

Esperion Therapeutics, Inc.
Form 10-Q
August 08, 2017
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, 2017

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

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

As of August 1, 2017, there were 22,593,162 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, 2017 and December 31, 2016</u>	3
<u>Condensed Statements of Operations and Comprehensive Loss for the three and six month periods ended June 30, 2017 and 2016</u>	4
<u>Condensed Statements of Cash Flows for the six month periods ended June 30, 2017 and 2016</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>	23
<u>Item 4. Controls and Procedures</u>	24
<u>PART II OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	25
<u>Item 1A. Risk Factors</u>	25
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	30
<u>Item 6. Exhibits</u>	30
<u>Signatures</u>	31

Table of Contents**Esperion Therapeutics, Inc.****Condensed Balance Sheets****(in thousands, except share data)**

	June 30, 2017 (unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 20,373	\$ 38,165
Short-term investments	147,035	173,418
Prepaid clinical development costs	2,554	560
Other prepaid and current assets	986	1,434
Total current assets	170,948	213,577
Property and equipment, net	558	674
Intangible assets	56	56
Long-term investments	13,680	30,906
Total assets	\$ 185,242	\$ 245,213
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	\$ 18,714	\$ 4,595
Current portion of long-term debt	1,764	1,709
Accrued clinical development costs	8,264	8,138
Other accrued liabilities	2,253	1,147
Total current liabilities	30,995	15,589
Long-term debt, net of discount and issuance costs	140	1,022
Total liabilities	31,135	16,611
Commitments and contingencies (Note 5)		
Stockholders equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized and no shares issued or outstanding as of June 30, 2017 and December 31, 2016		
Common stock, \$0.001 par value; 120,000,000 shares authorized as of June 30, 2017 and December 31, 2016; 22,593,162 shares issued and outstanding at June 30, 2017 and 22,555,413 shares issued and outstanding at December 31, 2016		
Additional paid-in capital	23	23
Accumulated other comprehensive loss	467,504	457,951
Accumulated deficit	(239)	(172)
Total stockholders equity	(313,181)	(229,200)
Total liabilities and stockholders equity	154,107	228,602
	\$ 185,242	\$ 245,213

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,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	\$ 38,248	\$ 9,698	\$ 74,108	\$ 19,489
General and administrative	5,412	4,633	10,441	9,664
Total operating expenses	43,660	14,331	84,549	29,153
Loss from operations	(43,660)	(14,331)	(84,549)	(29,153)
Interest expense	(55)	(99)	(122)	(209)
Other income, net	378	395	793	742
Net loss	\$ (43,337)	\$ (14,035)	\$ (83,878)	\$ (28,620)
Net loss per common share (basic and diluted)	\$ (1.92)	\$ (0.62)	\$ (3.72)	\$ (1.27)
Weighted-average shares outstanding (basic and diluted)	22,591,326	22,541,455	22,577,317	22,536,438
Other comprehensive loss:				
Unrealized (loss) gain on investments	\$ (11)	\$ 103	\$ (67)	\$ 600
Total comprehensive loss	\$ (43,348)	\$ (13,932)	\$ (83,945)	\$ (28,020)

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,	
	2017	2016
Operating activities		
Net loss	\$ (83,878)	\$ (28,620)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	134	127
Amortization of debt discount	7	12
Amortization of debt issuance costs	7	13
Amortization of premiums and discounts on investments	251	492
Stock-based compensation expense	9,130	8,677
Changes in assets and liabilities:		
Prepays and other assets	(1,546)	223
Accounts payable	14,119	859
Other accrued liabilities	1,232	1,107
Net cash used in operating activities	(60,544)	(17,110)
Investing activities		
Purchases of investments	(36,769)	(112,622)
Proceeds from sales/maturities of investments	80,059	101,923
Purchase of property and equipment	(19)	(5)
Net cash provided by (used in) investing activities	43,271	(10,704)
Financing activities		
Proceeds from exercise of common stock options	322	35
Payments on long-term debt	(841)	(789)
Net cash used in financing activities	(519)	(754)
Net decrease in cash and cash equivalents	(17,792)	(28,568)
Cash and cash equivalents at beginning of period	38,165	77,336
Cash and cash equivalents at end of period	\$ 20,373	\$ 48,768

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 the lipid management company, a late-stage pharmaceutical company focused on developing and commercializing convenient, complementary, cost-effective, once-daily, oral therapies for the treatment of patients with elevated low density lipoprotein cholesterol (LDL-C). Through scientific and clinical excellence, and a deep understanding of cholesterol biology, the experienced lipid management team at Esperion is committed to developing new LDL-C lowering therapies that will make a substantial impact on reducing global cardiovascular disease (CVD); the leading cause of death around the world. Bempedoic acid and the Company's lead product candidate, the bempedoic acid / ezetimibe combination, are targeted therapies that have been shown to significantly reduce elevated LDL-C levels in patients with hypercholesterolemia, including patients inadequately treated with current lipid-modifying therapies.

The clinical development program for the bempedoic acid / ezetimibe combination will include a single global pivotal Phase 3 bridging study (1002FDC-053) in patients with hypercholesterolemia and with atherosclerotic cardiovascular disease (ASCVD) and/or heterozygous familial hypercholesterolemia (HeFH), including high CVD risk primary prevention patients, whose LDL-C is not adequately controlled. The Company expects to initiate 1002FDC-053 in the fourth quarter of 2017 and to report top-line results by the end of 2018.

The global pivotal Phase 3 clinical development program for bempedoic acid includes four clinical studies in high CVD risk patients with hypercholesterolemia and ASCVD and/or HeFH, or who are high risk primary prevention, on optimized background lipid-modifying therapy and with elevated levels of LDL-C. These patients are on two distinct types of background lipid-modifying therapy: 1) patients on their maximally tolerated statin therapy, and 2) patients only able to tolerate less than the lowest approved daily starting dose, and can be considered statin intolerant. The Company initiated the global pivotal Phase 3 clinical development program in January 2016, and expects to report top-line results for each of the four studies in the second and third quarters of 2018.

The Company intends to use positive results from the Phase 3 bempedoic acid / ezetimibe combination and bempedoic acid programs to support global regulatory submissions for filing tandem LDL-C lowering indications in the U.S. by the first quarter of 2019 and Europe by the first half of 2019.

The Company is also conducting a global cardiovascular outcomes trial (CVOT) known as **Cholesterol Lowering via Bempedoic Acid, an ACL-inhibiting Regimen (CLEAR) Outcomes**, for bempedoic acid in patients with hypercholesterolemia who are at high risk of CVD and who are only able to tolerate less than the lowest approved starting dose of a statin and can be considered statin intolerant. The Company initiated the CLEAR Outcomes CVOT in December 2016, and intends to use positive results from this CVOT to support submissions for a CV risk reduction indication in the U.S. and Europe by 2022.

The Company's primary activities since incorporation have been conducting research and development activities, including nonclinical, preclinical and clinical testing, performing business and financial planning, recruiting personnel, and raising capital. Accordingly, the Company has not commenced commercial 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

Table of Contents

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, 2016, and the notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2016. 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 March 2016, the Financial Accounting Standards Board issued Accounting Standards Update (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 requires 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 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 was previously required. The Company adopted ASU 2016-09 effective January 1, 2017, and made a policy election to account for forfeitures as they occur. The cumulative effect of adoption was an increase of \$0.1 million to both additional paid-in capital and accumulated deficit as of January 1, 2017. The remaining provisions adopted in ASU 2016-09 did not have a material impact to the Company's balance sheets, statements of operations or statements of cash flows.

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, 2016.

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.

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

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 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, 2017, the remaining

Table of Contents

unamortized discount and debt issuance costs associated with the debt were less than \$0.1 million and less than \$0.1 million, respectively.

