

Esperion Therapeutics, Inc.
Form 10-Q
August 04, 2016
[Table of Contents](#)

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended June 30, 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.

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

(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, MI 48108

(Address of principal executive office) (Zip Code)

Registrant's telephone number, including area code:

(734) 887-3903

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 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.

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 Exchange Act). Yes No

As of August 1, 2016, there were 22,550,414 shares of the registrant's Common Stock, \$0.001 par value per share, outstanding.

Table of Contents

Esperion Therapeutics, Inc.

INDEX

	Page
PART I FINANCIAL INFORMATION	
Item 1. Financial Statements	
<u>Condensed Balance Sheets at June 30, 2016 and December 31, 2015</u>	3
<u>Condensed Statements of Operations and Comprehensive Loss for the three and six month periods ended June 30, 2016 and 2015</u>	4
<u>Condensed Statements of Cash Flows for the six month periods ended June 30, 2016 and 2015</u>	5
<u>Notes to Condensed Financial Statements</u>	6
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	21
<u>Item 4. Controls and Procedures</u>	21
<u>PART II OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	22
<u>Item 1A. Risk Factors</u>	22
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	29
<u>Item 6. Exhibits</u>	29
<u>Signatures</u>	30

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

(in thousands, except share data)

	June 30, 2016 (unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 48,768	\$ 77,336
Short-term investments	158,410	134,925
Prepaid clinical development costs	1,121	888
Other prepaid and current assets	789	1,245
Total current assets	209,088	214,394
Property and equipment, net	685	807
Intangible assets	56	56
Long-term investments	67,637	80,315
Total assets	\$ 277,466	\$ 295,572
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	\$ 1,566	\$ 707
Current portion of long-term debt	1,656	1,604
Accrued clinical development costs	2,505	2,191
Other accrued liabilities	1,908	1,123
Total current liabilities	7,635	5,625
Long-term debt, net of discount and issuance costs	1,871	2,688
Total liabilities	9,506	8,313
Stockholders equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized as of June 30, 2016 and December 31, 2015; no shares issued or outstanding at June 30, 2016 and December 31, 2015		
Common stock, \$0.001 par value; 120,000,000 shares authorized as of June 30, 2016 and December 31, 2015; 22,544,778 shares issued and outstanding at June 30, 2016 and 22,518,907 shares issued and 22,516,508 outstanding at December 31, 2015	23	23
Additional paid-in capital	450,661	441,940
Accumulated other comprehensive income (loss)	118	(482)
Accumulated deficit	(182,842)	(154,222)
Total stockholders equity	267,960	287,259
Total liabilities and stockholders equity	\$ 277,466	\$ 295,572

See accompanying notes to the condensed financial statements.

Table of Contents

Esperion Therapeutics, Inc.

Condensed Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	\$ 9,698	\$ 7,209	\$ 19,489	\$ 14,599
General and administrative	4,633	5,253	9,664	9,288
Total operating expenses	14,331	12,462	29,153	23,887
Loss from operations	(14,331)	(12,462)	(29,153)	(23,887)
Interest expense	(99)	(135)	(209)	(269)
Other income, net	395	202	742	295
Net loss	\$ (14,035)	\$ (12,395)	\$ (28,620)	\$ (23,861)
Net loss per common share (basic and diluted)	\$ (0.62)	\$ (0.55)	\$ (1.27)	\$ (1.11)
Weighted-average shares outstanding (basic and diluted)	22,541,455	22,465,175	22,536,438	21,531,509
Other comprehensive loss:				
Unrealized gain (loss) on investments	\$ 103	\$ (21)	\$ 600	\$ (1)
Total comprehensive loss	\$ (13,932)	\$ (12,416)	\$ (28,020)	\$ (23,862)

See accompanying notes to the condensed financial statements.

Table of Contents

Esperion Therapeutics, Inc.

