
**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 March 31, 2019

OR

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

For the transition period from _____ to _____

Commission file number: 001-35986

Esperion Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

26-1870780
(I.R.S. Employer
Identification No.)

3891 Ranchero Drive, Suite 150
Ann Arbor, 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 pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company
Emerging growth company

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

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

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

Title of each class	Name of each exchange on which registered	Ticker Symbol
Common Stock, par value \$0.001 per share	NASDAQ Stock Market LLC	ESPR

As of May 1, 2019, there were 26,917,456 shares of the registrant's Common Stock, \$0.001 par value per share, outstanding.

Esperion Therapeutics, Inc.

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Esperion Therapeutics, Inc.
Condensed Balance Sheets
(in thousands, except share data)

	March 31, 2019 (unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 174,836	\$ 36,973
Restricted cash	1,193	—
Short-term investments	53,692	99,050
Prepaid clinical development costs	4,392	5,275
Right of use operating lease assets	185	—
Other prepaid and current assets	923	1,334
Total current assets	<u>235,221</u>	<u>142,632</u>
Property and equipment, net	439	520
Intangible assets	56	56
Long-term investments	—	243
Right of use operating lease assets	766	—
Total assets	<u>\$ 236,482</u>	<u>\$ 143,451</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 33,270	\$ 44,893
Accrued clinical development costs	18,871	16,039
Other accrued liabilities	3,774	3,401
Deferred revenue from collaborations	3,926	—
Operating lease liabilities	184	—
Total current liabilities	<u>60,025</u>	<u>64,333</u>
Deferred revenue from collaborations	655	—
Operating lease liabilities	792	—
Total liabilities	<u>61,472</u>	<u>64,333</u>
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 March 31, 2019 and December 31, 2018	—	—
Common stock, \$0.001 par value; 120,000,000 shares authorized as of March 31, 2019 and December 31, 2018; 26,908,202 shares issued and outstanding at March 31, 2019 and 26,824,859 shares issued and outstanding at December 31, 2018	27	27
Additional paid-in capital	685,816	677,511
Accumulated other comprehensive loss	(111)	(319)
Accumulated deficit	(510,722)	(598,101)
Total stockholders' equity	<u>175,010</u>	<u>79,118</u>
Total liabilities and stockholders' equity	<u>\$ 236,482</u>	<u>\$ 143,451</u>

See accompanying notes to the condensed financial statements.

Esperion Therapeutics, Inc.

Condensed Statements of Operations and Comprehensive Income (Loss)
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended	
	March 31,	
	2019	2018
Revenues:		
Collaboration revenue	\$ 145,419	\$ —
Total Revenues	<u>145,419</u>	<u>—</u>
Operating expenses:		
Research and development	46,308	40,940
General and administrative	12,182	5,954
Total operating expenses	<u>58,490</u>	<u>46,894</u>
Income (loss) from operations	86,929	(46,894)
Other income, net	450	764
Net income (loss)	<u>\$ 87,379</u>	<u>\$ (46,130)</u>
Net income (loss) per common share - basic	<u>\$ 3.26</u>	<u>\$ (1.73)</u>
Net income (loss) per common share - diluted	<u>\$ 3.07</u>	<u>\$ (1.73)</u>
Weighted-average shares outstanding - basic	<u>26,842,785</u>	<u>26,605,189</u>
Weighted-average shares outstanding - diluted	<u>28,449,767</u>	<u>26,605,189</u>
Other comprehensive income (loss):		
Unrealized gain (loss) on investments	\$ 208	\$ (118)
Comprehensive income (loss)	<u>\$ 87,587</u>	<u>\$ (46,248)</u>

See accompanying notes to the condensed financial statements.

Esperion Therapeutics, Inc.

Statements of Stockholders' Equity
(in thousands, except share data)
(unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance December 31, 2017	26,304,669	\$ 26	\$ 641,801	\$ (396,291)	\$ (845)	\$ 244,691
Exercise of stock options	285,413	1	9,775	—	—	9,776
Exercise of warrants	159,944	—	—	—	—	—
Vesting of restricted stock units	1,562	—	—	—	—	—
Stock-based compensation	—	—	5,921	—	—	5,921
Other comprehensive loss	—	—	—	—	(118)	(118)
Net loss	—	—	—	(46,130)	—	(46,130)
Balance March 31, 2018	<u>26,751,588</u>	<u>\$ 27</u>	<u>\$ 657,497</u>	<u>\$ (442,421)</u>	<u>\$ (963)</u>	<u>\$ 214,140</u>
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance December 31, 2018	26,824,859	\$ 27	\$ 677,511	\$ (598,101)	\$ (319)	\$ 79,118
Exercise of stock options	80,218	—	1,669	—	—	1,669
Vesting of restricted stock units	3,125	—	—	—	—	—
Stock-based compensation	—	—	6,636	—	—	6,636
Other comprehensive gain	—	—	—	—	208	208
Net income	—	—	—	87,379	—	87,379
Balance March 31, 2019	<u>26,908,202</u>	<u>\$ 27</u>	<u>\$ 685,816</u>	<u>\$ (510,722)</u>	<u>\$ (111)</u>	<u>\$ 175,010</u>

See accompanying notes to the condensed financial statements.

Esperion Therapeutics, Inc.
Condensed Statements of Cash Flows
(in thousands)
(unaudited)

	<u>Three Months Ended March 31,</u>	
	<u>2019</u>	<u>2018</u>
Operating activities		
Net income (loss)	\$ 87,379	\$ (46,130)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation expense	71	61
Accretion of premiums and discounts on investments	(75)	—
Stock-based compensation expense	6,636	5,921
Changes in assets and liabilities:		
Prepays and other assets	1,294	(421)
Deferred revenue	4,581	—
Accounts payable	(11,549)	(8,413)
Other accrued liabilities	3,354	5,761
Net cash provided by (used in) operating activities	<u>91,691</u>	<u>(43,221)</u>
Investing activities		
Purchases of investments	—	(14,620)
Proceeds from sales/maturities of investments	45,885	44,903
Purchase of property and equipment	(189)	—
Net cash provided by investing activities	<u>45,696</u>	<u>30,283</u>
Financing activities		
Proceeds from exercise of common stock options	1,669	9,738
Payments on long-term debt	—	(445)
Net cash provided by financing activities	<u>1,669</u>	<u>9,293</u>
Net increase (decrease) in cash and cash equivalents	139,056	(3,645)
Cash and cash equivalents at beginning of period	36,973	34,468
Cash, cash equivalents and restricted cash at end of period	<u>\$ 176,029</u>	<u>\$ 30,823</u>
Supplemental disclosure of cash flow information:		
Non cash right of use asset	\$ 25	\$ —

See accompanying notes to the condensed financial statements.

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 complementary, cost-effective, convenient, 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 bempedoic acid / ezetimibe combination tablet are targeted therapies that have been shown to significantly lower elevated LDL-C levels in patients with hypercholesterolemia, including patients inadequately treated with current lipid-modifying therapies.