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

Years Ending December 31,	(in thousands)	
2017	\$	868
2018		1,049
Total	\$	1,917

During the three and six months ended June 30, 2017, the Company recognized less than \$0.1 million and \$0.1 million of interest expense and made cash interest payments of less than \$0.1 million and \$0.1 million related to the Credit Facility, respectively. 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.

4. Warrants

In connection with the Credit Facility entered into in June 2014, the Company issued a warrant to purchase 8,230 shares of common stock at an exercise price of \$15.19. The warrant will terminate on the earlier of June 30, 2019, and the closing of a merger or consolidation transaction in which the Company is not the surviving entity. The warrant was recorded at fair value of \$0.1 million to additional-paid-in-capital in accordance with ASC 815-10 based upon the allocation of the debt proceeds. The Company estimated the fair value of the warrant using a Black-Scholes option-pricing model, which is based, in part, upon subjective assumptions including but not limited to stock price volatility, the expected life of the warrant, the risk-free interest rate and the fair value of the common stock underlying the warrant. The Company estimates the volatility of its stock based on public company peer group historical volatility that is in line with the expected remaining life of the warrant. The risk-free interest rate is based on the U.S. Treasury zero-coupon bond for a maturity similar to the 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, 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. The remaining 248,360 warrants outstanding as of June 30, 2017, expire in February 2018.

As of June 30, 2017, 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

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

On January 12, 2016, a purported stockholder of the Company filed a putative class action lawsuit in the United States District Court for the Eastern District of Michigan, against the Company and Tim Mayleben, captioned *Kevin L. Dougherty v. Esperion Therapeutics, Inc., et al.* (No. 16-cv-10089). The lawsuit alleges that the Company and Mr. Mayleben violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 by allegedly failing to disclose in an August 17, 2015, public statement that the FDA would require a cardiovascular outcomes trial before approving the Company's lead product candidate. The lawsuit seeks, among other things, compensatory damages in connection with an allegedly inflated stock price between August 18, 2015 and September 28, 2015, as well as attorneys' fees and costs. On May 20, 2016, an amended complaint was filed in the lawsuit and on July 5, 2016, the Company filed a motion to dismiss the amended complaint. On December 27, 2016, the court granted the Company's motion to dismiss with prejudice and entered judgment in the Company's favor. On January 24, 2017, the plaintiffs in this lawsuit filed a motion to alter or amend the judgment. In May 2017, the court denied the plaintiff's motion to alter or amend the judgment. On June 19, 2017, the plaintiffs filed a notice of appeal to the Sixth Circuit Court of Appeals. The Company is unable to predict the outcome of this matter and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from an unfavorable outcome.

Table of Contents

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, 2016.

6. Investments

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

(in thousands)				
Cash equivalents:				
Money market funds	\$ 19,488	\$	\$	\$ 19,488
Short-term investments:				
Certificates of deposit	17,345	1	(17)	17,329
U.S. treasury notes	61,640		(102)	61,538
U.S. government agency securities	68,236		(68)	68,168
Long-term investments:				
Certificates of deposit	735		(2)	733
U.S. treasury notes	9,508		(47)	9,461
U.S. government agency securities	3,490		(4)	3,486
Total	\$ 180,442	\$ 1	\$ (240)	\$ 180,203

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

At June 30, 2017, remaining contractual maturities of available-for-sale investments classified as current on the balance sheets 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, 2017, other income, net in the statements of operations includes interest income on available-for-sale investments of \$0.4 million and \$1.0 million, and expense for the amortization of premiums and discounts on investments of approximately \$0.2 million and \$0.3 million, respectively. 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 investments of \$0.2 million and \$0.5 million, respectively.

There were no unrealized gains or losses on investments reclassified from accumulated other comprehensive loss to other income in the statements of operations during the three and six months ended June 30, 2017 and 2016.

Table of Contents**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 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, 2017				
Assets:				
Money market funds	\$ 19,488	\$ 19,488	\$	\$
Available-for-sale securities:				
Certificates of deposit	18,062	18,062		
U.S. treasury notes	70,999	70,999		
U.S. government agency securities	71,654		71,654	
Total assets at fair value	\$ 180,203	\$ 108,549	\$ 71,654	\$
December 31, 2016				
Assets:				
Money market funds	\$ 33,661	\$ 33,661	\$	\$
Available-for-sale securities:				
Certificates of deposit	28,984	28,984		
U.S. treasury notes	70,022	70,022		
U.S. government agency securities	105,318		105,318	
Total assets at fair value	\$ 237,985	\$ 132,667	\$ 105,318	\$

There were no transfers between Levels 1, 2 or 3 during the three and six months ended June 30, 2017.

8. Stock Compensation**2017 Inducement Equity Plan**

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

In May 2017, the Company's board of directors approved the 2017 Inducement Equity Plan (the "2017 Plan"). The number of shares of common stock available for awards under the 2017 Plan was set to 750,000, with any shares of common stock that are forfeited, cancelled, held back upon the exercise or settlement of an award to cover the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of common stock or otherwise terminated (other than by exercise) under the 2017 Plan added back to the shares of common stock available for issuance under the 2017 Plan.

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 available for issuance under

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

Table of Contents

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 2017 Plan provides for the granting of stock options, stock appreciation rights, restricted stock awards, restricted stock units (RSUs), unrestricted stock awards and dividend equivalent rights. The 2013 Plan provides for the granting of stock options, stock appreciation rights, restricted stock awards, RSUs, unrestricted stock awards, cash-based awards, performance share awards and dividend equivalent rights. The Company incurs stock-based compensation expense related to stock options and RSUs. The fair value of RSUs is determined by the closing market price of the Company s common stock on the date of grant. The fair value of stock options is calculated using a Black-Scholes option pricing model. The Company accounts for stock-based compensation in accordance with the provisions of ASC 718, Compensation Stock Compensation. Accordingly, compensation costs related to equity instruments granted are recognized over the requisite service periods of the awards on a straight-line basis at the grant-date fair value. In accordance with the adoption of ASU 2016-09, the Company accounts for forfeitures as they occur.

The following table summarizes the activity relating to the Company s options to purchase common stock for the six months ended June 30, 2017:

	Number of Options	Weighted-Average		Aggregate Intrinsic Value (in thousands)
		Exercise Price Per Share	Remaining Contractual Term (Years)	
Outstanding at December 31, 2016	3,255,987	\$ 28.53	7.73	\$ 5,214
Granted	1,243,900	\$ 22.37		
Forfeited or expired	(96,125)	\$ 25.08		
Exercised	(49,033)	\$ 14.17		
Outstanding at June 30, 2017	4,354,729	\$ 27.01	7.78	\$ 101,745

The following table summarizes information about the Company s stock option plan as of June 30, 2017:

	Number of Options	Weighted-Average		Aggregate Intrinsic Value (in thousands)
		Exercise Price Per Share	Remaining Contractual Term (Years)	
Vested and expected to vest at June 30, 2017	4,354,729	\$ 27.01	7.78	\$ 101,745
Exercisable at June 30, 2017	2,065,245	\$ 26.08	6.49	\$ 52,542

During the three and six months ended June 30, 2017, the Company recognized \$4.8 million and \$8.9 million, respectively, of stock-based compensation expense related to stock options. During the three and six months ended June 30, 2016, the Company recognized

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

approximately \$4.0 million and \$8.5 million, respectively, of stock-based compensation expense related to stock options. As of June 30, 2017, there was \$38.0 million of unrecognized stock-based compensation expense related to unvested options, which will be recognized over a weighted-average period of 2.5 years.

The following table summarizes the activity relating to the Company's RSUs for the six months ended June 30, 2017:

	Number of RSUs	Weighted-Average Fair Value Per Share
Outstanding and unvested at December 31, 2016	16,251	\$ 57.54
Vested	(3,124)	\$ 57.54
Outstanding and unvested at June 30, 2017	13,127	\$ 57.54

During the three and six months ended June 30, 2017, the Company recognized \$0.1 million and \$0.2 million, respectively, of stock-based compensation expense recognized related to RSUs. 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, 2017, there was \$0.7 million of unrecognized stock-based compensation expense related to unvested RSUs, which will be recognized over a weighted-average period of 2.0 years.