Condensed Statements of Cash Flows

(in thousands)

(unaudited)

	Six Months Ended June 30,	
	2016	2015
Operating activities		
Net loss	\$ (28,620)	\$ (23,861)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	127	115
Amortization of debt discount	12	15
Amortization of debt issuance costs	13	16
Amortization of premiums and discounts on investments	492	178
Stock-based compensation expense	8,677	4,970
Changes in assets and liabilities:		
Prepays and other assets	223	(73)
Accounts payable	859	1,265
Other accrued liabilities	1,107	(502)
Net cash used in operating activities	(17,110)	(17,877)
Investing activities		
Purchases of investments	(112,622)	(168,134)
Proceeds from sales/maturities of investments	101,923	39,995
Proceeds from sale of assets	6	6
Purchase of property and equipment	(5)	(21)
Net cash used in investing activities	(10,704)	(128,154)
Financing activities		
Proceeds from issuance of common stock, net of issuance costs	189,982	189,982
Proceeds from exercise of common stock options	35	798
Payments on long-term debt	(789)	-
Net cash (used in) provided by financing activities	(754)	190,780
Net (decrease) increase in cash and cash equivalents	(28,568)	44,749
Cash and cash equivalents at beginning of period	77,336	85,038
Cash and cash equivalents at end of period	\$ 48,768	\$ 129,787

See accompanying notes to the condensed financial statements.

Table of Contents

Esperion Therapeutics, Inc.

Notes to the Condensed Financial Statements

(unaudited)

1. The Company and Basis of Presentation

The Company is a pharmaceutical company whose planned principal operations are focused on developing and commercializing oral therapies for the treatment of patients with elevated low density lipoprotein cholesterol (LDL-C). Bempedoic acid, the Company's lead product candidate, is a first-in-class 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 June 2016, the Company provided a clinical development and regulatory update for bempedoic acid and the Phase 3 clinical program, known as Cholesterol Lowering via Bempedoic Acid, an ACL-inhibiting Regimen (CLEAR). The CLEAR program has two major components: 1) the global pivotal efficacy and safety studies and 2) the global cardiovascular outcomes trial, known as CLEAR Outcomes, in patients with elevated LDL-C levels who are unable to tolerate statins. In the fourth quarter of 2016, the Company intends to initiate the CLEAR efficacy studies for LDL-C lowering in patients with hypercholesterolemia, including patients who are intolerant to statins, and the CLEAR Outcomes study specifically in patients with hypercholesterolemia who have or are at high risk for cardiovascular disease and who are intolerant to statins. The Company owns the exclusive worldwide rights to bempedoic acid.

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.

Basis of Presentation

The accompanying condensed financial statements are unaudited and were prepared by the Company in accordance with generally accepted accounting principles in the United States of America (GAAP). In the opinion of management, the Company has made all adjustments, which include only normal recurring adjustments necessary for a fair statement of the Company's financial position and results of operations for the interim periods presented. Certain information and disclosures normally included in the annual financial statements prepared in accordance with GAAP have been condensed or omitted. These condensed interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2015, and the notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015. The results of operations for the interim periods are not necessarily indicative of the results to be expected for a full year, any other interim periods or any future year or period.

2. Summary of Significant Accounting Policies

In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (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. 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 require all income tax effects of awards to be recognized in the income statement when the awards vest or are settled. Additionally, under the updated

Table of Contents

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.

There have been no other material changes to the significant accounting policies previously disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

3. Debt

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 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 June 30, 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)	
2016	\$	815
2017		1,709
2018		1,049
Total	\$	3,573

During the three and six months ended June 30, 2016, the Company recognized \$0.1 million and \$0.2 million, respectively, of interest expense, and made cash interest payments of \$0.1 million and \$0.1 million, respectively, related to the Credit Facility. During the three and six months ended June 30, 2015, the Company recognized \$0.1 million and \$0.3 million, respectively, of interest expense and made cash interest payments of \$0.1 million and \$0.2 million, respectively, related to the Credit Facility.

Table of Contents

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 Accounting Standards Codification (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 United States (U.S.) Treasury zero-coupon bond for a maturity similar to the 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 initial public offering in July 2013, 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 six months ended June 30, 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 June 30, 2016, expire in February 2018.

As of June 30, 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

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). An amended complaint was filed on May 20, 2016. The amended complaint 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 Food and Drug Administration would require a cardiovascular outcomes trial before approving the Company s lead product candidate. The lawsuit seeks, among other things, compensatory damages in connection with an allegedly inflated stock price between August 18, 2015, and September 28, 2015, as well as attorneys fees and costs. On July 5, 2016, the Company filed a motion to dismiss the amended complaint. 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.

There have been no other material changes to the Company s contractual obligations and commitments and contingencies outside the ordinary course of business from those previously disclosed in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

Table of Contents**6. Investments**

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

	June 30, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
Cash equivalents:				
Money market funds	\$ 46,286	\$	\$	\$ 46,286
Short-term investments:				
Certificates of deposit	26,108	2	(14)	26,096
U.S. treasury notes	28,514	19		28,533
U.S. government agency securities	103,729	57	(5)	103,781
Long-term investments:				
Certificates of deposit	10,753	7	(12)	10,748
U.S. treasury notes	27,068	52		27,120
U.S. government agency securities	29,757	18	(6)	29,769
Total	\$ 272,215	\$ 155	\$ (37)	\$ 272,333

	December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(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 June 30, 2016, and December 31, 2015, 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.

