Esperion Therapeutics, Inc.
Form 10-Q
November 06, 2013
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# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

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# Form 10-Q

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

**For the quarterly period ended September 30th 2013**

**OR**

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

**For the transition period from to**

**Commission file number: 001-35986**

# Esperion Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

| **Delaware** | **26-1870780** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |

**46701 Commerce Center Drive**
**Plymouth, MI 48170**

(Address of principal executive office) (Zip Code)

Registrant s telephone number, including area code:

**(734)862-4840**

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 x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

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

| | |
|---|---|
| Large accelerated filer o | Accelerated filer o |
| Non-accelerated filer x (Do not check if a smaller reporting company) | Smaller reporting company o |

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

As of November 1, 2013, there were 15,357,413 shares of the registrant s Common Stock, $0.001 par value per share, outstanding.

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**Esperion Therapeutics, Inc.**

**(A Development Stage Company)**

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**Esperion Therapeutics, Inc.**

**(A Development Stage Company)**

**Condensed Balance Sheets**

| | September 30, 2013 (Unaudited) | December 31, 2012 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 71,895,828 | $ 6,511,521 |
| Prepaid clinical development costs | 503,394 | 367,216 |
| Other prepaid and current assets | 535,716 | 150,325 |
| Assets held for sale | 29,108 | 109,344 |
| Total current assets | 72,964,046 | 7,138,406 |
| | | |
| Property and equipment, net | 78,749 | 120,210 |
| Intangible assets | 55,740 | 53,825 |
| Investments | 13,477,277 | |
| Total assets | $ 86,575,812 | $ 7,312,441 |
| | | |
| **Liabilities, convertible preferred stock and stockholders deficit** | | |
| Current liabilities: | | |
| Short term borrowings with related parties, net of debt discount | $ | $ 15,241,007 |
| Accrued interest | | 738,192 |
| Accounts payable | 1,944,604 | 476,277 |
| Accrued clinical development costs | 449,976 | 242,171 |
| Warrant liabilities | | 265,323 |
| Other accrued liabilities | 948,376 | 210,329 |
| Total current liabilities | 3,342,956 | 17,173,299 |
| | | |
| Long-term debt | | 7,528,845 |
| Total liabilities | 3,342,956 | 24,702,144 |
| Commitments and contingencies (Note 5) | | |
| **Convertible preferred stock:** | | |
| | | |
| Series A preferred stock par value $0.001; no shares authorized, issued or outstanding as of September 30, 2013; 34,785,000 shares authorized and 23,975,000 shares issued and outstanding at December 31, 2012, aggregate liquidation preference of $23,975,000 at December 31, 2012 | | 23,975,000 |
| **Stockholders deficit:** | | |
| Preferred stock, $0.001 par value; 5,000,000 shares authorized as of September 30, 2013, no shares issued or outstanding at September 30, 2013 | | |
| Common stock, $0.001 par value; 120,000,000 shares authorized as of September 30, 2013 and 50,000,000 shares authorized as of December 31, 2012, respectively; 15,357,413 shares issued and 15,335,223 outstanding at September 30, 2013 and 346,478 shares issued and outstanding at December 31, 2012 | 15,357 | 346 |
| Additional paid-in capital | 141,585,222 | 609,976 |
| Accumulated other comprehensive income | 5,989 | |
| Deficit accumulated during the development stage | (58,373,712) | (41,975,025) |

| | | |
|---|---|---|
| Total stockholders (deficit) equity | 83,232,856 | (41,364,703) |
| Total liabilities, convertible preferred stock and stockholders (deficit) equity | $ 86,575,812 | $ 7,312,441 |

*See accompanying notes to the condensed financial statements.*

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**Esperion Therapeutics, Inc.**