Table of Contents**9. Income Taxes**

There was no provision for income taxes for the three and six months ended June 30, 2017 and 2016, because the Company has incurred operating losses since inception. At June 30, 2017, 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. For purposes of this calculation, warrants for common stock, stock options and unvested 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, 2017	December 31, 2016
Warrants for common stock	256,590	256,590
Common shares under option	4,354,729	3,255,987
Unvested RSUs	13,127	16,251
Total potential dilutive shares	4,624,446	3,528,828

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, 2016.

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 the bempedoic acid / ezetimibe combination and bempedoic acid to be materially different from any future results, performance or achievements, including in relation to the clinical development of the bempedoic acid / ezetimibe combination and 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 the Lipid Management Company, a late-stage pharmaceutical company focused on developing and commercializing convenient, complementary, cost-effective, once-daily, oral therapies for the treatment of patients with elevated low density lipoprotein cholesterol, or LDL-C. Through scientific and clinical excellence, and a deep understanding of cholesterol biology, the experienced lipid management team at Esperion is committed to developing new LDL-C lowering therapies that will make a substantial impact on reducing global cardiovascular disease, or CVD; the leading cause of death around the world. Bempedoic acid and our lead product candidate, the bempedoic acid / ezetimibe combination, are targeted therapies that have been shown to significantly reduce elevated LDL-C levels in patients with hypercholesterolemia, including patients inadequately treated with current lipid-modifying therapies.

The clinical development program for the bempedoic acid / ezetimibe combination will include a single global pivotal Phase 3 bridging study (1002FDC-053) in patients with hypercholesterolemia and with atherosclerotic cardiovascular disease, or ASCVD, and/or heterozygous familial hypercholesterolemia, or HeFH, including high CVD risk primary prevention patients, whose LDL-C is not adequately controlled. We expect to initiate 1002FDC-053 in the fourth quarter of 2017 and to report top-line results by the end of 2018.

The global pivotal Phase 3 clinical development program for bempedoic acid includes four clinical studies in high CVD risk patients with hypercholesterolemia and ASCVD and/or HeFH, or who are high risk primary prevention, on optimized background lipid-modifying therapy and with elevated levels of LDL-C. These patients are on two distinct types of background lipid-modifying therapy: 1) patients on their maximally tolerated statin therapy, and 2) patients only able to tolerate less than the lowest approved daily starting dose, and can be considered statin intolerant. We initiated our global

Table of Contents

pivotal Phase 3 clinical development program in January 2016, and expect to report top-line results for each of the four studies in the second and third quarters of 2018.

We intend to use positive results from our Phase 3 bempedoic acid / ezetimibe combination and bempedoic acid programs to support our global regulatory submissions for filing tandem LDL-C lowering indications in the U.S. by the first quarter of 2019 and Europe by the first half of 2019.

We are also conducting a global cardiovascular outcomes trial, or CVOT, known as Cholesterol Lowering via Bempedoic Acid, an ACL-inhibiting Regimen (CLEAR) Outcomes, for bempedoic acid in patients with hypercholesterolemia and high CVD risk and who are only able to tolerate less than the lowest approved starting dose of a statin and can be considered statin intolerant. We initiated the CLEAR Outcomes CVOT in December 2016, and intend to use positive results from this CVOT to support our submissions for a CV risk reduction indication in the U.S. and Europe by 2022.

We were incorporated in Delaware in January 2008, and commenced our operations in April 2008. Since our inception, we have focused substantially all of our efforts and financial resources on developing bempedoic acid. We have funded our operations to date primarily through proceeds from sales of preferred stock, convertible promissory notes and warrants, public offerings of common stock and the incurrence of indebtedness, and we have incurred losses in each year since our inception. We own the exclusive worldwide rights to bempedoic acid.

We 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 \$43.3 million and \$14.0 million for the three months ended June 30, 2017 and 2016, respectively, and were \$83.9 million and \$28.6 million for the six months ended June 30, 2017 and 2016, respectively. Substantially all of our net losses resulted from costs incurred in connection with research and development programs, general and administrative costs associated with our operations. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, including, among others:

- completing the clinical development of bempedoic acid, including the completion of the global pivotal Phase 3 LDL-C lowering program and the CLEAR Outcomes CVOT;
- undertaking and completing the clinical development activities for the bempedoic acid / ezetimibe combination;
- seeking regulatory approval for the bempedoic / ezetimibe combination and bempedoic acid;

- commercializing the bempedoic acid / ezetimibe combination and 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

Through the complementary mechanisms of action of inhibition of cholesterol synthesis (bempedoic acid) and inhibition of cholesterol absorption (ezetimibe), the bempedoic acid / ezetimibe combination pill is our lead, non-statin, orally available, once-daily, LDL-C lowering therapy. Inhibition of ATP-citrate lyase, or ACL, by bempedoic acid reduces cholesterol biosynthesis and lowers LDL-C by up-regulating the LDL receptor. Inhibition of Niemann-Pick C1-Like 1 by ezetimibe results in reduced absorption of cholesterol from the gastrointestinal tract, thereby reducing delivery of cholesterol to the liver, which in turn upregulates LDL receptors. Previously completed Phase 2 data demonstrated that this safe and well tolerated combination results in a 48 percent lowering of LDL-C, a 26 percent reduction in high sensitivity C-reactive protein, or hsCRP, and may potentially be associated with a lower occurrence of muscle-related side effects. The bempedoic acid / ezetimibe combination is being developed for patients at high CVD risk with hypercholesterolemia.

Table of Contents

With a targeted mechanism of action, bempedoic acid is a first-in-class, complementary, orally available, once-daily ACL inhibitor that reduces cholesterol biosynthesis and lowers LDL-C by up-regulating the LDL receptor, and may potentially be associated with a lower occurrence of muscle-related side effects. Previously completed Phase 1 and 2 studies conducted in more than 1,000 patients and over 800 patients treated with bempedoic acid have produced clinically relevant LDL-C lowering results of up to 30 percent as monotherapy. Bempedoic acid is being developed for patients at high CVD risk with hypercholesterolemia. We acquired the rights to bempedoic acid from Pfizer in 2008. We own the exclusive worldwide rights to bempedoic acid and we are not obligated to make any royalty or milestone payments to Pfizer.

During the six months ended June 30, 2017, we incurred \$56.3 million in expenses related to the four studies in our global pivotal Phase 3 LDL-C lowering program, our CLEAR Outcomes CVOT and our Phase 2 (1002-038) clinical study of the bempedoic acid / ezetimibe combination plus statin oral therapy with bempedoic acid 180 mg, ezetimibe 10 mg and atorvastatin 20 mg in patients with hypercholesterolemia.

During the six months ended June 30, 2016, we incurred \$7.4 million in expenses related to the 52-week global pivotal Phase 3 long-term safety and tolerability study (Study 1), our Phase 2 (1002-35) PK/PD clinical study of bempedoic acid in patients treated with atorvastatin 80 mg and our Phase 1 (1002-037) clinical pharmacology 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.