On February 20, 2019, the Company submitted the new drug application (“NDA”) for bempedoic acid and on February 26, 2019, the Company submitted the NDA for the bempedoic acid / ezetimibe combination tablet to the Food and Drug Administration (“FDA”) for LDL-C lowering indications. On May 5, 2019, the Company announced that the FDA accepted the NDAs for bempedoic acid and the bempedoic acid / ezetimibe combination tablet for filing and regulatory review. The Prescription Drug User Fee Act (“PDUFA”) goal date for completion of the bempedoic acid NDA review is set for February 21, 2020, and the PDUFA goal date for completion of the bempedoic acid / ezetimibe combination tablet NDA review is set for February 26, 2020. These dates are consistent with the Company’s expectations and reflect the standard review period. The FDA has communicated that there is no current plan to hold an advisory committee meeting to discuss the applications. On February 11, 2019, the Company submitted the Marketing Authorization Applications (“MAAs”) for bempedoic acid and the bempedoic acid / ezetimibe combination tablet to the European Medicines Agency (“EMA”). On February 28, 2019, the EMA completed formal validation of the MAAs for bempedoic acid and the bempedoic acid / ezetimibe combination tablet for LDL-C lowering indications.

The Company is conducting a global cardiovascular outcomes trial (“CVOT”)—known as **C**holesterol **L**owering via **B**empedoic Acid, an **A**CL-inhibiting **R**egimen (CLEAR) Outcomes, for bempedoic acid in 12,604 patients with hypercholesterolemia and high CVD risk and who can be considered statin averse. The Company initiated the CLEAR Outcomes CVOT in December 2016 and expects the study to be fully enrolled in the third quarter of 2019. The Company 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 principal operations and is subject to risks and uncertainties which include the need to research, develop, and clinically test potential therapeutic products; obtain regulatory approvals for its products and commercialize them, if approved; expand its management and scientific staff; and finance its operations with an ultimate goal of achieving profitable operations.

The Company has sustained annual operating losses since inception and expects such losses to continue over the foreseeable future. While management believes current cash resources and future cash received from the Company’s collaboration agreement with Daiichi Sankyo Europe GmbH (“DSE”), entered into on January 2, 2019, will fund operations for the foreseeable future, management may continue to fund operations and advance the development of the Company’s product candidates through a combination of collaborations with third parties, strategic alliances, licensing arrangements, debt financings, royalty-based financings, and private and public equity offerings or through other sources. If adequate funds are not available, the Company may not be able to continue the development of its current 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 presentation of the Company’s financial position and results of operations for the interim periods presented. Certain information and disclosures normally included in the annual financial statements prepared in accordance with GAAP have been condensed or omitted. These condensed interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2018, and the notes thereto, which are included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2018. 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

Use of Estimates

The preparation of financial statements in accordance with generally accepted accounting principles in the United States requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company invests its excess cash in bank deposits, money market accounts, and short-term investments. The Company considers all highly liquid investments with an original maturity of 90 days or less at the time of purchase to be cash equivalents. Cash equivalents are reported at fair value.

Restricted Cash

Restricted cash consists of legally restricted amounts held by financial institutions pursuant to contractual arrangements.

Investments

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

Concentration of Credit Risk

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

Segment Information

The Company views its operations and manages its business in one operating segment, which is the business of researching, developing and commercializing therapies for the treatment of patients with elevated LDL-C.

Fair Value of Financial Instruments

The Company's cash, cash equivalents, restricted cash and investments are carried at fair value. Financial instruments, including other prepaid and current assets, accounts payable and accrued liabilities are carried at cost, which approximates fair value. Debt is carried at amortized cost, which approximates fair value.

Property and Equipment, Net

Property and equipment are recorded at cost, less accumulated depreciation. Depreciation is provided using the straight-line method over the estimated useful lives of the respective assets, generally three to ten years. Leasehold improvements are amortized over the lesser of the lease term or the estimated useful lives of the related assets.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value. No impairment losses have been recorded through March 31, 2019.

Leases

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

Revenue Recognition

a. Collaboration Revenue

The Company has entered into an agreement related to its activities to develop, manufacture, and commercialize its product candidates. The Company earns collaboration revenue in connection with a collaboration agreement to develop and/or commercialize product candidates where the Company deems the collaborator to be the customer. The Company has adopted ASC 606, Revenue from Contracts with Customers, and under the terms of the standard, revenue is measured as the amount of consideration expected to be entitled to in exchange for transferring promised goods or providing services to a customer. Revenue is recognized when (or as) the Company satisfies performance obligations under the terms of a contract. Depending on the terms of the arrangement, the Company may defer the recognition of all or a portion of the consideration received as the performance obligations are satisfied.

The collaboration agreement may require the Company to deliver various rights, services, and/or goods across the entire life cycle of a product or product candidate. In the agreement involving multiple goods or services promised to be transferred to a customer, the Company must assess, at the inception of the contract, whether each promise represents a separate performance obligation (i.e., is “distinct”), or whether such promises should be combined as a single performance obligation.

The terms of the agreement typically include consideration to be provided to the Company in the form of non-refundable up-front payments, development milestones, sales milestones, and royalties on sales of products within a respective territory.

At the inception of the contract, the transaction price reflects the amount of consideration the Company expects to be entitled to in exchange for transferring promised goods or services to its customer. In the arrangement where the Company satisfies performance obligation(s) during the regulatory phase over time, the Company recognizes collaboration revenue typically using an input method on the basis of regulatory costs incurred relative to the total expected cost which determines the extent of progress toward completion. The Company reviews the estimate of the transaction price and the total expected cost each period, and makes revisions to such estimates as necessary.

Under the Company’s collaboration agreement, product sales and cost of sales may be recorded by the Company’s collaborators as they are deemed to be the principal in the transaction. The Company receives royalties from the commercialization of such products, and records its share of the variable consideration, representing a percentage of net product sales, as collaboration revenue in the period in which such underlying sales occur and costs are incurred by the collaborator. The collaborator will provide the Company with estimates of its royalties for such quarter; these estimates are reconciled to actual results in the subsequent quarter, and the royalty is adjusted accordingly, as necessary.

Please refer to the discussion in Note 3 “Collaborations with Third Parties” for further discussion of accounting related to the collaboration agreement.

Research and Development

Research and development expenses consist of costs incurred to further the Company’s research and development activities and include salaries and related benefits, costs associated with clinical activities, nonclinical activities, regulatory activities, manufacturing activities to support clinical activities, research-related overhead expenses and fees paid to external service providers that conduct certain research and development, clinical, and manufacturing activities on behalf of the Company. Research and development costs are expensed as incurred.

Accrued Clinical Development Costs

Outside research costs are a component of research and development expense. These expenses include fees paid to clinical research organizations and other service providers that conduct certain clinical and product development activities on behalf of the Company. Depending upon the timing of payments to the service providers, the Company recognizes prepaid expenses or accrued expenses related to these costs. These accrued or prepaid expenses are based on management's estimates of the work performed under service agreements, milestones achieved and experience with similar contracts. The Company monitors each of these factors and adjusts estimates accordingly.

Income Taxes

The Company utilizes the liability method of accounting for income taxes as required by ASC 740, Income Taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and the tax basis of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company has incurred annual operating losses since inception. Accordingly, it is not more likely than not that the Company will realize a tax benefit from its deferred tax assets and as such, it has recorded a full valuation allowance.

Warrants

The Company accounts for its warrants issued in connection with its various financing transactions based upon the characteristics and provisions of the instrument. Warrants classified as additional-paid-in-capital are recorded on the Company's balance sheet at their fair value on the date of issuance. The warrants are measured using the Black-Scholes option-pricing model.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with the provisions of ASC 718, Compensation—Stock Compensation. Accordingly, compensation costs related to equity instruments granted are recognized over the requisite service periods of the awards on a straight-line basis at the grant-date fair value calculated using a Black-Scholes option-pricing model. The Company accounts for forfeitures as they occur. Expense is recognized during the period the related services are rendered.