During the three and six months ended June 30, 2016, other income, net in the statements of operations includes interest income on available-for-sale investments of \$0.6 million and \$1.2 million, respectively, and expense for the amortization of premiums and discounts on

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

investments of \$0.2 million and \$0.5 million, respectively. During the three and six months ended June 30, 2015, other income, net in the statements of operations includes interest income on available-for-sale investments of \$0.4 million and \$0.5 million, respectively, and expense for the amortization of premiums and discounts on investments of \$0.2 million and \$0.2 million, respectively.

There were no unrealized gains or losses on investments reclassified from accumulated other comprehensive income (loss) to other income in the Statements of Operations during the three and six months ended June 30, 2016, and June 30, 2015.

7. 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

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

Table of Contents

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)			
June 30, 2016				
Assets:				
Money market funds	\$ 46,286	\$ 46,286	\$	\$
Available-for-sale securities:				
Certificates of deposit	36,844	36,844		
U.S. treasury notes	55,653	55,653		
U.S. government agency securities	133,550		133,550	
Total assets at fair value	\$ 272,333	\$ 138,783	\$ 133,550	\$
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	\$

There were no transfers between Levels 1, 2 or 3 during the three and six months ended June 30, 2016.

8. 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). The number of shares of common stock available for awards under the 2013 Plan was set 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

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

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, 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 restricted stock units (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.

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

Table of Contents

The following table summarizes the activity relating to the Company's options to purchase common stock for the six months ended June 30, 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	510,250	\$ 16.88		
Forfeited or expired	(65,087)	\$ 31.80		
Exercised	(22,121)	\$ 1.56		
Outstanding at June 30, 2016	3,085,904	\$ 30.08	8.07	\$ 3,503

The following table summarizes information about the Company's stock option plan as of June 30, 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 June 30, 2016	3,026,776	\$ 29.95	8.05	\$ 3,500
Exercisable at June 30, 2016	1,407,434	\$ 22.71	6.92	\$ 3,063

During the three and six months ended June 30, 2016, the Company recognized approximately \$4.0 million and \$8.5 million, respectively, of stock-based compensation related to stock options. During the three and six months ended June 30, 2015, the Company recognized approximately \$2.9 million and \$5.0 million, respectively, of stock-based compensation related to stock options. As of June 30, 2016, there was approximately \$34.5 million of unrecognized stock-based compensation expense related to unvested options, adjusted for forfeitures, which will be recognized over a weighted-average period of approximately 2.7 years.

The following table summarizes the activity relating to the Company's RSUs for the six months ended June 30, 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	(3,750)	\$ 57.54
Outstanding and unvested at June 30, 2016	21,250	\$ 57.54

During the three and six months ended June 30, 2016, the Company recognized approximately \$0.1 million and \$0.2 million, respectively, of stock-based compensation expense recognized related to RSUs. As of June 30, 2016, there was approximately \$1.0 million of unrecognized stock-based compensation expense related to unvested RSUs, adjusted for forfeitures, which will be recognized over a weighted-average period

of approximately 3.0 years.

9. Income Taxes

There was no provision for income taxes for the three and six months ended June 30, 2016 and 2015 because the Company has incurred operating losses since inception. At June 30, 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.

10. 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.

Table of Contents

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.

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:

	June 30, 2016	December 31, 2015
Warrants for common stock	256,590	256,590
Common shares under option	3,085,904	2,662,862
Unvested restricted stock and RSUs	21,250	27,399
Total potential dilutive shares	3,363,744	2,946,851

Table of Contents

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our annual report on Form 10-K for the fiscal year ended December 31, 2015.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). These forward-looking statements are based on our management's belief and assumptions and on information currently available to management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events, including our clinical development plans, or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements, including in relation to the clinical development of bempedoic acid to be materially different from any future results, performance or achievements, including in relation to the clinical development of bempedoic acid, expressed or implied by these forward-looking statements.

Forward-looking statements are often identified by the use of words such as, but not limited to, may, will, should, expects, intends, plans, anticipates, believes, estimates, predicts, potential, continue or the negative of these terms or other similar terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and that could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those referred to or discussed in or incorporated by reference into the section titled Risk Factors included in Item 1A of Part II of this Quarterly Report on Form 10-Q. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance.