Program Developments

1002-038 Phase 2 efficacy and safety study of the bempedoic acid / ezetimibe combination plus atorvastatin in patients with hypercholesterolemia

On August 8, 2017, we announced top-line results from the Phase 2 clinical study (1002-038), also known as the triplet oral therapy study. The six-week, Phase 2, randomized, double-blind, placebo-controlled study evaluated the efficacy and safety of bempedoic acid 180 mg, ezetimibe 10 mg and atorvastatin 20 mg (the bempedoic acid / ezetimibe combination plus atorvastatin, or Combo + Statin), versus placebo, in patients with hypercholesterolemia. The primary objective of the study is to assess the LDL-C lowering efficacy of the bempedoic acid / ezetimibe combination plus atorvastatin versus placebo. Secondary objectives include assessing the percent of treated patients achieving a reduction in LDL-C levels of $\geq 50\%$, the percent of treated patients reaching LDL-C levels of < 70 mg/d, assessment of the effect of the bempedoic acid / ezetimibe combination plus atorvastatin therapy on additional lipid and cardiometabolic risk markers, including total cholesterol, apolipoprotein B, or apoB, non-high-density lipoprotein-cholesterol, or non-HDL-C, and hsCRP, and assessment of the safety and tolerability of the bempedoic acid / ezetimibe combination plus atorvastatin therapy, including muscle-related adverse events, or AEs. Prior to randomization, patients were washed out of all lipid-lowering therapies for six weeks. 43 patients received the bempedoic acid / ezetimibe combination plus atorvastatin and 20 patients received placebo. While analyses of the complete efficacy and safety results from 100-038 are ongoing, the top-line results are summarized as follows:

LDL-Cholesterol Percent Change from Baseline to Week 6 Endpoint

Number of

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

Treatment Group	Patients	LDL-C	LDL-C	Percent Change from Baseline	P Value
		Baseline Mean (SD)	Week 6 Endpoint Mean (SD)		
		mg/dL	mg/dL	LS Mean (SE)	
Combo + Statin	41	154 (18)	56 (17)	64% (1.7)	<0.001
Placebo	20	156 (14)	152 (27)	3% (3.34)	

LS = least squares; SD = standard deviation; SE = standard error; mITT population

hsCRP Nonparametric Analysis

Treatment Group	Number of Patients	Baseline Level (mg/L)	Percent Change from Baseline	
			Median Change	P Value
Combo + Statin	41	1.94	48%	<0.001
Placebo	19	1.64	3%	

mITT population

Table of Contents

- After six weeks of treatment with the bempedoic acid / ezetimibe combination plus atorvastatin, the primary endpoint of the study, LDL-C levels were lowered by 64% ($p < 0.001$), with an average reduction of 3% for patients dosed with placebo. The maximal effect on LDL-C lowering was seen at 3 weeks into the study.
- 95% of patients treated with the bempedoic acid / ezetimibe combination plus atorvastatin achieved an LDL-C reduction of $\geq 50\%$. 90% of the treated patients with the bempedoic acid / ezetimibe combination plus atorvastatin achieved an LDL-C level of < 70 mg/dL.
- hsCRP, a marker of the underlying inflammation associated with CVD, was reduced by 48% ($p < 0.001 = 0.26$) for patients dosed with the bempedoic acid / ezetimibe combination plus atorvastatin after six weeks of therapy, versus a 3% reduction with placebo.
- Clinically significant reductions in total cholesterol, apoB and non-HDL-C were seen in the patients treated with the bempedoic acid / ezetimibe combination plus atorvastatin.
- Discontinuation rates for the bempedoic acid / ezetimibe combination plus atorvastatin were low and comparable to placebo. There were no increases (repeated and confirmed) in liver function tests or levels of creatine kinase, or CK, an enzyme associated with muscle damage. Elevations in liver function tests and CK have been observed with use of statins.

Recent Regulatory Pathway Announcements

On June 26, 2017, we announced that the U.S. Food and Drug Administration, or FDA, recently confirmed the regulatory pathway to approval for the once-daily, oral combination pill of bempedoic acid 180 mg and ezetimibe 10 mg. Based on feedback from the FDA, we plan to initiate a single global pivotal Phase 3 bridging study (1002FDC-053) for the bempedoic acid / ezetimibe combination pill that will be conducted concurrently with the ongoing global pivotal Phase 3 program for bempedoic acid. The randomized, double-blind, placebo-controlled study is expected to enroll up to 350 patients with hypercholesterolemia and with ASCVD and/or HeFH, including high CVD risk primary prevention patients, whose LDL-C is not adequately controlled. The goal of this study is to evaluate the efficacy and safety of the bempedoic acid / ezetimibe combination, a convenient, cost-effective, once-daily, oral pill. We expect to initiate 1002FDC-053 in the fourth quarter of 2017 and to report top-line results by the end of 2018, and intend to use positive results from this study to support our New Drug Application, or NDA, submission for the bempedoic acid / ezetimibe combination through the abbreviated 505(b)(2) pathway by the first quarter of 2019, and our Marketing Authorization Application, or MAA, submission for an LDL-C lowering indication by the first half of 2019.

On March 20, 2017, we announced that the FDA recently confirmed that our LDL-C lowering program is adequate to support approval of bempedoic acid for an LDL-C lowering indication. Based on the successful completion of the global pivotal Phase 3 LDL-C lowering program we plan to submit our NDA for an LDL-C lowering indication by the first quarter of 2019 and our MAA for an LDL-C lowering indication by

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

the first half of 2019. The proposed product label would include specific language for use of bempedoic acid as an adjunct to maximally tolerated statin therapy in patients with hypercholesterolemia, specifically those at high CVD risk with ASCVD and/or HeFH, who require additional LDL-C lowering.

In addition, our interactions with the FDA also addressed the ongoing CLEAR Outcomes CVOT for bempedoic acid in patients with hypercholesterolemia who are at high risk of CVD and who are only able to tolerate less than the lowest approved starting dose of a statin and can be considered statin intolerant. For purposes of the CVOT, we reached an agreement with the FDA that the following definition of statin intolerance is acceptable: the inability to tolerate two or more statins, one at the lowest approved daily starting dose, due to an adverse effect, as defined in CLEAR Outcomes. The lowest approved daily starting statin doses include an average daily dose of <5 mg rosuvastatin, <10 mg of atorvastatin, <10 mg simvastatin, <20 mg lovastatin, <40 mg pravastatin, <40 mg fluvastatin and <2 mg of pitavastatin. Additionally, patients and investigators will provide written confirmation that the patient is statin intolerant and that the patient is aware of the benefits of statins in reducing the risk of cardiovascular events and death.

Table of Contents

Ongoing Clinical Studies

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

Study 1 is a 52-week global pivotal Phase 3 randomized, double-blind, placebo-controlled study evaluating the long-term safety and tolerability of bempedoic acid 180 mg versus placebo in high CVD risk patients with hypercholesterolemia and with ASCVD and/or HeFH whose LDL-C is not adequately controlled with current lipid-modifying therapies, and who are taking maximally tolerated statin therapy. The study enrolled 2,230 patients at approximately 100 sites in the U.S., Canada and Europe. The primary objective is to assess safety and tolerability of patients treated with bempedoic acid for 52 weeks. Secondary objectives include assessing the LDL-C lowering efficacy of bempedoic acid on top of maximally tolerated statin and other lipid-modifying therapies at 12, 24 and 52 weeks versus placebo. Effects on other risk markers, including non-high-density lipoprotein, or non-HDL-C, total cholesterol, apolipoprotein B, or apoB, and hsCRP, will also be evaluated. We initiated Study 1 in January 2016, and completed patient enrollment ahead of schedule in January 2017. We expect to report top-line results by the second quarter of 2018.

Additional safety data will be obtained from an open-label extension study which will enroll approximately 1,400 patients of the 2,230 patients enrolled in Study 1. Initiated in February 2017, this open-label extension study will evaluate the long-term safety of bempedoic acid 180 mg versus placebo in high CVD risk patients with hypercholesterolemia and with ASCVD and/or HeFH whose LDL-C is not adequately controlled with current lipid-modifying therapies, and who are taking maximally tolerated statin therapy. This open-label extension study will be conducted at approximately 100 sites included in the parent study in the U.S., Canada and Europe. The primary objective is to assess the long-term safety in patients treated with bempedoic acid for up to 1.5 years. Secondary objectives include evaluating the 52- and 78-week effects of bempedoic acid on lipid and cardiometabolic risk markers, including LDL-C, non-HDL-C, total cholesterol, apoB and hsCRP.