Recent Accounting Pronouncements

In November 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2018-08, which clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Accounting Standards Codification ("ASC") 606 when the collaborative arrangement participant is a customer in the context of a unit of account. The standard is effective for public companies for fiscal years beginning after December 15, 2019, and interim periods within those years. Early adoption is permitted, included in any interim period, provided an entity has already adopted ASC 606 or does so concurrently with the adoption of this guidance. The Company early adopted this guidance as of January 1, 2019, and implemented the new guidance in its consideration of the accounting for the DSE collaboration signed on January 2, 2019. Refer to Note 3 "Collaborations with Third Parties" and the Collaboration Revenue accounting policy above for further information.

In February 2016, the FASB issued ASU 2016-02, which was amended by subsequent updates (collectively the "lease standard" or "ASC 842"), and is intended to improve financial reporting about leasing transactions. The updated guidance requires a lessee to recognize assets and liabilities for leases with lease terms of more than twelve months. The Company adopted the standard on January 1, 2019 using the modified retrospective method. Results for the reporting period beginning after December 31, 2018 have been presented in accordance with the standard, while results for prior periods have not been adjusted. The Company recognized \$1.0 million and \$1.0 million of operating lease assets and operating lease liabilities, respectively, on the Company's balance sheets as of January 1, 2019, primarily related to the lease agreement for the Company's principal executive office. Refer to Note 9 "Leases" for more information on the Company's leases.

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, 2018.

3. Collaborations with Third Parties

Agreement Terms

On January 2, 2019, the Company entered into a license and collaboration agreement with DSE. Pursuant to the agreement, the Company granted DSE exclusive commercialization rights to bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the European Economic Area and Switzerland (“DSE Territory”). DSE will be responsible for commercialization in the DSE Territory. The Company remains responsible for clinical development, regulatory and manufacturing activities for the licensed products globally, including in the DSE Territory.

Pursuant to the agreement, the consideration consists of a \$150 million upfront cash payment as well as \$150 million cash payment to the Company upon first commercial sales in the DSE Territory. The Company is also eligible to receive a substantial additional regulatory milestone payment upon the grant of the marketing authorization in the European Union for the CV risk reduction label, depending on the range of relative risk reduction in the CLEAR Outcomes study. In addition, the Company is eligible to receive additional sales milestone payments related to total net sales achievements for DSE in the DSE Territory. Finally, the Company will receive tiered fifteen percent (15%) to twenty-five percent (25%) royalties on net DSE Territory sales.

The agreement calls for both parties to participate in a Joint Collaboration Committee (the “JCC”). The JCC is comprised of executive management from each company and the Company will lead in all aspects related to development and DSE will lead in all aspects related to commercialization in the DSE Territory.

Collaboration Revenue

The Company considered the guidance under ASC 606 and concluded that the agreement was in the scope of ASC 606. The Company concluded that the upfront payment of \$150 million should be included in the transaction price and related to the following performance obligations under the agreement: 1) the license to the Company’s intellectual property and 2) the obligation to provide ongoing regulatory and development activities. The Company used the adjusted market assessment approach in determining the standalone selling price of the Company’s intellectual property and the expected cost plus margin approach in determining the standalone selling price of the Company’s obligation to provide ongoing regulatory and development activities. Accordingly, for the three months ended March 31, 2019, the Company recognized \$145.4 million of collaboration revenue related to the \$150 million upfront payment. The \$145.4 million relates to the performance obligations for the license to the Company’s intellectual property and a portion of ongoing regulatory and development activities conducted during the period ended March 31, 2019, in the amounts of \$144.4 million and \$1.0, respectively. The remaining \$4.6 million of the upfront payment was deferred as of March 31, 2019 due to an on-going performance obligation related to the ongoing regulatory efforts related to the MAA in the DSE Territory. This deferred revenue will be recognized ratably over the period leading up to the approval of the MAA acceptance by the EMA.

All future potential milestone amounts were not included in the transaction price, as they were all determined to be fully constrained following the concepts of ASC 606 due to the fact that such amounts hinge on regulatory approval. Additionally, the Company expects that any consideration related to royalties and sales-based milestones will be recognized when the subsequent sales occur.

The Company has not yet recognized any revenue for milestone payments as the related regulatory and commercial milestones have not yet been achieved.

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.

As of March 31, 2019, the Company had warrants outstanding that were exercisable for a total of 8,230 shares of common stock at a weighted-average exercise price of \$15.19 per share.

5. Commitments and Contingencies

On January 12, 2016, a purported stockholder of the company filed a putative class action lawsuit in the United States District Court for the Eastern District of Michigan, against the Company and Tim Mayleben, captioned *Kevin L. Dougherty v. Esperion Therapeutics, Inc., et al.* (No. 16-cv-10089). 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 and on September 14, 2017, they filed their opening brief in support of the appeal. The appeal was fully briefed on December 7, 2017, and it was argued before the Sixth Circuit on March 15, 2018. On September 27, 2018, the Sixth Circuit issued an opinion in which it reversed the district court's dismissal and remanded for further proceedings. On October 11, 2018, the Company filed a petition for rehearing en banc and, on October 23, 2018, the Sixth Circuit Court of Appeals directed plaintiffs to respond to that petition. On December 3, 2018, the Sixth Circuit denied the Company's petition for en banc rehearing, and on December 11, 2018, the case was returned to the federal district court by mandate from the Sixth Circuit. On December 26, 2018, the Company filed an answer to the amended complaint, and on March 28, 2019, the Company filed its amended answer to the amended complaint. 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.

On December 15, 2016, a purported stockholder of the Company filed a derivative lawsuit in the Court of Chancery of the State of Delaware against Tim Mayleben, Roger Newton, Mary McGowan, Nicole Vitullo, Dov Goldstein, Daniel Janney, Antonio Gotto Jr., Mark McGovern, Gilbert Omenn, Scott Braunstein, and Patrick Enright. The Company is named as a nominal defendant. The lawsuit alleges that the defendants breached their fiduciary duties to the Company when they made or approved improper statements on August 17, 2015, regarding the Company's lead product candidate's path to FDA approval, and failed to ensure that reliable systems of internal controls were in place at the Company. On February 8, 2019, the Company and defendants filed a motion to dismiss the derivative lawsuit. On April 23, 2019, the plaintiff filed an opposition to the motion to dismiss the derivative lawsuit. The lawsuit seeks, among other things, any damages sustained by the Company as a result of the defendants' alleged breaches of fiduciary duties, including damages related to the above-referenced securities class action, an order directing the Company to take all necessary actions to reform and improve its corporate governance and internal procedures, restitution from the defendants, and attorneys' fees and costs. 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.

On May 7, 2018, a purported stockholder of the Company filed a putative class action lawsuit in the United States District Court for the Eastern District of Michigan, captioned *Kevin Bailey v. Esperion Therapeutics, Inc., et al.* (No. 18-cv-11438). An amended complaint was filed on October 22, 2018, against the Company and certain directors and officers. The amended complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 based on allegedly making false and misleading statements and omissions about the safety and tolerability of bempedoic acid, and specifically facts and circumstances surrounding the Phase 3 trial results for bempedoic acid that the Company announced on May 2, 2018. On November 13, 2018, the Company filed a motion to dismiss the amended complaint, and that motion was fully briefed on December 18, 2018. The lawsuit sought, among other things, compensatory damages in connection with an allegedly inflated stock price between February 22, 2017, and May 22, 2018, as well as attorneys' fees and costs. On February 19, 2019, the court granted the Company's motion to dismiss with prejudice and entered judgment in the Company's favor.