The forward-looking statements in this report represent our views as of the date of this quarterly report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

Corporate Overview

We are a pharmaceutical company focused on developing and commercializing oral therapies for the treatment of patients with elevated low density lipoprotein cholesterol, or LDL-C. Bempedoic acid, our lead product candidate, is a first-in-class 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 June 2016, we provided a clinical development and regulatory update for bempedoic acid and our Phase 3 clinical program, known as Cholesterol Lowering via Bempedoic Acid, an ACL-inhibiting Regimen, or CLEAR. Our CLEAR program has two major components: 1) the global pivotal efficacy and safety studies and 2) the global cardiovascular outcomes trial, or CVOT (CLEAR Outcomes), in patients with elevated LDL-C levels who are unable to tolerate statins (statin intolerance). In the fourth quarter of 2016, we intend to initiate the CLEAR efficacy studies for LDL-C lowering in patients with hypercholesterolemia, including patients with statin intolerance, and the CLEAR Outcomes study specifically in patients with hypercholesterolemia who have or are at high risk for cardiovascular disease, or CV disease, and who are intolerant to statins. We own the exclusive worldwide rights to bempedoic acid.

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. 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 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 \$14.0 million and \$12.4 million for the three months ended June 30, 2016 and 2015, respectively, and were \$28.6 and \$23.9 million for the six months ended June 30, 2016 and 2015, 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:

- initiating the CLEAR efficacy studies and the CLEAR Outcomes study for bempedoic acid;
- completing the clinical development of bempedoic acid;

Table of Contents

- undertaking development activities on a fixed dose combination, or FDC, of bempedoic acid and ezetimibe;
- 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

Bempedoic acid, our lead product candidate, is a first-in-class 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 elevated LDL-C. 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 six months ended June 30, 2016, we incurred \$7.4 million in expenses related to our CLEAR Harmony (1002-040) long-term safety and tolerability study of bempedoic acid in patients with hypercholesterolemia whose LDL-C is not adequately controlled with low- and moderate-dose statins, our Phase 2 (1002-035) pharmacokinetics/pharmacodynamics, or PK/PD, clinical study of bempedoic acid in patients treated with atorvastatin 80 mg and our Phase 1 (1002-037) clinical PK study to assess the safety and tolerability of bempedoic acid, as well as the effects of bempedoic acid on the PK of single doses of four high-dose statins.

During the six months ended June 30, 2015, we incurred \$9.2 million in expenses related to our Phase 2b (1002-009) clinical study in patients with elevated LDL-C already receiving statin therapy and our Phase 2 (1002-014) exploratory clinical safety study in patients with both elevated LDL-C and hypertension.

Program Developments

Ongoing Clinical Studies

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

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 FDC formulation tablets in healthy human subjects. The development of the FDC was prompted by the results of a 12-week, Phase 2b (1002-008) study of co-administered 180 mg of bempedoic acid and 10 mg of ezetimibe, which demonstrated an almost 50 percent lowering of LDL-C from baseline; significantly greater reductions in high-sensitivity C-reactive protein, or hsCRP, an important marker of inflammation in coronary disease; and a favorable safety and tolerability profile. 1002-034, which was initiated in July 2016, will help determine the appropriate formulation for the FDC for use in our future clinical studies of patients with elevated levels of LDL-C.

1002-035 Phase 2 pharmacokinetics/pharmacodynamics clinical study in patients treated with high-dose statin therapy

1002-035 is a Phase 2 randomized, double-blind, parallel group study evaluating 180 mg of bempedoic acid in 60 patients on stable atorvastatin 80 mg per day. All patients in the study receive 80 mg of atorvastatin for four weeks. Patients are then randomized to receive either 180 mg of bempedoic acid, or placebo, for four weeks. The study enrolled patients at approximately 20 centers across the United States, or U.S. The primary objectives of the study are to assess the LDL-C lowering efficacy of bempedoic acid 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 include assessing the effect of bempedoic acid on lipid and cardiometabolic biomarkers, including hsCRP; characterizing the tolerability and safety of bempedoic acid; and evaluating the steady-state plasma PK of bempedoic acid. We initiated 1002-035 in January 2016, and expect to report top-line results in September 2016.