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

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

Study 3 Global pivotal Phase 3 LDL-C lowering efficacy and safety study in patients with hypercholesterolemia not adequately controlled with current lipid-modifying therapy, including patients considered statin intolerant

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

Study 3 is a 24-week global pivotal Phase 3 randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of bempedoic acid 180 mg versus placebo. This study is expected to enroll approximately 300 high CVD risk patients with ASCVD and/or HeFH, or who are high risk primary prevention, whose LDL-C is not adequately controlled with current lipid-modifying therapies, and who are only able to tolerate less than the lowest approved daily starting dose of a statin and can be considered statin intolerant. The study will be conducted at approximately 70 sites in the U.S. and Canada. The primary objective is to assess the 12-week LDL-C lowering efficacy of patients treated with bempedoic acid versus placebo. Secondary objectives include evaluating the 24-week LDL-C lowering efficacy, safety and tolerability of bempedoic acid versus placebo and effects on other risk markers, including non-HDL-C, total cholesterol, apoB and hsCRP. We initiated Study 3 in December 2016, and expect to report top-line results by the second quarter of 2018.

Study 4 Global pivotal Phase 3 LDL-C lowering efficacy and safety study in patients with hypercholesterolemia not adequately controlled with current lipid-modifying therapy, including ezetimibe, and patients considered statin intolerant

Study 4 is a 12-week global pivotal Phase 3 randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of bempedoic acid 180 mg versus placebo as an add-on to ezetimibe 10 mg. This study is expected to enroll approximately 225 high CVD risk patients with ASCVD and/or HeFH, whose LDL-C is not adequately controlled with current lipid-modifying therapies, including ezetimibe, and who are only able to tolerate the lowest approved daily starting

Table of Contents

dose of a statin and can be considered statin intolerant. The study will be conducted at approximately 75 sites in the U.S., Canada and Europe. The primary objective is to assess the 12-week LDL-C lowering efficacy of patients treated with bempedoic acid versus placebo when added to ezetimibe. Secondary objectives include evaluating safety and tolerability of bempedoic acid when added to ezetimibe, and effects on other risk markers, including non-HDL-C, total cholesterol, apoB and hsCRP. We initiated Study 4 in December 2016, and expect to report top-line results by the second quarter of 2018.

Global Cardiovascular Outcomes Trial CLEAR Outcomes

CLEAR Outcomes is an event driven, global, randomized, double-blind, placebo-controlled study to assess the effects of bempedoic acid in patients with hypercholesterolemia and with ASCVD and/or HeFH, or who are at high risk for CVD and who are only able to tolerate less than the lowest approved daily starting dose of a statin and can be considered statin intolerant. The CLEAR Outcomes CVOT is expected to enroll approximately 12,600 patients with ASCVD or at high risk for CVD at more than 600 sites in approximately 30 countries. The study is expected to enroll over a 30 month period with a total estimated study duration of approximately 4.75 years. The expected average treatment duration will be 3.75 years with a minimum treatment duration of approximately 2.25 years. Patients enrolling in the study will be required to have a history of, or be at high risk for, CVD with LDL-C levels between 100 mg/dL and 190 mg/dL in secondary prevention and > 100 mg/dL in primary prevention despite background lipid-lowering therapy, resulting in an expected average baseline LDL-C level in all patients of approximately 135 mg/dL. The primary efficacy endpoint of the event-driven global study is the effect of bempedoic acid versus placebo on the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, or coronary revascularization; also referred to as four-component MACE). We initiated CLEAR Outcomes in December 2016, and the study is intended to support our submissions for a CV risk reduction indication in the U.S. and Europe by 2022.

1002-039 Phase 2 efficacy and safety study of bempedoic acid when added-on to an injectable proprotein convertase subtilisin/kexin type 9 inhibitor in patients with hypercholesterolemia

On July 26, 2017, we announced the initiation of the Phase 2 clinical study to assess the efficacy and safety of bempedoic acid when added-on to an injectable proprotein convertase subtilisin/kexin type 9 inhibitor, or PCSK9i, therapy. The eight-week, Phase 2, randomized, double-blind, placebo-controlled study will evaluate the efficacy and safety of once-daily, oral bempedoic acid 180 mg and once-monthly injection of Repatha® (evolocumab) 420 mg versus placebo. The study is expected to enroll approximately 50 patients with hypercholesterolemia at approximately 20 sites across the U.S. The primary objective of the study is to assess the incremental LDL-C lowering efficacy of bempedoic acid versus placebo in patients receiving PCSK9i therapy. Secondary objectives include assessing the safety and tolerability of bempedoic acid versus placebo in patients on PCSK9i therapy and effects on other risk markers, including non-HDL-C, total cholesterol, apoB and hsCRP. This non-registrational study will assess the incremental LDL-C lowering efficacy and continued safety and tolerability of a once-daily, oral bempedoic acid pill added-on to an injectable biologic therapy in patients with elevated LDL-C levels. Top-line results are expected by the first quarter of 2018.

Financial Operations Overview

Revenue

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

To date, we have not generated any revenue. In the future, we may never generate revenue from the sale of the bempedoic acid / ezetimibe combination or bempedoic acid or other product candidates. If we fail to complete the development of the bempedoic acid / ezetimibe combination or 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 the bempedoic acid / ezetimibe combination and bempedoic acid, which include:

- expenses incurred under agreements with consultants, contract research organizations, or CROs, and investigative sites that conduct our preclinical and clinical studies;
- the cost of acquiring, developing and manufacturing clinical study materials, including the procurement of ezetimibe in our continued development of our bempedoic acid / ezetimibe combination;

Table of Contents

- employee-related expenses, including salaries, benefits, stock-based compensation and travel expenses;
- allocated expenses for rent and maintenance of facilities, insurance and other supplies; and
- costs related to compliance with regulatory requirements.

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

Our research and development expenses are expected to increase in the foreseeable future. Costs associated with bempedoic acid will increase as we further its clinical development, including in connection with our global pivotal Phase 3 LDL-C lowering program and our CLEAR Outcomes CVOT. We also expect to incur increased research and development costs as we pursue the clinical development of the bempedoic acid / ezetimibe combination pill. We cannot determine with certainty the duration and completion costs associated with the ongoing or future clinical studies of the bempedoic acid / ezetimibe combination and bempedoic acid. Also, we cannot conclude with certainty if, or when, we will generate revenue from the commercialization and sale of the bempedoic acid / ezetimibe combination or bempedoic acid, if ever. We may never succeed in obtaining regulatory approval for the bempedoic acid / ezetimibe combination or bempedoic acid. The duration, costs and timing associated with the development and commercialization of the bempedoic acid / ezetimibe combination and bempedoic acid will depend on a variety of factors, including uncertainties associated with the results of our clinical studies and our ability to obtain regulatory approval. For example, if the FDA or another regulatory authority were to require us to conduct clinical studies beyond those that we currently anticipate will be required for the completion of clinical development or post-commercialization clinical studies of the bempedoic acid / ezetimibe combination or 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 the bempedoic acid / ezetimibe combination and bempedoic acid.

General and Administrative Expenses

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

We anticipate that our general and administrative expenses will increase in the future in connection with the continued research and development and commercialization of the bempedoic acid / ezetimibe combination and 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. 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

Table of Contents

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 March 2016, the Financial Accounting Standards Board issued Accounting Standards Update, or 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 requires 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 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 was previously required. We adopted ASU 2016-09 effective January 1, 2017, and made a policy election to account for forfeitures as they occur. The cumulative effect of adoption was an increase of \$0.1 million to both additional paid-in capital and accumulated deficit as of January 1, 2017. The remaining provisions adopted in ASU 2016-09 did not have a material impact to our balance sheets, statements of operations or statements of cash flows.

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, 2016.