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, 2018.

6. Investments

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

	March 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
(in thousands)				
Cash equivalents:				
Money market funds	\$ 166,196	\$ —	\$ —	\$ 166,196
Short-term investments:				
Certificates of deposit	735	—	(2)	733
U.S. treasury notes	30,946	3	(53)	30,896
U.S. government agency securities	22,122	—	(59)	22,063
Total	\$ 219,999	\$ 3	\$ (114)	\$ 219,888
	December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
(in thousands)				
Cash equivalents:				
Money market funds	\$ 34,526	\$ —	\$ —	\$ 34,526
Short-term investments:				
Certificates of deposit	3,873	—	(7)	3,866
U.S. treasury notes	44,897	—	(142)	44,755
U.S. government agency securities	50,598	—	(169)	50,429
Long-term investments:				
Certificates of deposit	244	—	(1)	243
Total	\$ 134,138	\$ —	\$ (319)	\$ 133,819

At March 31, 2019, remaining contractual maturities of investments classified as current on the balance sheets were less than 12 months and at December 31, 2018, remaining contractual maturities of investments classified as long-term were less than two years.

During the three months ended March 31, 2019 and 2018, other income, net in the statements of operations includes interest income on available-for-sale of investments of \$0.4 million and \$0.8 million. Other income, net in the statements of operations includes income for the accretion of premiums and discounts on investments of \$0.1 million during the three months March 31, 2019 and expense for the amortization of premiums and discounts on investments of less than \$0.1 million during the three months ended March 31, 2018.

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 months ended March 31, 2019 and 2018.

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)			
March 31, 2019				
Assets:				
Money market funds	\$ 166,196	\$ 166,196	\$ —	\$ —
Investments:				
Certificates of deposit	733	733	—	—
U.S. treasury notes	30,896	30,896	—	—
U.S. government agency securities	22,063	—	22,063	—
Total assets at fair value	\$ 219,888	\$ 197,825	\$ 22,063	\$ —
December 31, 2018				
Assets:				
Money market funds	\$ 34,526	\$ 34,526	\$ —	\$ —
Available-for-sale securities:				
Certificates of deposit	4,109	4,109	—	—
U.S. treasury notes	44,755	44,755	—	—
U.S. government agency securities	50,429	—	50,429	—
Total assets at fair value	\$ 133,819	\$ 83,390	\$ 50,429	\$ —

There were no transfers between Levels 1, 2 or 3 during the three months ended March 31, 2019 and 2018.

8. Stock Compensation

2017 Inducement Equity Plan

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 the 2013 Plan, and (ii) on January

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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 three months ended March 31, 2019:

	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2018	5,303,723	\$ 37.01	7.42	\$ 83,473
Granted	139,500	\$ 46.54		
Forfeited or expired	(81,530)	\$ 50.16		
Exercised	(80,218)	\$ 20.81		
Outstanding at March 31, 2019	<u>5,281,475</u>	<u>\$ 37.30</u>	7.21	<u>\$ 63,263</u>

The following table summarizes information about the Company’s stock option plan as of March 31, 2019:

	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Vested and expected to vest at March 31, 2019	5,281,475	\$ 37.30	7.21	\$ 63,263
Exercisable at March 31, 2019	2,993,824	\$ 30.32	5.90	\$ 51,567

During the three months ended March 31, 2019 and 2018, the Company recognized \$6.4 million and \$5.8 million, respectively, of stock-based compensation expense related to stock options. As of March 31, 2019, there was \$61.6 million of unrecognized stock-based compensation expense related to unvested options, which will be recognized over a weighted-average period of 3.1 years.

The following table summarizes the activity relating to the Company’s RSUs for the three months ended March 31, 2019:

	Number of RSUs	Weighted-Average Fair Value Per Share
Outstanding and unvested at December 31, 2018	37,475	\$ 66.96
Granted	2,000	\$ 46.54
Vested	(3,125)	\$ 73.86
Outstanding and unvested at March 31, 2019	<u>36,350</u>	<u>\$ 65.24</u>

During the three months ended March 31, 2019 and 2018, the Company recognized \$0.2 million and \$0.1 million, respectively, of stock-based compensation expense related to RSUs. As of March 31, 2019, there was \$1.9 million of unrecognized stock-based compensation expense related to unvested RSUs, which will be recognized over a weighted-average period of 3.0 years.

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9. Leases

The Company has operating leases primarily related to the Company's principal executive office and other IT related equipment. The lease for the principal executive office has a lease term of 5 years and the IT equipment primarily has a term of 3 years. During the three months ended March 31, 2019, the Company recognized \$0.1 million of operating lease costs, recognized on the Condensed Statements of Operations, and paid cash for the amounts included in the measurement of lease liabilities of \$0.1 million, which were included in operating cash flows on the Condensed Statements of Cash Flows. At March 31, 2019, the weighted-average remaining lease term of operating leases was 4.5 years and the weighted average discount rate was 8.6%. There were no right of use assets obtained in exchange for lease obligations in the three months ended March 31, 2019. The Company had no additional operating and finance leases that have not yet commenced as of March 31, 2019.

The following table summarizes the Company's future maturities of operating lease liabilities as of March 31, 2019:

	(in thousands)
2019	\$ 195
2020	266
2021	249
2022	256
2023	216
Total lease payments	1,182
Less imputed interest	206
Total	<u>\$ 976</u>

The following table summarizes supplemental balance sheet information related to leases as of March 31, 2019:

Operating Leases

	(in thousands)
Right of use operating lease assets (short-term)	\$ 185
Right of use operating lease assets (long-term)	766
Total right of use operating lease assets	<u>\$ 951</u>
Operating lease liabilities (short-term)	\$ 184
Operating lease liabilities (long-term)	792
Total lease obligations under operating leases	<u>\$ 976</u>

10. Income Taxes

There was no provision for income taxes for the three months ended March 31, 2019 and 2018, because the Company has incurred annual operating losses since inception. At March 31, 2019, the Company continues to conclude 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.

11. Net Income (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, including shares that potentially could be dilutive if they were exercised during the period, determined using the treasury-stock method.

	<u>March 31,</u> <u>2019</u>	<u>March 31,</u> <u>2018</u>
Net income (loss) (in thousands)	\$ 87,379	\$ (46,130)
Weighted average shares - basic	26,842,785	26,605,189
Effect of dilutive shares:		
Warrants for common stock	5,443	—
Common shares under option	1,601,288	—
Unvested RSUs	251	—
Dilutive shares	<u>1,606,982</u>	<u>—</u>
Weighted average shares - diluted	<u>28,449,767</u>	<u>26,605,189</u>
Net income (loss) per common share - basic	\$ 3.26	\$ (1.73)
Net income (loss) per common share - diluted	\$ 3.07	\$ (1.73)

The shares outstanding at the end of the respective periods presented below were excluded from the calculation of diluted net income (loss) per share due to their anti-dilutive effect:

	<u>March 31,</u> <u>2019</u>	<u>March 31,</u> <u>2018</u>
Warrants for common stock	—	8,230
Common shares under option	2,288,037	4,211,025
Unvested RSUs	34,350	13,750
Total potential dilutive shares	<u>2,322,387</u>	<u>4,233,005</u>

12. Statements of Cash Flows

The following table provides a reconciliation of cash and cash equivalents and restricted cash presented on the Condensed Balance Sheets to the same amounts presented on the Condensed Statements of Cash Flows on March 31, 2019 and 2018.

