and RSUs	16,251	27,399	9,551
Total potential dilutive shares	3,528,828	2,946,851	2,025,057

14. Selected Quarterly Financial Data (Unaudited)

The following table summarizes the unaudited quarterly financial data for the last two years:

	2016			
	March 31	June 30	September 30	December 31
(in thousands, except share and per share data)				
Operating expenses:				
Research and development	\$ 9,791	\$ 9,698	\$ 13,498	\$ 24,881
General and administrative	5,031	4,633	4,214	4,404
Total operating expenses	14,822	14,331	17,712	29,285
Loss from operations:	(14,822)	(14,331)	(17,712)	(29,285)
Interest expense	(110)	(99)	(89)	(78)
Other income, net	347	395	399	407
Net loss	\$ (14,585)	\$ (14,035)	\$ (17,402)	\$ (28,956)
Net loss per common share (basic and diluted)	\$ (0.65)	\$ (0.62)	\$ (0.77)	\$ (1.29)
Weighted-average shares outstanding (basic and diluted)	22,532,031	22,541,455	22,550,438	22,554,418

	2015			
	March 31	June 30	September 30	December 31
(in thousands, except share and per share data)				
Operating expenses:				
Research and development	\$ 7,390	\$ 7,209	\$ 7,247	\$ 7,956
General and administrative	4,035	5,253	5,672	5,278
Total operating expenses	11,425	12,462	12,919	13,234
Loss from operations:	(11,425)	(12,462)	(12,919)	(13,234)

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

Interest expense	(134)	(135)	(130)	(121)
Other income, net	93	202	248	233

Net loss \$ (11,466) \$ (12,395) \$ (12,801) \$ (13,122)

Net loss per common share (basic and diluted) \$ (0.56) \$ (0.55) \$ (0.57) \$ (0.58)

Weighted-average shares outstanding (basic and diluted) 20,589,293 22,465,175 22,494,075 22,515,136

F-23

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

Table of Contents

Exhibit List

Exhibit No.	Exhibit Index
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Amendment No. 2 to the Registration Statement on Form S-1, File No. 333-188595, filed on June 12, 2013)
3.2	Amended and Restated By-laws of the Registrant (incorporated by reference to Exhibit 3.4 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-1, File No. 333-188595, filed on June 7, 2013)
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Amendment No. 2 to the Registration Statement on Form S-1, File No. 333-188595, filed on June 12, 2013)
4.2	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, File No. 333-188595, filed on May 14, 2013)
4.3	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)
4.4	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)
4.5	Warrant dated June 30, 2014 issued to Oxford Finance LLC (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on July 2, 2014)
10.1*	License Agreement between Pfizer Inc. and the Registrant dated April 28, 2008 and amended on November 17, 2010 (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1, File No. 333-188595, filed on May 14, 2013)
10.2	Termination Agreement, dated December 2, 2015, by and between the Registrant and Michigan Land Bank Fast Track Authority (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on December 3, 2015)
10.3	Valley Ranch Business Park Lease by and between the Registrant and McMullen SPE, LLC, dated February 4, 2014 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on February 7, 2014)
10.4	Form of Officer Indemnification Agreement entered into between the Registrant and its officers (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1, File No. 333-188595, filed on May 14, 2013)
10.5	Form of Director Indemnification Agreement entered into between the Registrant and its directors (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1, File No. 333-188595, filed on May 14, 2013)
10.6#	2008 Incentive Stock Option and Restricted Stock Plan and forms of agreements thereunder (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, File No. 333-188595, filed on May 14, 2013)

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

Table of Contents

Exhibit No.	Exhibit Index
10.7#	Amended and Restated 2013 Stock Option and Incentive Plan and forms of agreements thereunder (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q, File No. 001-35986, filed on November 3, 2016).
10.8#	Senior Executive Cash Bonus Plan (incorporated by reference to Exhibit 10.11 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-1, File No. 333-188595, filed on June 7, 2013)
10.9#	Employment Agreement by and between the Registrant and Dr. Roger S. Newton dated December 4, 2012 (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1, File No. 333-188595, filed on May 14, 2013)
10.11	Loan and Security Agreement, dated June 30, 2014, by and between the Registrant and Oxford Finance LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, File No. 001- 35986, filed on July 2, 2014).
10.12#	Employment Agreement, dated May 14, 2015, between the Registrant and Tim M. Mayleben (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, File No. 001- 35986, filed on May 20, 2015).
10.13#	Employment Agreement, dated May 14, 2015, between the Registrant and Narendra D. Lalwani (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, File No. 001- 35986, filed on August 6, 2015).
10.14#	Employment Agreement, effective June 15, 2015, between the Registrant and Mary P. McGowan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on June 15, 2015).
10.14#	Advisor Agreement, dated December 8, 2016, between the Company and Roger Newton, Ph.D. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, File No. 001-35986, filed on December 9, 2016).
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 and 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.INS**	XBRL Instance Document.
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE**	XBRL Taxonomy Extension Presentation Link Document.

(#) Management contract or compensatory plan or arrangement.

(*) Confidential treatment has been granted by the Securities and Exchange Commission as to certain portions.

Edgar Filing: Esperion Therapeutics, Inc. - Form 10-K

Table of Contents

(**) 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.