Results of Operations*Comparison of the Three Months Ended June 30, 2017 and 2016*

The following table summarizes our results of operations for the three months ended June 30, 2017 and 2016:

	Three Months Ended June 30,		
	2017	2016	Change
	<i>(unaudited, in thousands)</i>		
Operating Expenses:			
Research and development	\$ 38,248	\$ 9,698	\$ 28,550
General and administrative	5,412	4,633	779
Loss from operations	(43,660)	(14,331)	(29,329)
Interest expense	(55)	(99)	44
Other income, net	378	395	(17)
Net loss	\$ (43,337)	\$ (14,035)	\$ (29,302)

Research and development expenses

Research and development expenses for the three months ended June 30, 2017, were \$38.2 million, compared to \$9.7 million for the three months ended June 30, 2016, an increase of approximately \$28.6 million. The increase in research and development expenses was primarily related to the further clinical development of bempedoic acid, including costs to support the global pivotal Phase 3 LDL-C lowering program

and the CVOT, and further increases in our headcount, and stock-based compensation expense.

General and administrative expenses

General and administrative expenses for the three months ended June 30, 2017, were \$5.4 million, compared to \$4.6 million for the three months ended June 30, 2016, an increase of \$0.8 million. The increase in general and administrative expenses was primarily attributable to 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, 2017 and 2016, respectively. Interest expense was related to our credit facility.

Other income, net

Other income, net for the three months ended June 30, 2017, was \$0.4 million, compared to \$0.4 million for the three months ended June 30, 2016. Other income was primarily related to 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, 2017 and 2016*

The following table summarizes our results of operations for the six months ended June 30, 2017 and 2016:

	Six Months Ended June 30,		
	2017	2016	Change
	(unaudited, in thousands)		
Operating Expenses:			
Research and development	\$ 74,108	\$ 19,489	\$ 54,619
General and administrative	10,441	9,664	777
Loss from operations	(84,549)	(29,153)	(55,396)
Interest expense	(122)	(209)	87
Other income, net	793	742	51
Net loss	\$ (83,878)	\$ (28,620)	\$ (55,258)

Research and development expenses

Research and development expenses for the six months ended June 30, 2017, were \$74.1 million, compared to \$19.5 million for the six months ended June 30, 2016, an increase of \$54.6 million. The increase in research and development expenses was primarily related to the further clinical development of bempedoic acid, including costs to support the global pivotal Phase 3 LDL-C lowering program and the CVOT, and further increases in our headcount and stock-based compensation expense.

General and administrative expenses

General and administrative expenses for the six months ended June 30, 2017, were \$10.4 million, compared to \$9.7 million for the six months ended June 30, 2016, an increase of approximately \$0.8 million. The increase in general and administrative expenses was primarily attributable to 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 \$0.2 million for the six months ended June 30, 2017 and 2016, respectively. Interest expense was related to our credit facility.

Other income, net

Other income, net for the six months ended June 30, 2017, was \$0.8 million, compared to \$0.7 million for the six months ended June 30, 2016. This increase was primarily related to a reduction in expense for the amortization of premiums and discounts on our investments.

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. 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, 2017, our primary sources of liquidity were our cash and cash equivalents and available-for-sale investments, which totaled \$20.4 million and \$160.7 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,	
	2017	2016
	(in thousands)	
Cash used in operating activities	\$ (60,544)	\$ (17,110)
Cash provided by (used in) investing activities	43,271	(10,704)
Cash used in financing activities	(519)	(754)
Net decrease in cash and cash equivalents	\$ (17,792)	\$ (28,568)

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 the bempedoic acid / ezetimibe combination and bempedoic acid and our operations.

Net cash used in operating activities totaled \$60.5 million and \$17.1 million for the six months ended June 30, 2017 and 2016, respectively. The primary use of our cash was to fund the development of bempedoic acid, adjusted for non-cash expenses such as stock-based compensation expense, depreciation and amortization and changes in working capital.

Investing Activities

Net cash provided by investing activities of \$43.3 million for the six months ended June 30, 2017, consisted primarily of proceeds from the sale and maturities of highly liquid, interest bearing investment-grade and government securities. 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 \$0.5 million and \$0.8 million for the six months ended June 30, 2017 and 2016, respectively, was related primarily to payments on our credit facility.

Plan of Operations and Funding Requirements

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

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 the bempedoic acid/ ezetimibe combination and bempedoic acid. We estimate that current cash resources are sufficient to fund operations through the announcement of top-line results from all global pivotal Phase 3 safety and efficacy studies and into early 2019. We will likely need to raise additional capital to continue to fund the further development and commercialization efforts for the bempedoic acid / ezetimibe combination and bempedoic acid and our operations, including to fund our initial submissions for LDL-C lowering indications for the bempedoic acid / ezetimibe combination and bempedoic acid in the U.S. and Europe and to complete the CLEAR Outcomes CVOT. We have based these estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of the bempedoic acid / ezetimibe combination and bempedoic acid and the extent to which we may enter into collaborations with pharmaceutical partners regarding the development and commercialization of the bempedoic acid / ezetimibe combination and bempedoic acid, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development and commercialization of the bempedoic acid / ezetimibe combination and bempedoic acid. Our future funding requirements will depend on many factors, including, but not limited to:

- our ability to successfully develop and commercialize the bempedoic acid / ezetimibe combination and bempedoic acid or other product candidates;
- the costs, timing and outcomes of our ongoing and planned clinical studies of the bempedoic acid / ezetimibe combination and bempedoic acid;
- the time and cost necessary to obtain regulatory approvals for the bempedoic acid / ezetimibe combination and bempedoic acid, if at all;
- our ability to establish a sales, marketing and distribution infrastructure to commercialize the bempedoic acid / ezetimibe combination and bempedoic acid or our ability to establish any future collaboration or commercialization arrangements on favorable terms, if at all;

Table of Contents

- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the implementation of operational and financial information technology.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners or royalty-based financing arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or through collaborations, strategic alliances or licensing arrangements or royalty-based financing arrangements when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market the bempedoic acid / ezetimibe combination and 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, 2016.

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We had cash and cash equivalents and available-for-sale investments of approximately \$20.4 million and \$160.7 million at June 30, 2017, and \$38.2 million and \$204.3 million at December 31, 2016, 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, cash equivalents and available-for-sale investments have significant risk of default or illiquidity. While we believe our cash and cash equivalents do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

We contract with CROs and investigational sites globally. We are therefore subject to fluctuations in foreign currency rates in connection with these agreements. We do not hedge our foreign currency exchange rate risk. We do not believe that fluctuations in foreign currency rates have had a material effect on our results of operations during the six months ended June 30, 2017.

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, 2017.

Table of Contents

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, 2017, 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, 2017, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

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

Table of Contents

PART II OTHER INFORMATION

Item 1. Legal Proceedings

On January 12, 2016, a purported stockholder of our company filed a putative class action lawsuit in the United States District Court for the Eastern District of Michigan, against us and Tim Mayleben, captioned *Kevin L. Dougherty v. Esperion Therapeutics, Inc., et al.* (No. 16-cv-10089). The lawsuit alleges that we and Mr. Mayleben violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 by allegedly failing to disclose in an August 17, 2015, public statement that the FDA would require a cardiovascular outcomes trial before approving our lead product candidate. The lawsuit seeks, among other things, compensatory damages in connection with an allegedly inflated stock price between August 18, 2015, and September 28, 2015, as well as attorneys' fees and costs. On May 20, 2016, an amended complaint was filed in the lawsuit and on July 5, 2016, we filed a motion to dismiss the amended complaint. On December 27, 2016, the court granted our motion to dismiss with prejudice and entered judgment in our favor. On January 24, 2017, the plaintiffs in this lawsuit filed a motion to alter or amend the judgment. In May 2017, the court denied the plaintiff's motion to alter or amend the judgment. On June 19, 2017, the plaintiff's filed a notice of appeal to the Sixth Circuit Court of Appeals. 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.