	<u>March 31,</u> <u>2019</u>	<u>March 31,</u> <u>2018</u>
Cash and cash equivalents	\$ 174,836	\$ 30,823
Restricted cash	1,193	—
Total cash and cash equivalents and restricted cash shown on the Condensed Statements of Cash Flows	<u>\$ 176,029</u>	<u>\$ 30,823</u>

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, 2018.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). These forward-looking statements are based on our management's belief and assumptions and on information currently available to management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events, including our clinical development plans, or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements, including in relation to the clinical development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet to be materially different from any future results, performance or achievements, including in relation to the clinical development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, 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 complementary, cost-effective, convenient, 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 the bempedoic acid / ezetimibe combination tablet are targeted therapies that have been shown to significantly lower elevated LDL-C levels in patients with hypercholesterolemia, including patients inadequately treated with current lipid-modifying therapies.

On February 20, 2019, we submitted the new drug application, or NDA, for bempedoic acid and on February 26, 2019, we submitted the NDA for the bempedoic acid / ezetimibe combination tablet to the Food and Drug Administration, or FDA, for LDL-C lowering indications. On May 5, 2019, we announced that the FDA accepted our NDAs for bempedoic acid and the bempedoic acid / ezetimibe combination tablet for filing and regulatory review. The Prescription Drug User Fee Act, or PDUFA, goal date for completion of the bempedoic acid NDA review is set for February 21, 2020, and the PDUFA goal date for completion of the bempedoic acid / ezetimibe combination tablet NDA review is set for February 26, 2020. These dates are consistent with our expectations and reflect the standard review period. The FDA has communicated that there is no current plan to hold an advisory committee meeting to discuss the applications. On February 11, 2019, we submitted the Marketing Authorization Applications, or MAAs, for bempedoic acid and the bempedoic acid / ezetimibe combination tablet to the European Medicines Agency, or EMA. On February 28, 2019, the EMA completed formal validation of the MAAs for bempedoic acid and the bempedoic acid / ezetimibe combination tablet for LDL-C lowering indications.

On January 2, 2019, we entered into a license and collaboration agreement with Daiichi Sankyo Europe GmbH, or DSE. Pursuant to the agreement, we have granted DSE exclusive commercialization rights to bempedoic acid and the bempedoic acid /

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ezetimibe combination tablet in the European Economic Area and Switzerland, or the DSE Territory. DSE will be responsible for commercialization in the DSE Territory. We remain responsible for clinical development, regulatory and manufacturing activities for the licensed products globally, including in the DSE Territory. Pursuant to the agreement, the consideration consists of a \$150 million upfront cash payment as well as \$150 million cash payment upon first commercial sales in the DSE Territory. We are also eligible to receive a substantial additional regulatory milestone payment upon the grant of the marketing authorization in the European Union for the CV risk reduction label, depending on the range of relative risk reduction in the CLEAR Outcomes study. In addition, we are eligible to receive additional sales milestone payments. Finally, we will receive tiered fifteen percent (15%) to twenty-five percent (25%) royalties on net DSE Territory sales.

We are conducting a global cardiovascular outcomes trial, or CVOT, — known as **C**holesterol **L**owering via **B**empedoic Acid, an **A**CL-inhibiting **R**egimen (CLEAR) Outcomes, for bempedoic acid in 12,604 patients with hypercholesterolemia and high CVD risk and who can be considered statin averse. We initiated the CLEAR Outcomes CVOT in December 2016 and expect the study to be fully enrolled in the third quarter of 2019. We intend to use positive results from this CVOT to support 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 and the bempedoic acid / ezetimibe combination tablet. 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, the incurrence of indebtedness and through collaborations with third parties, and we have incurred losses in each year since our inception.

We do not have any products approved for sale. To date, we have not generated any revenue from the sales of bempedoic acid or the bempedoic acid / ezetimibe combination tablet. In the three months ended March 31, 2019, the initial upfront payment from the collaboration agreement with DSE provided \$145.4 million in revenue, driving net income of \$87.4 million, which was the first quarter we have been profitable. We incurred a net loss of \$46.1 million for the three months ended March 31, 2018. All of our prior 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 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 activities for the CLEAR Outcomes CVOT;
- seeking regulatory approvals for bempedoic acid and the bempedoic acid / ezetimibe combination tablet;
- commercializing bempedoic acid and the bempedoic acid / ezetimibe combination tablet, if approved; and
- operating as a public company.

Accordingly, we may need additional financing to support our continuing operations and further the development of our product candidates. We may seek to fund our operations and further development activities through collaborations with third parties, strategic alliances, licensing arrangements, debt financings, public or private equity offerings or through other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a material adverse effect on our financial condition and our ability to pursue our business strategy or continue operations. We will need to generate significant revenues to achieve profitability, and we may never do so.

Product Overview

Bempedoic acid is our lead, non-statin, complementary, orally available, once-daily, LDL-C lowering therapy. With a targeted mechanism of action, bempedoic acid is a first-in-class, ATP Citrate Lyase, or ACL, inhibitor that reduces cholesterol biosynthesis and lowers LDL-C by up-regulating the LDL receptor. Similar to statins, bempedoic acid also reduces high sensitivity C-reactive protein, or hsCRP, a key marker of inflammation associated with cardiovascular disease. Completed Phase 3 studies conducted in more than 4,000 patients, with over 2,600 patients treated with bempedoic acid, have produced an additional 18 percent LDL-C lowering when used with moderate- and high-intensity statins and 28 percent LDL-C lowering when used with no background statin.

Through the complementary mechanisms of action of inhibition of cholesterol synthesis (bempedoic acid) and inhibition of cholesterol absorption (ezetimibe), the bempedoic acid / ezetimibe combination tablet is a non-statin, orally available, once-daily, LDL-C lowering therapy. Inhibition of 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 the LDL receptors. Phase 3 data demonstrated that this combination results in a 29 percent LDL-C lowering when used with maximally tolerated statins, a 44 percent LDL-C lowering when used with no background statin (post-hoc analysis), and a 34 percent reduction in hsCRP.

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During the three months ended March 31, 2019, we incurred \$30.3 million in expenses related to our CLEAR Outcomes CVOT, our open-label extension study, and our 1002FDC-058 study.

During the three months ended March 31, 2018, we incurred \$30.0 million in expenses related to the four studies in our global pivotal Phase 3 LDL-C lowering program, our CLEAR Outcomes CVOT, our 1002FDC-053 study and our Phase 2 (1002-39) clinical study of bempedoic acid when added-on to an injectable proprotein convertase subtilisin/kexin type 9 inhibitor, or PCSK9i, therapy in patients with hypercholesterolemia.

Program Developments

Results from the initial clinical study of the 100 mg sustained release formulation of bempedoic acid demonstrated consistent twenty nine percent (29%) LDL-C lowering, with approximately one-half the active pharmaceutical ingredient of the current 180 mg bempedoic acid tablet, as well as favorable safety and Pharmacokinetics, or PK, parameters. These results provide initial proof-of-concept for the sustained release formulation of bempedoic acid to increase efficacy, extend the patent life of the bempedoic acid franchise into 2038 while utilizing a 505(b)(2) regulatory pathway to approval, and reduce manufacturing costs.