Table of Contents

1002-037 Phase 1 clinical pharmacology study to assess the safety and tolerability of bempedoic acid added-on to maximally tolerated statin therapy

1002-037 is a Phase 1, open-label, single-sequence study to assess the effect of steady-state bempedoic acid on the single-dose PK of atorvastatin 80 mg, simvastatin 40 mg, pravastatin 80 mg and rosuvastatin 40 mg in 48 healthy subjects. The study enrolled patients at one center in the U.S. The primary objective of this study is to assess the single-dose PK of the four high-dose statins alone or in combination with bempedoic acid 180 mg. Secondary objectives include characterizing the safety and tolerability of bempedoic acid alone and when used with high-dose statins. We initiated 1002-037 in February 2016, and expect to report top-line results in September 2016.

CLEAR Harmony (1002-040) Phase 3 global long-term safety and tolerability study in patients with hypercholesterolemia whose LDL-C is not adequately controlled with low- and moderate-dose statins

CLEAR Harmony (1002-040) is a global Phase 3 randomized, multicenter, double-blind, placebo-controlled study evaluating 180 mg of bempedoic acid versus placebo in 900 patients with hypercholesterolemia at high CV disease risk and whose LDL-C is not adequately controlled with maximally tolerated lipid-modifying therapy. The study will enroll patients at approximately 125 sites in the U.S., Canada and the European Union. The primary objective is to assess safety and tolerability of patients treated with bempedoic acid for 52 weeks. Secondary objectives include assessing the effects of bempedoic acid on lipid and cardiometabolic risk markers, including LDL-C and hsCRP. We initiated CLEAR Harmony in January 2016, and expect to report top-line results in the fourth quarter of 2017.

Additional Studies

Global Pivotal Phase 3 LDL-C Lowering Program CLEAR Efficacy Studies

We intend to initiate our CLEAR efficacy studies for bempedoic acid in patients with elevated LDL-C levels, including statin intolerant patients, in the fourth quarter of 2016. The CLEAR efficacy studies are anticipated to include approximately 2,000 patients on lipid-modifying therapy with LDL-C levels of ≥ 130 mg/dL for patients without atherosclerotic cardiovascular disease, or ASCVD, and ≥ 100 mg/dL for patients with ASCVD or heterozygous familial hypercholesterolemia. The CLEAR efficacy studies are expected to measure the change in LDL-C from baseline at 12 and 24 weeks. These studies, together with the CLEAR Harmony (1002-040) study, are intended to support our initial submissions for an LDL-C lowering indication in U.S. and Europe by 2019.

Global Cardiovascular Outcomes Trial CLEAR Outcomes

We intend to initiate our CLEAR Outcomes study for bempedoic acid in statin intolerant patients who are at high risk for CV disease in the fourth quarter of 2016. The CLEAR Outcomes study is a randomized, double-blind, placebo-controlled study to assess the effects of bempedoic acid in statin intolerant patients who are at high risk of CV disease. CLEAR Outcomes is expected to enroll approximately 12,600 patients at up to 1,000 sites in approximately 30 countries. Patients enrolled in the study will be required to have a history of, or be at high risk for, CV disease

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

with LDL-C levels between 100 mg/dL and 190 mg/dL despite background lipid-modifying therapy. The trial will be an event-driven study with the primary efficacy endpoint of 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). CLEAR Outcomes is intended to support our submissions for a CV disease risk reduction indication in the U.S. and Europe by 2022.

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:

Table of Contents

- 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 the development of bempedoic acid will increase as we further its clinical development, including in connection with the commencement of our Phase 3 CLEAR clinical program and our CLEAR Outcomes study. 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 Food and Drug Administration, or 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 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 and travel expenses, 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 from an emerging growth company to a large accelerated filer 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 of America. 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.

In February 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2016-02 which is intended to improve financial reporting about leasing transactions. The updated guidance will require a lessee to recognize

Table of Contents

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 require all income tax effects of awards to be recognized in the income statement when the awards vest or are settled. 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.

There have been no other material changes to the significant accounting policies previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

Results of Operations*Comparison of the Three Months Ended June 30, 2016 and 2015*

The following table summarizes our results of operations for the three months ended June 30, 2016 and 2015:

	Three Months Ended June 30,		
	2016	2015	Change
	<i>(unaudited, in thousands)</i>		
Operating Expenses:			
Research and development	\$ 9,698	\$ 7,209	\$ 2,489
General and administrative	4,633	5,253	(620)
Loss from operations	(14,331)	(12,462)	(1,869)
Interest expense	(99)	(135)	36
Other income, net	395	202	193
Net loss	\$ (14,035)	\$ (12,395)	\$ (1,640)

Research and development expenses

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

Research and development expenses for the three months ended June 30, 2016, were \$9.7 million, compared to \$7.2 million for the three months ended June 30, 2015, an increase of \$2.5 million. The increase in research and development expenses was primarily related to the further clinical development of bempedoic acid, which includes increases in our headcount and increased stock-based compensation expense.