There have been no other material changes to our legal proceedings 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, 2016.

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 I, Item 2 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 Part I, Item 1A in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, and those set forth in Part II, Item 1A of our Quarterly Report for the quarter ended March 31, 2017, and in all of the other information included or incorporated in this report. The following risk factors represent new risk factors or those containing changes, including material changes, to the risk factors set forth in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and in Part II, Item 1A of our Quarterly Report for the quarter ended March 31, 2017. If any of the previously identified or 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 our Product Candidates

We depend almost entirely on the success of two product candidates, the bempedoic acid / ezetimibe combination pill and bempedoic acid, which are in Phase 3 clinical development. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, our product candidates.

The bempedoic acid / ezetimibe combination pill and bempedoic acid are our only product candidates in clinical development, and our business depends almost entirely on their 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.

Table of Contents

The bempedoic acid / ezetimibe combination and bempedoic acid will require substantial additional clinical development, testing, and regulatory approvals before we are permitted to commence their commercialization. The clinical studies of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the U.S. and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through preclinical testing and clinical studies that the product candidate is safe and effective for use in each target indication. This process can take many years and require the expenditure of substantial resources beyond the proceeds we have raised, and may include post-marketing studies and surveillance, including a Risk Evaluation and Mitigation Strategy, or REMS program. Of the large number of drugs in development in the U.S., only a small percentage successfully complete the approval process at the FDA, EMA or any other foreign regulatory agency, and are commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development and clinical programs, we cannot assure you that the bempedoic acid / ezetimibe combination and bempedoic acid or any other of our product candidates will be successfully developed or commercialized.

We are not permitted to market our product candidates in the U.S. or Europe until we receive approval of an NDA from the FDA, a MAA from the EMA, or in any other foreign countries until we receive the requisite approval from such countries. As a condition to submitting an NDA or MAA for the bempedoic acid / ezetimibe combination to treat patients with hypercholesterolemia, we intend to initiate and complete the global pivotal Phase 3 bridging study (1002FDC-053) in addition to the global pivotal Phase 3 LDL-C lowering program for bempedoic acid, to support an NDA submission for an LDL-C lowering indication. As a condition to submitting an NDA or MAA for bempedoic acid to treat patients with hypercholesterolemia, we have currently completed eight Phase 2 clinical studies and expect to complete the global pivotal Phase 3 LDL-C lowering efficacy and safety studies to support an NDA submission for an LDL-C lowering indication, and to complete the CLEAR Outcomes CVOT to support an NDA submission for a CVD risk reduction indication.

Additionally, we currently intend to submit NDAs in tandem for the bempedoic acid / ezetimibe combination and for bempedoic acid for LDL-C lowering indications by the first quarter of 2019 if we successfully complete our Phase 3 bridging study and Phase 3 LDL-C lowering program, based on the FDA's recent guidance that these programs are adequate to support approval of an LDL-C lowering indication. However, there is no guarantee that the FDA will view results from our Phase 3 bridging study or global pivotal Phase 3 LDL-C lowering program alone as sufficient to support approval of an LDL-C lowering indication for the bempedoic acid / ezetimibe combination or bempedoic acid. In the event that FDA determines LDL-C lowering is no longer a surrogate endpoint for initial approval of the bempedoic acid / ezetimibe combination or bempedoic acid in the future, we would plan to submit our NDA for bempedoic acid with a proposed indication of CV risk reduction in statin intolerant patients on the basis of a completed and successful CLEAR Outcomes CVOT, which would include the results of the global pivotal Phase 3 LDL-C lowering program, 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 the bempedoic acid / ezetimibe combination pill and 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 the bempedoic acid / ezetimibe combination or bempedoic acid;
- the FDA, EMA or any other regulatory authorities may change their approval policies for an LDL-C lowering indication for the bempedoic acid / ezetimibe combination or bempedoic acid if there is a shift in the future standard-of-care for statin intolerant patients with hypercholesterolemia;
- we may not be able to demonstrate that the bempedoic acid / ezetimibe combination and bempedoic acid are

safe and effective in treating patients with hypercholesterolemia to the satisfaction of the FDA, EMA or any other regulatory agency;

- the results of our clinical studies may not meet the level of statistical or clinical significance required by the FDA or EMA for marketing approval;
- the magnitude of the treatment effect must also be clinically meaningful along with the drug's safety for a favorable benefit/risk assessment by the FDA, EMA or any other regulatory agency;
- the FDA, EMA or any other regulatory agency may change in the future the number, design, size, duration, patient enrollment criteria, exposure of patients, or conduct or implementation of our clinical studies;
- the FDA, EMA or any other regulatory agency may require that we conduct additional clinical studies;

Table of Contents

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

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

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

The development and approvals required for the approval of the bempedoic acid / ezetimibe combination pill are substantially identical to those for bempedoic acid, and the risks relating to the clinical development and approval of bempedoic acid apply equally to the bempedoic acid / ezetimibe combination pill. The FDA accepted our submission of an IND application for the bempedoic acid / ezetimibe combination in the second quarter of 2016 and we completed a bioavailability study. We announced the clinical development and regulatory plans for the bempedoic acid / ezetimibe combination in June 2017. Any failure in our development of bempedoic acid would materially and adversely affect our ability to develop, seek approval for and commercialize the bempedoic acid / ezetimibe combination pill for the planned indications. In addition, even if bempedoic acid succeeds in its clinical development and is approved for one or more indications, there can be no assurance that the bempedoic acid / ezetimibe combination pill would be developed successfully and approved for the same indications or at all, and vice versa.

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

We reported top-line results from our Phase 2 (1002-008) clinical study in October 2014, our Phase 2 (1002-009) clinical study in March 2015, our Phase 2 (1002-014) exploratory clinical safety study in July 2015, and our Phase 2 PK/PD (1002-035) clinical study and Phase 1 PK (1002-037) study in October 2016. We held our End-of-Phase 2 meeting with the FDA in August 2015. In January 2016, we commenced our global pivotal Phase 3 long-term safety study (Study 1). We engaged in active dialogue in 2016 with the FDA and EMA to discuss our global pivotal Phase 3 clinical program for bempedoic acid in the statin intolerant patient population and, based on that dialogue, announced our clinical development and regulatory plans for bempedoic acid in June 2016. We initiated our global pivotal Phase 3 LDL-C lowering efficacy studies and our CLEAR Outcomes CVOT in December 2016. In March 2017, we announced that the FDA confirmed that our global pivotal Phase 3 LDL-C lowering program is adequate to support approval of an LDL-C lowering indication for bempedoic acid, and reached an agreement with the FDA on the definition of statin intolerance. In June 2017, we announced that the FDA confirmed the regulatory pathway to approval for the bempedoic acid / ezetimibe combination pill. However, there is no guarantee that the FDA will view results from our Phase 3 bridging study or global pivotal Phase 3 LDL-C

Table of Contents

lowering program alone as sufficient to support approval for the bempedoic acid / ezetimibe combination or bempedoic acid. We currently intend to submit an NDA for an LDL-C lowering indication for the bempedoic acid / ezetimibe combination through the abbreviated 505(b)(2) pathway by the first quarter of 2019 if we successfully complete our Phase 3 bridging study and our global pivotal Phase 3 LDL-C lowering program. We currently intend to submit an NDA for bempedoic acid for an LDL-C lowering indication in patients with hypercholesterolemia by the first quarter of 2019 if we successfully complete our global pivotal Phase 3 LDL-C lowering program.