Ongoing Clinical Studies

1002FDC-058 — Phase 2 efficacy and safety study of the bempedoic acid / ezetimibe combination tablet in patients with hypercholesterolemia and Type 2 Diabetes

1002FDC-058 is a Phase 2 clinical study assessing the efficacy and safety of the bempedoic acid / ezetimibe combination tablet in patients with hypercholesterolemia and type 2 diabetes. Initiated in June 2018, the 12-week, randomized, double-blind, placebo-controlled, parallel-dose study consists of three treatment arms evaluating the efficacy and safety of a once-daily, oral fixed dose combination tablet of bempedoic acid 180 mg and ezetimibe 10 mg versus placebo and versus ezetimibe 10 mg alone. The study is expected to enroll approximately 242 patients at approximately 45 sites across the U.S. The co-primary objectives of the study are to assess the 12-week LDL-C lowering efficacy in patients treated with the bempedoic acid / ezetimibe combination tablet versus placebo and versus ezetimibe 10 mg alone. Secondary objectives include evaluating 12-week hsCRP, non-HDL-C, apolipoprotein B, or apoB, total cholesterol and triglycerides. Exploratory objectives include 12-week HbA1c, fasting glucose, fasting insulin and additional glycemic measurements. We expect to report top-line results in the second half of 2019.

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

Safety data will be obtained from an open-label extension study which completed enrollment of 1,462 of the 2,230 patients enrolled in Study 1 in March 2018. Initiated in February 2017, this open-label extension study will evaluate the long-term safety of bempedoic acid 180 mg in high CVD risk patients with hypercholesterolemia and with atherosclerotic cardiovascular disease, or ASCVD, and/or heterozygous familial hypercholesterolemia, 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. The open-label extension study will be completed in the fourth quarter of 2019.

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 ASCVD and/or HeFH, or who are at high risk for CVD, with hypercholesterolemia and who are only able to tolerate less than the lowest approved daily starting dose of a statin and can be considered statin averse. The CLEAR Outcomes CVOT is expected to enroll approximately 12,600 patients with ASCVD or at high risk for CVD in over 1,000 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

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LDL-C levels greater than 100 mg/dL despite background lipid-lowering therapy, resulting in an expected average baseline LDL-C level in all patients of approximately 135 mg/dL. The primary efficacy endpoint of the event-driven global study is the effect of bempedoic acid versus placebo on the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, 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.

Financial Operations Overview

Revenue

To date, we have not generated any revenue from product sales. In the future, we may never generate revenue from the sale of bempedoic acid or the bempedoic acid / ezetimibe combination tablet or other product candidates. In the three months ended March 31, 2019, we recognized \$145.4 million of revenue associated with the \$150.0 million upfront payment from our collaboration agreement with DSE. We expect to recognize the remaining \$4.6 million ratably over the period leading up to the approval of the MAA acceptance by the EMA due to an ongoing performance obligation related to the ongoing regulatory efforts for the MAA in the DSE Territory. If we fail to complete the development of bempedoic acid or the bempedoic acid / ezetimibe combination tablet or any other product candidates and secure approval from regulatory authorities, our ability to generate future revenue and our results of operations and financial position will be adversely affected.

Research and Development Expenses

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

- expenses incurred under agreements with consultants, contract research organizations, or CROs, and investigative sites that conduct our preclinical and clinical studies;
- the cost of acquiring, developing and manufacturing clinical study materials, including the procurement of ezetimibe in our continued development of our bempedoic acid / ezetimibe combination tablet;
- employee-related expenses, including salaries, benefits, stock-based compensation and travel expenses;
- allocated expenses for rent and maintenance of facilities, insurance and other supplies; and
- costs related to compliance with regulatory requirements.

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

Our research and development expenses are expected to continue in the foreseeable future as they relate to our ongoing CLEAR Outcomes CVOT, our NDA and MAA submissions and any other development programs or additional indications we choose to pursue. We cannot determine with certainty the duration and completion costs associated with the ongoing or future clinical studies of bempedoic acid and the bempedoic acid / ezetimibe combination tablet. Also, we cannot conclude with certainty if, or when, we will generate revenue from the commercialization and sale of bempedoic acid or the bempedoic acid / ezetimibe combination tablet, if ever. We may never succeed in obtaining regulatory approval for bempedoic acid or the bempedoic acid / ezetimibe combination tablet. The duration, costs and timing associated with the development and commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablet will depend on a variety of factors, including uncertainties associated with the results of our clinical studies and our ability to obtain regulatory approval. For example, if the FDA or another regulatory authority were to require us to conduct clinical studies beyond those that we currently anticipate will be required for the completion of clinical development or post-commercialization clinical studies of bempedoic acid or the bempedoic acid / ezetimibe combination tablet, or if we experience significant delays in enrollment in any of our clinical studies, we could be

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required to expend significant additional financial resources and time on the completion of clinical development or post-commercialization clinical studies of bempedoic acid and the bempedoic acid / ezetimibe combination tablet.

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, commercial, operational and other administrative functions. Other general and administrative expenses include facility-related costs, communication expenses and professional fees for legal, patent prosecution, protection and review, consulting and accounting services.

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

Other Income, Net

Other income, net, primarily relates to interest income and the accretion or amortization of premiums and discounts earned on our cash, cash equivalents and investment securities. Costs during the three months ended March 31, 2018 also includes interest expense associated with our credit facility and non-cash interest costs associated with the amortization of the related debt discount, deferred issuance costs and final payment fee.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. We evaluate our estimates and judgments on an ongoing basis, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, contractual milestones and other various factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

Revenue Recognition - Collaboration Revenue

We have entered into an agreement related to our activities to develop, manufacture, and commercialize our product candidates. We earn collaboration revenue in connection with a collaboration agreement to develop and/or commercialize product candidates where we deem the collaborator to be our customer. We have adopted ASC 606, Revenue from Contracts with Customers, and under the terms of the standard, revenue is measured as the amount of consideration we expect to be entitled to in exchange for transferring promised goods or providing services to a customer. Revenue is recognized when (or as) we satisfy performance obligations under the terms of a contract. Depending on the terms of the arrangement, we may defer the recognition of all or a portion of the consideration received as the performance obligations are satisfied.

The collaboration agreement may require us to deliver various rights, services, and/or goods across the entire life cycle of a product or product candidate. In the agreement involving multiple goods or services promised to be transferred to a customer, we must assess, at the inception of the contract, whether each promise represents a separate performance obligation (i.e., is “distinct”), or whether such promises should be combined as a single performance obligation.

The terms of the agreement typically include consideration to be provided to us in the form of non-refundable up-front payments, development milestones, sales milestones, and royalties on sales of products within a respective territory.

At the inception of the contract, the transaction price reflects the amount of consideration we expect to be entitled to in exchange for transferring promised goods or services to our customer. In the arrangement where we satisfy performance obligation(s) during the regulatory phase over time, we recognize collaboration revenue typically using an input method on the basis of our regulatory costs incurred relative to the total expected cost which determines the extent of our progress toward completion. We review the estimate of the transaction price and the total expected cost each period, and make revisions to such estimates as necessary.

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Under our collaboration agreement, product sales and cost of sales may be recorded by our collaborators as they are deemed to be the principal in the transaction. We receive royalties from the commercialization of such products, and record our share of the variable consideration, representing a percentage of net product sales, as collaboration revenue in the period in which such underlying sales occur and costs are incurred by our collaborator. Our collaborator will provide us with estimates of our royalties for such quarter; these estimates are reconciled to actual results in the subsequent quarter, and the royalty is adjusted accordingly, as necessary.