General and administrative expenses

General and administrative expenses for the three months ended June 30, 2016, were \$4.6 million, compared to \$5.3 million for the three months ended June 30, 2015, a decrease of approximately \$0.7 million. The decrease in general and administrative expenses was primarily attributable 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

We incurred interest expense of \$0.1 million and \$0.1 million for the three months ended June 30, 2016 and 2015, respectively. Interest expense was related to our credit facility.

Other income, net

Other income, net for the three months ended June 30, 2016, was \$0.4 million, compared to \$0.2 million for the three months ended June 30, 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 Six Months Ended June 30, 2016 and 2015*

The following table summarizes our results of operations for the six months ended June 30, 2016 and 2015:

	Six Months Ended June 30,		
	2016	2015	Change
	(unaudited, in thousands)		
Operating Expenses:			
Research and development	\$ 19,489	\$ 14,599	\$ 4,890
General and administrative	9,664	9,288	376
Loss from operations	(29,153)	(23,887)	(5,266)
Interest expense	(209)	(269)	60
Other income, net	742	295	447
Net loss	\$ (28,620)	\$ (23,861)	\$ (4,759)

Research and development expenses

Research and development expenses for the six months ended June 30, 2016, were \$19.5 million, compared to \$14.6 million for the six months ended June 30, 2015, an increase of \$4.9 million. The increase in research and development expenses was primarily related to the further clinical development of bempedoic acid, which includes increases in our headcount and increased stock-based compensation expense.

General and administrative expenses

General and administrative expenses for the six months ended June 30, 2016, were \$9.7 million, compared to \$9.3 million for the six months ended June 30, 2015, an increase of \$0.4 million. The increase in general and administrative expenses was primarily attributable to costs to support public company operations, increases in our headcount, which includes increased stock-based compensation expense, and other costs to support our growth.

Interest expense

We incurred interest expense of \$0.2 million and \$0.3 million for the six months ended June 30, 2016 and 2015, respectively. Interest expense was related to our credit facility.

Other income, net

Other income, net for the six months ended June 30, 2016, was \$0.7 million, compared to \$0.3 million for the six months ended June 30, 2015. This increase was primarily related to an increase in interest income earned on our cash, cash equivalents and investment securities.

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 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 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 June 30, 2016, our primary sources of liquidity were our cash and cash equivalents and available-for-sale investments, which totaled \$48.8 million and \$226.0 million, respectively. We invest our cash equivalents and investments in highly liquid, interest-bearing investment-grade and government securities to preserve principal.

Table of Contents

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

	Six Months Ended June 30,	
	2016	2015
	(in thousands)	
Cash used in operating activities	\$ (17,110)	\$ (17,877)
Cash used in investing activities	(10,704)	(128,154)
Cash (used in) provided by financing activities	(754)	190,780
Net (decrease) increase in cash and cash equivalents	\$ (28,568)	\$ 44,749

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 the development of bempedoic acid and our operations.

Net cash used in operating activities totaled \$17.1 million and \$17.9 million for the six months ended June 30, 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 used in investing activities of \$10.7 million for the six months ended June 30, 2016, consisted primarily of purchases of highly liquid, interest bearing investment-grade and government securities.

Financing Activities

Net cash used in financing activities of \$0.8 million for the six months ended June 30, 2016, related primarily to payments on our credit facility.

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 expect that our existing cash and cash equivalents and available-for-sale investments will enable us to fund our operating expenses and capital expenditure requirements into early 2019 and the anticipated announcement of top-line results from our CLEAR efficacy and safety studies and that we will likely need to raise additional capital thereafter to continue to fund the further

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

development and commercialization efforts for bempedoic acid and our operations, including our initial submissions for an LDL-C lowering indication in the U.S. and Europe and to complete the CLEAR Outcomes study. In January 2016, we initiated our CLEAR Harmony (1002-040) safety and tolerability study in patients with hypercholesterolemia whose LDL-C is not adequately controlled with low- and moderate-dose statins and our Phase 2 (1002-035) PK/PD clinical study in patients treated with atorvastatin 80 mg. In February 2016, we initiated our Phase 1 (1002-037) clinical PK study to assess the safety and tolerability of bempedoic acid, as well as the effects of bempedoic acid on the PK of single doses of four high-dose statins. In July 2016, we initiated our Phase 1 (1002-034) bioavailability study to assess the relative oral bioavailability of bempedoic acid 180 mg and ezetimibe 10 mg. We plan to initiate our CLEAR clinical efficacy studies and the CLEAR Outcomes study for bempedoic acid in the fourth quarter of 2016. 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 in the U.S. and abroad 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

Table of Contents

- 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, we may have to relinquish valuable rights to our technologies, future revenue streams or bempedoic acid 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 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.