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

- the scope, size, rate of progress, results and costs of completing our CLEAR Outcomes CVOT of bempedoic acid;
- the scope, size, rate of progress, results and costs of completing our global pivotal Phase 3 LDL-C lowering program of bempedoic acid, which currently includes multiple global pivotal Phase 3 clinical efficacy and safety studies;
- the scope, size, rate of progress, results and costs of clinical development of the bempedoic acid / ezetimibe combination pill for the same indications as bempedoic acid, including that of our planned global pivotal Phase 3 bridging study;
- the cost, timing and outcome of our efforts to obtain marketing approval for the bempedoic acid / ezetimibe combination and bempedoic acid, including to fund the preparation and filing of two NDAs with the FDA and two MAAs with the EMA for the bempedoic acid / ezetimibe combination and 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 the bempedoic acid / ezetimibe combination and 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 the bempedoic acid / ezetimibe

combination and bempedoic acid or any future product candidates;

- the cost of manufacturing the bempedoic acid / ezetimibe combination and 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 the bempedoic acid / ezetimibe combination and 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 the bempedoic acid / ezetimibe combination and bempedoic acid or any future product candidate, or to commercialize the bempedoic acid / ezetimibe combination and 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 global pivotal Phase 3 clinical studies, our global pivotal Phase 3 bridging study for the bempedoic acid / ezetimibe combination, or our CVOT of bempedoic acid may occur, which may result in changes to clinical study protocols or additional clinical study requirements, which could result in increased costs to us and could delay our development timeline.

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

Even though we completed enrollment of Study 1 ahead of schedule, we may not be able to identify and enroll the requisite number of patients in our Phase 3 bridging study, our remaining global pivotal Phase 3 LDL-C lowering studies, our CLEAR Outcomes CVOT, or any study that we undertake to support the development of our product candidates. Even if we are successful in enrolling patients, we may not ultimately be able to demonstrate sufficient clinical benefits from the bempedoic acid / ezetimibe combination and bempedoic acid, and our failure to do so may delay or hinder our ability to obtain FDA or EMA approval for these product candidates. We currently intend to submit NDAs in tandem for the bempedoic acid / ezetimibe combination and for bempedoic acid for LDL-C lowering indications by the first quarter of 2019 if we successfully complete our Phase 3 bridging study and Phase 3 LDL-C lowering program, based on the FDA's recent guidance that these programs are adequate to support approval of an LDL-C lowering. However, 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 hypercholesterolemia, and there is no guarantee that the FDA will view results from our Phase 3 bridging study and global pivotal Phase 3 LDL-C lowering program alone as sufficient to support approvals of an LDL-C lowering indication. Conducting our CLEAR Outcomes CVOT will be costly and time-consuming, and any requirement to complete the CVOT prior to approval of bempedoic acid would adversely affect our development timeline and financial condition.

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

Government agencies issue regulations and guidelines directly applicable to us and to the bempedoic acid / ezetimibe combination and bempedoic acid, including guidelines generally relating to therapeutically significant LDL-C levels. In addition, professional societies, practice management groups, private health or science foundations and other organizations involved in the research, treatment and prevention of various diseases from time to time publish guidelines or recommendations to the medical and patient communities. These various sorts of recommendations may relate to such matters as product usage and use of related or competing therapies. For example, organizations such as the AHA have made recommendations about therapies in the cardiovascular therapeutics market. In addition, while we recently reached an agreement with the FDA on the definition of statin intolerance, there is no guarantee that the FDA's view of this definition would not change in the future. We expect that the FDA's view of the standard of care for patients with hypercholesterolemia at the time we submit our NDAs for LDL-C lowering indications in patients with hypercholesterolemia will impact the evaluation of such NDAs, 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 the bempedoic acid / ezetimibe combination and bempedoic acid, which would adversely affect our results of operations.

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

We have limited experience using the 505(b)(2) regulatory pathway to submit an NDA or any similar drug approval filing to the FDA, and we cannot be certain that any of our product candidates will receive regulatory approval.

We are developing bempedoic acid / ezetimibe combination for which we may seek FDA approval through the Section 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act, or FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2) would

Table of Contents

allow an NDA we submit to FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. We could need to obtain additional funding, which could result in significant dilution to the ownership interests of our existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that the bempedoic acid / ezetimibe combination will receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to accelerated product development or earlier approval.

Moreover, even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

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.

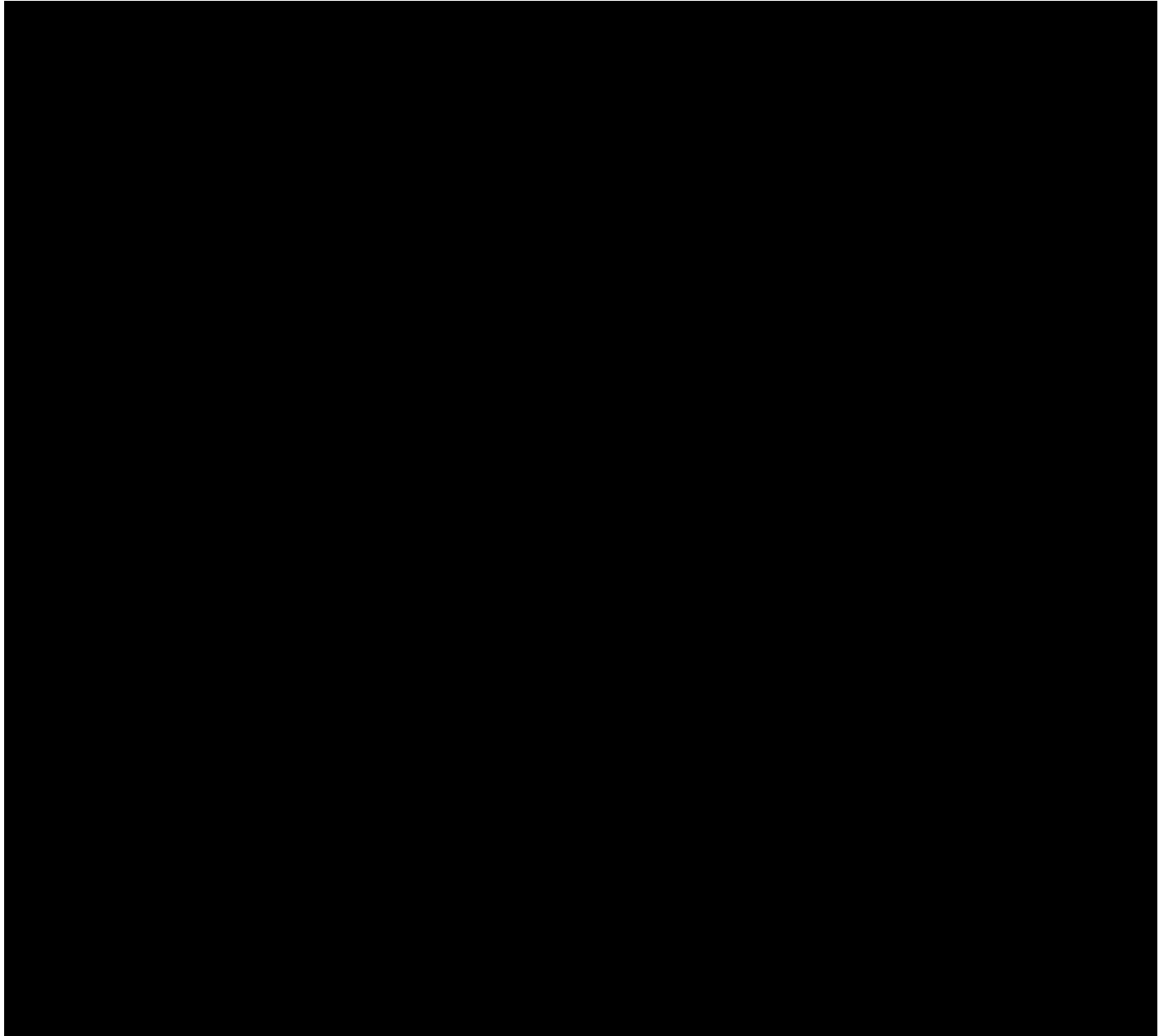
August 8, 2017

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



* 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.