Recent Accounting Pronouncements

In November 2018, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update, or ASU, 2018-08, which clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Accounting Standards Codification, or ASC, 606 when the collaborative arrangement participant is a customer in the context of a unit of account. The standard is effective for public companies for fiscal years beginning after December 15, 2019, and interim periods within those years. Early adoption is permitted, included in any interim period, provided an entity has already adopted ASC 606 or does so concurrently with the adoption of this guidance. We early adopted this guidance as of January 1, 2019, and implemented the new guidance in our consideration of the accounting for the DSE collaboration signed on January 2, 2019. Refer to Note 2 “Summary of Significant Accounting Policies” and Note 3 “Collaborations with Third Parties” in the Notes to the Condensed Financial Statements for further information.

In February 2016, the FASB issued ASU 2016-02, which was amended by subsequent updates (collectively the “lease standard” or “ASC 842”), and is intended to improve financial reporting about leasing transactions. The updated guidance requires a lessee to recognize assets and liabilities for leases with lease terms of more than twelve months. We adopted the standard on January 1, 2019 using the modified retrospective method. Results for the reporting period beginning after December 31, 2018 have been presented in accordance with the standard, while results for prior periods have not been adjusted. We recognized \$1.0 million and \$1.0 million of operating lease assets and operating lease liabilities, respectively, on our balance sheets as of January 1, 2019, primarily related to the lease agreement for our principal executive office. Refer to Note 9 “Leases” in the Notes to the Condensed Financial Statements for further information.

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, 2018.

Results of Operations

Comparison of the Three Months Ended March 31, 2019 and 2018

The following table summarizes our results of operations for the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,		Change
	2019	2018	
	(unaudited, in thousands)		
Revenue:			
Collaboration revenue	\$ 145,419	\$ —	\$ 145,419
Operating Expenses:			
Research and development	46,308	40,940	5,368
General and administrative	12,182	5,954	6,228
Income (loss) from operations	86,929	(46,894)	133,823
Other income, net	450	764	(314)
Net income (loss)	<u>\$ 87,379</u>	<u>\$ (46,130)</u>	<u>\$ 133,509</u>

Revenue

Collaboration revenue recognized from our collaboration agreement with DSE for the three months ended March 31, 2019 was \$145.4 million. Revenue was attributable to the initial recognition of the upfront payment from our collaboration agreement signed on January 2, 2019.

Research and development expenses

Research and development expenses for the three months ended March 31, 2019, were \$46.3 million, compared to \$40.9 million for the three months ended March 31, 2018, an increase of \$5.4 million. The increase in research and development expenses was primarily related to clinical development costs for bempedoic acid and the bempedoic acid / ezetimibe combination tablet, including costs to support the ongoing CLEAR CVOT, regulatory submissions and increases in our headcount.

General and administrative expenses

General and administrative expenses for the three months ended March 31, 2019, were \$12.2 million, compared to \$6.0 million for the three months ended March 31, 2018, an increase of \$6.2 million. The increase in general and administrative expenses was primarily attributable to costs to support public company operations, including costs to support pre-commercialization activities, further increases in our headcount and stock-based compensation expense, and other costs to support our growth.

Other income, net

Other income, net for the three months ended March 31, 2019, was \$0.5 million, compared to \$0.8 million for the three months ended March 31, 2018. This decrease was primarily related to a decrease in interest income earned on our cash, cash equivalents and investment securities.

Liquidity and Capital Resources

We have funded our operations to date primarily through proceeds from sales of preferred stock, convertible promissory notes and warrants, public offerings of common stock, the incurrence of indebtedness and milestone payments from collaboration agreements. In August 2017, we completed an underwritten public offering of 3,100,000 shares of common stock. We also granted the underwriters a 30-day option to purchase up to 465,000 additional shares of our common stock, which was exercised in full in September 2017. All of the shares were offered by us at a price to the public of \$49.00 per share for net proceeds of \$164.0 million. Pursuant to the license and collaboration agreement with DSE signed on January 2, 2019, we received an upfront cash payment of \$150.0 million from DSE and are eligible for substantial additional sales and regulatory milestone payments and royalties. To date, we have not generated any revenue from product sales and we anticipate that we will incur losses for the foreseeable future.

As of March 31, 2019, our primary sources of liquidity were our cash and cash equivalents and available-for-sale investments, which totaled \$174.8 million and \$53.7 million, respectively. We invest our cash equivalents and investments in highly liquid, interest-bearing investment-grade and government securities to preserve principal.

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

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Cash provided by (used in) operating activities	\$ 91,691	\$ (43,221)
Cash provided by investing activities	45,696	30,283
Cash provided by financing activities	1,669	9,293
Net increase (decrease) in cash and cash equivalents	\$ 139,056	\$ (3,645)

Operating Activities

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

Net cash provided by operating activities totaled \$91.7 million for three months ended March 31, 2019, consisting of the \$150.0 million upfront payment from the DSE collaboration offset by cash used to fund the development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, adjusted for non-cash expenses such as stock-based compensation expense, depreciation and amortization and changes in working capital. Net cash used in operating activities totaled \$43.2 million for the three months ended March 31, 2018. The primary use of our cash for the three months ended March 31, 2018 was to fund the development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, 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 \$45.7 million and \$30.3 million for the three months ended March 31, 2019 and 2018, respectively, consisted primarily of proceeds from the sale and maturities of highly liquid, interest bearing investment-grade and government securities.

Financing Activities

Net cash provided by financing activities of \$1.7 million and \$9.3 million for the three months ended March 31, 2019 and 2018, respectively, related primarily to proceeds from exercise of our common stock options.

Plan of Operations and Funding Requirements

We expect to continue to incur significant expenses and operating losses for the foreseeable future in connection with our ongoing CLEAR Outcomes CVOT, NDA and MAA submissions and commercial launch activities. Pursuant to the license and collaboration agreement with DSE, we received an upfront cash payment of \$150.0 million from DSE and are eligible for substantial additional sales and regulatory milestone payments and royalties, including an additional \$150.0 million upon first commercial sale in the DSE Territory. We estimate that current cash resources and proceeds to be received in the future under the DSE collaboration agreement are sufficient to fund operations through the expected approvals of bempedoic acid and the bempedoic acid / ezetimibe combination tablet and the commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, if approved for an LDL-C lowering indication. We may, however, need to secure additional cash resources to continue to fund the commercialization and further development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet. We have based these estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablet and the extent to which we entered and may enter into collaborations with pharmaceutical partners regarding the development and commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development and commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablet. Our future funding requirements will depend on many factors, including, but not limited to:

- our ability to successfully develop and commercialize bempedoic acid and the bempedoic acid / ezetimibe combination tablet or other product candidates;
- the costs, timing and outcomes of our CLEAR Outcomes CVOT and other ongoing clinical studies of bempedoic acid and the bempedoic acid / ezetimibe combination tablet;
- the time and cost necessary to obtain regulatory approvals for bempedoic acid and the bempedoic acid / ezetimibe combination tablet, if at all;
- our ability to establish a sales, marketing and distribution infrastructure to commercialize bempedoic acid and the bempedoic acid / ezetimibe combination tablet or our ability to establish any future collaboration or commercialization arrangements on favorable terms, if at all;
- our ability to realize the intended benefits of our existing and future collaboration and partnerships;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the implementation of operational and financial information technology.