Contractual Obligations and Commitments

There have been no other material changes to our contractual obligations and commitments outside the ordinary course of business from those previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

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 3. Quantitative and Qualitative Disclosures About Market Risk

We had cash and cash equivalents and available-for-sale investments of approximately \$48.8 million and \$226.0 million at June 30, 2016, and \$77.3 million and \$215.2 million at December 31, 2015, respectively. 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 and 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 and 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.

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 six months ended June 30, 2016.

Item 4. 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 June 30, 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 June 30, 2016, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

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

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.

Table of Contents

PART II OTHER INFORMATION

Item 1. 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). An amended complaint was filed on May 20, 2016. The amended complaint 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 July 5, 2016, we filed a motion to dismiss the amended complaint. 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.

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 those set forth in Item 1A in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, and in 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.

We currently have only one product candidate, bempedoic acid, in clinical development, and our business depends almost entirely on its 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 CLEAR 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. Any other product candidates are still in preclinical development stages. 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 may include post-marketing studies and surveillance, including a Risk Evaluation and Mitigation Strategy, or REMS program, which will require the expenditure of substantial resources beyond the proceeds we have raised. Of the large number of drugs in development in the U.S., only a small percentage successfully complete the approval process at the FDA, European Medicines Authority (EMA) or any other foreign regulatory agency, and are commercialized.

Table of Contents

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 New Drug Application (NDA), from the FDA, a Marketing Authorization Application (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 two Phase 2b clinical studies and four Phase 2a clinical studies and expect to complete another Phase 2 clinical study, the CLEAR efficacy and safety studies, and to at least initiate, and potentially complete, the CLEAR Outcomes study.

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 cardiovascular disease reduction in statin intolerant patients on the basis of a completed and successful CLEAR Outcomes study, which would include the results of the CLEAR efficacy 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;
- the FDA, EMA or any other regulatory agency may require the development of a REMS as a condition of approval or post-approval; or
- the FDA, EMA or any other regulatory agency may not approve the manufacturing processes or facilities of third-party manufacturers with which we contract.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market bempedoic acid. 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.

Failures or delays in the completion of our ongoing Phase 1, Phase 2, CLEAR efficacy and safety studies or our CLEAR Outcomes study 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 a Phase 2 (1002-035) clinical study in patients treated with high-dose statin therapy, and CLEAR Harmony (1002-040) safety and tolerability study in patients with hypercholesterolemia whose LDL-C is not adequately

Table of Contents

controlled with low- and moderate-dose statins. In February 2016, we initiated a Phase 1 (1002-037) clinical PK study to assess the safety and tolerability of bempedoic acid added-on to maximally tolerated statin therapy. We do not know whether our ongoing clinical studies will be completed on schedule, if at all. We also plan to initiate additional CLEAR efficacy studies and the CLEAR Outcomes study, and we do not know whether these studies or the CLEAR efficacy studies will begin or 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 study, 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 study, 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;
- 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 Phase 1, Phase 2 and Phase 3 and planned Phase 3 clinical studies 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 Phase 1, Phase 2 and Phase 3 and planned Phase 3 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. Our ongoing Phase 2 (1002-035) clinical study is evaluating the LDL-C lowering efficacy of bempedoic acid as an add-on to patients on stable 80 mg dose of atorvastatin. This is the first clinical study in which we are testing bempedoic acid in patients already being administered a high-dose statin. Our ongoing CLEAR Harmony (1002-040) clinical study is evaluating the safety and tolerability of bempedoic acid in patients with hypercholesterolemia at high CV disease risk and whose LDL-C is not adequately controlled with maximally tolerated lipid-modifying therapy. Our ongoing Phase 1 (1002-037) clinical PK study is evaluating the safety and tolerability of bempedoic acid added-on to four high-dose statins in healthy subjects. Even if we are able to complete our ongoing Phase 1, Phase 2 and Phase 3 and planned Phase 3 clinical studies and CLEAR Outcomes study 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 may not be replicated in our ongoing Phase 1, Phase 2 or Phase 3 or planned Phase 3 clinical studies or CLEAR Outcomes 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