Until such time, if ever, as we can generate U.S. substantial product revenues, we expect to finance our cash needs through a combination of collaborations with third parties, strategic alliances, licensing arrangements, debt financings and equity offerings or other sources. 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, such as the collaboration arrangement with DSE, 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

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financings or through collaborations, strategic alliances or licensing arrangements or royalty-based financing arrangements when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market bempedoic acid and the bempedoic acid / ezetimibe combination tablet that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

There have been no 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, 2018.

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 \$174.8 million and \$53.7 million at March 31, 2019, and \$37.0 million and \$99.3 million at December 31, 2018, 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 three months ended March 31, 2019.

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 three months ended March 31, 2019.

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 our Chief Financial Officer, who is our principal financial officer, to allow timely decisions regarding required disclosure.

As of March 31, 2019, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of March 31, 2019, 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.

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 plaintiffs filed a notice of appeal to the Sixth Circuit Court of Appeals and on September 14, 2017, they filed their opening brief in support of the appeal. The appeal was fully briefed on December 7, 2017, and it was argued before the Sixth Circuit on March 15, 2018. On September 27, 2018, the Sixth Circuit issued an opinion in which it reversed the district court's dismissal and remanded for further proceedings. On October 11, 2018, we filed a petition for rehearing en banc and, on October 23, 2018, the Sixth Circuit of Appeals directed plaintiffs to respond to that petition. On December 3, 2018, the Sixth Circuit denied our petition for en banc rehearing, and on December 11, 2018, the case was returned to the federal district court by mandate from the Sixth Circuit. On December 26, 2018, we filed our answer to the amended complaint, and on March 28, 2019, we filed our amended answer to the amended complaint. 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.

On December 15, 2016, a purported stockholder of our company filed a derivative lawsuit in the Court of Chancery of the State of Delaware against Tim Mayleben, Roger Newton, Mary McGowan, Nicole Vitullo, Dov Goldstein, Daniel Janney, Antonio Gotto Jr., Mark McGovern, Gilbert Omenn, Scott Braunstein, and Patrick Enright. Our company is named as a nominal defendant. The lawsuit alleges that the defendants breached their fiduciary duties to the company when they made or approved improper statements on August 17, 2015, regarding our lead product candidate's path to FDA approval, and failed to ensure that reliable systems of internal controls were in place at our company. On February 8, 2019, we and the defendants filed a motion to dismiss the derivative lawsuit. On April 23, 2019, the plaintiff filed an opposition to the motion to dismiss the derivative lawsuit. The lawsuit seeks, among other things, any damages sustained by us as a result of the defendants' alleged breaches of fiduciary duties, including damages related to the above-referenced securities class action, an order directing us to take all necessary actions to reform and improve our corporate governance and internal procedures, restitution from the defendants, and attorneys' fees and costs. 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.

On May 7, 2018, a purported stockholder of our company filed a putative class action lawsuit in the United States District Court for the Eastern District of Michigan, captioned *Kevin Bailey v. Esperion Therapeutics, Inc., et al.* (No. 18-cv-11438). An amended complaint was filed on October 22, 2018, against us and certain directors and officers. The amended complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 based on allegedly making false and misleading statements and omissions about the safety and tolerability of bempedoic acid, and specifically facts and circumstances surrounding the Phase 3 trial results for bempedoic acid that we announced on May 2, 2018. On November 13, 2018, we filed a motion to dismiss the amended complaint, and that motion was fully briefed on December 18, 2018. The lawsuit sought, among other things, compensatory damages in connection with an allegedly inflated stock price between February 22, 2017, and May 22, 2018, as well as attorneys' fees and costs. On February 19, 2019, the court granted our motion to dismiss with prejudice and entered judgment in our favor.

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, 2018.

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, 2018 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, 2018. 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 the Securities Markets and Investment in our Common Stock

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

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. For example, a purported securities class action lawsuit was filed in January 2016 naming us and certain of our officers as defendants. In December 2016, the federal district court granted our motion to dismiss with prejudice and entered judgment in our favor. In May 2017, the court denied plaintiffs’ motion to alter or amend that judgment. On June 19, 2017, plaintiffs filed a notice of appeal to the Sixth Circuit Court of Appeals and on September 14, 2017, they filed their opening brief in support of the appeal. The appeal was fully briefed on December 7, 2017, and it was argued before the Sixth Circuit on March 15, 2018. On September 27, 2018, the Sixth Circuit issued an opinion in which it reversed the district court’s dismissal and remanded for further proceedings. On October 11, 2018, we filed a petition for rehearing en banc and, on October 23, 2018, the Sixth Circuit Court of Appeals directed plaintiffs to respond to that petition. On December 3, 2018, the Sixth Circuit Court of Appeals denied our petition for en banc rehearing, and on December 11, 2018, the case was returned to the federal district court by mandate from the Sixth Circuit. On December 26, 2018, we filed our answer to the amended complaint, and on March 28, 2019, we filed our amended answer to the amended complaint.

Additionally, in December 2016, a purported derivative action was filed in Delaware against certain of our directors and officers. In February 2019, our company and defendants filed a motion to dismiss the derivative lawsuit. In April 2019, the plaintiff filed an opposition to the motion to dismiss the derivative lawsuit. In May 2018, a purported securities class action lawsuit was filed naming us and certain of our officers as defendants. In November 2018, we filed a motion to dismiss and such motion was fully briefed in December 2018. In February 2019, the court granted our motion to dismiss with prejudice and entered judgment in our favor.

Any lawsuit to which we or our directors or officers are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our offerings or business practices. Any of these results could adversely affect our business. In addition, defending claims is costly and can impose a significant burden on our management. This proceeding and any others in which we may become involved could result in substantial costs and a diversion of management’s attention and resources, which could harm our business.

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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.

EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference to:			
		Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	S-1/A	3.2	6/12/2013	333-188595
3.2	Amended and Restated By-Laws of the Registrant.	S-1/A	3.4	6/12/2013	333-188595
4.1	Specimen Common Stock Certificate of the Registrant.	S-1/A	4.1	6/12/2013	333-188595
10.1**	License and Collaboration Agreement by and between the Company and Daiichi Sankyo Europe GmbH, dated January 2, 2019.	10-K	10.16	2/28/2019	001-35986
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
32.1 ⁺	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101.INS*	XBRL Instance Document.				
101.SCH*	XBRL Taxonomy Extension Schema Document.				
101.CAL*	XBRL Taxonomy Extension Calculation Document.				
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document.				
101.PRE*	XBRL Taxonomy Extension Presentation Link Document.				

* Filed herewith.

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

+ 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.

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.

May 8, 2019

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

May 8, 2019

By: /s/ Richard B. Bartram
Richard B. Bartram
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Certification

I, Tim M. Mayleben certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended March 31, 2019, of Esperion Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2019

/s/ Tim M. Mayleben

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

Certification

I, Richard B. Bartram, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended March 31, 2019, of Esperion Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 8, 2019

/s/ Richard B. Bartram

Richard B. Bartram

Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the quarterly report on Form 10-Q of Esperion Therapeutics, Inc. (the "Company") for the period ended March 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of Esperion Therapeutics, Inc., hereby certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that, to my knowledge as of the date hereof:

- 1) the Report which this statement accompanies fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 8, 2019

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

/s/ Richard B. Bartram
Richard B. Bartram
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)