Table of Contents

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 positive results in our ongoing Phase 1, Phase 2 and Phase 3 and planned Phase 3 clinical studies and CVOT 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 2b (1002-008) clinical study in October 2014, our Phase 2b (1002-009) clinical study in March 2015, and our Phase 2a (1002-014) exploratory clinical safety study in July 2015. We held our End-of-Phase 2 meeting with the FDA in August 2015. In January 2016, we commenced our Phase 2 (1002-035) clinical study and our CLEAR Harmony (1002-040) clinical study. In February 2016, we commenced our Phase 1 (1002-037) clinical PK study. We have engaged in active dialogue in the first half of 2016 with the FDA and EMA to discuss our Phase 3 clinical program for bempedoic acid in the statin intolerant patient population, and we plan to initiate Phase 3 clinical efficacy studies and our CLEAR Outcomes study in the fourth quarter of 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 cardiovascular disease reduction indication on the basis of a completed and successful CVOT, which would include the results of the LDL-C lowering efficacy studies, by 2022. However, we expect that these clinical studies will consume substantial additional financial resources, and that our existing cash and cash equivalents only will be sufficient to fund our operations through early 2019 and the anticipated announcement of top-line results from the global pivotal Phase 3 LDL-C lowering and long-term safety clinical studies. We will likely 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 initiating and completing our CLEAR Outcomes study of bempedoic acid;
- the scope, size, rate of progress, results and costs of completing our CLEAR clinical program of bempedoic acid, which currently includes multiple global pivotal Phase 3 clinical efficacy and safety studies;
- 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.

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.

Table of Contents

Changes in regulatory requirements, FDA or EMA guidance or unanticipated events during our Phase 2 or 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 Phase 2 or Phase 3 clinical studies or our CLEAR Outcomes study, 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.

We may not be able to identify and enroll the requisite number of patients in our CLEAR clinical program or CLEAR Outcomes study. Even if we are successful in enrolling patients in these studies, 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 study, 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 study 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 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., or 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.

Table of Contents

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 disease 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 disease 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;
- availability of alternative treatments, including a number of competitive therapies already approved for LDL-C lowering or CV disease 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.

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 American Heart Association 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

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

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.

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:

Table of Contents

- Branded statins and their cheaper generic versions;
- Cholesterol absorption inhibitors, such as Zetia® (ezetimibe), a monotherapy marketed by Merck & Co.;
- 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 Aegerion Pharmaceuticals, Inc.;

- Apo B Anti-Sense therapy, such as KYNAMRO® (mipomersen), marketed by Genzyme Corp. a Sanofi company;
- 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:

- Bococizumab, a separate PCSK9 inhibitor therapy in Phase 3 clinical testing being developed by Pfizer Inc., and five additional PCSK9 inhibitors in earlier phases of development from Lilly, Novartis, 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.

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

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

revenue unless and 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:

- initiate and successfully complete our CLEAR Outcomes study;
- successfully complete our CLEAR clinical program;
- successfully complete our ongoing Phase 2 (1002-035) clinical study;
- 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 cardiovascular disease 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.

Table of Contents

You should carefully review and consider the information regarding certain factors that could materially affect our business, financial condition or future results set forth under Item 1A. (Risk Factors) in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015. Except for the factors disclosed above, there have been no material changes from the factors disclosed in our 2015 Annual Report on Form 10-K.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 6. Exhibits

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ESPERION THERAPEUTICS, INC.

August 4, 2016

By:

/s/ Tim M. Mayleben
Tim M. Mayleben
President and Chief Executive Officer
(Principal Executive Officer and Principal
Financial Officer)

Table of Contents**EXHIBIT INDEX**

Exhibit No.	Description	Form or Schedule	Incorporated by Reference to:		
			Exhibit No.	Filing Date with SEC	SEC File Number
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	S-1/A	3.1	6/12/2013	333-188595
3.2	Amended and Restated By-Laws of the Registrant.	S-1/A	3.2	6/12/2013	333-188595
4.1	Specimen Common Stock Certificate of the Registrant.	S-1/A	4.1	6/12/2013	333-188595
31.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Exchange Act rules 13a-14 or 15d-14.				
32.1+	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Exchange Act rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350.				
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.				

* Filed herewith.

+ The certification furnished in Exhibit 32.1 hereto is deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