**(A Development Stage Company)**

**Condensed Statements of Operations and Comprehensive Loss**

**(Unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | | Period from January 22, 2008 (Inception) to September 30, 2013 |
|---|---|---|---|---|---|
| | 2013 | 2012 | 2013 | 2012 | |
| **Grant income** | $ | $ | $ | $ | $ 244,479 |
| **Operating expenses:** | | | | | |
| Research and development | 3,482,673 | 2,456,412 | 8,675,688 | 6,343,846 | 36,089,549 |
| General and administrative | 1,924,150 | 533,837 | 4,346,994 | 1,699,867 | 15,796,690 |
| Acquired in-process research and development | | | | | 85,612 |
| Total operating expenses | 5,406,823 | 2,990,249 | 13,022,682 | 8,043,713 | 51,971,851 |
| **Loss from operations** | (5,406,823) | (2,990,249) | (13,022,682) | (8,043,713) | (51,727,372) |
| | | | | | |
| Interest expense | | (361,426) | (936,580) | (925,021) | (4,320,696) |
| Change in fair value of warrant liability | | | (2,586,865) | | (2,554,498) |
| Other income, net | 168,389 | 401 | 147,440 | 2,354 | 228,854 |
| **Net loss** | $ (5,238,434) | $ (3,351,274) | $ (16,398,687) | $ (8,966,380) | $ (58,373,712) |
| Net loss per common share (basic and diluted) | $ (0.34) | $ (10.31) | $ (3.05) | $ (28.27) | |
| Weighted-average shares outstanding (basic and diluted) | 15,253,704 | 325,023 | 5,371,335 | 317,208 | |
| **Other comprehensive income:** | | | | | |
| Unrealized gain on investments | 5,989 | | 5,989 | | |
| **Total comprehensive loss** | $ (5,232,445) | $ (3,351,274) | $ (16,392,698) | $ (8,966,380) | |

*See accompanying notes to the condensed financial statements.*

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**Esperion Therapeutics, Inc.**

**(A Development Stage Company)**

**Condensed Statements of Cash Flows**

**(Unaudited)**

| | Nine Months Ended September 30, 2013 | Nine Months Ended September 30, 2012 | Period from January 22, 2008 (Inception) to September 30, 2013 |
|---|---|---|---|
| **Operating activities** | | | |
| Net loss | $ (16,398,687) | $ (8,966,380) | $ (58,373,712) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation expense | 59,664 | 106,901 | 1,436,835 |
| Amortization of debt discount and beneficial conversion | 458,993 | 18,424 | 575,981 |
| Amortization of debt issuance costs | 18,533 | 6,886 | 33,911 |
| Amortization of premiums and discounts on investments | 12,283 | | 12,283 |
| Revaluation of warrants | 2,586,865 | | 2,554,498 |
| Noncash interest expense on convertible notes | 459,055 | 744,417 | 3,726,092 |
| Write-off of acquired in-process research and development | | | 85,612 |
| Stock-based compensation expense | 673,244 | 60,578 | 930,352 |
| Common stock issued in license agreement | | | 4,400 |
| Loss related to assets held for sale | 29,000 | | 324,701 |
| Gain on sale of assets | (140,029) | (1,949) | (158,488) |
| Changes in assets and liabilities: | | | |
| Prepaids and other assets | (504,568) | (372,943) | (1,041,338) |
| Accounts payable | 1,299,100 | (486,537) | 1,775,377 |
| Other accrued liabilities | 863,535 | 451,840 | 1,316,032 |
| Net cash used in operating activities | (10,583,012) | (8,438,763) | (46,797,464) |
| | | | |
| **Investing activities** | | | |
| Purchases of investments | (13,521,020) | | (45,090,186) |
| Proceeds from sales/maturities of investments | | | 31,515,350 |
| Cash obtained in stock acquisition | | | 2,500,000 |
| Proceeds from sale of assets | 191,265 | 7,060 | 942,464 |
| Purchase of property and equipment | (18,203) | (10,668) | (285,762) |
| Other investing | | | 50,626 |
| Net cash (used in) provided by investing activities | (13,347,958) | (3,608) | (10,367,508) |
| | | | |
| **Financing activities** | | | |
| Proceeds from initial public offering, net of issuance costs | 72,367,768 | | 72,367,768 |
| Proceeds from issuance of preferred stock, net of issuance costs | 16,824,235 | | 40,799,235 |
| Proceeds from exercise of common stock options | 123,274 | 32,362 | 184,097 |
| Proceeds from warrant issuance | | 141,779 | 297,690 |
| Proceeds from debt issuance with related parties | | 9,862,220 | 15,412,010 |
| Net cash provided by financing activities | 89,315,277 | 10,036,361 | 129,060,800 |

| | | | |
|---|---|---|---|
| Net increase (decrease) in cash and cash equivalents | 65,384,307 | 1,593,990 | 71,895,828 |
| Cash and cash equivalents at beginning of period | 6,511,521 | 1,571,084 | |
| Cash and cash equivalents at end of period | $ 71,895,828 | $ 3,165,074 | $ 71,895,828 |
| | | | |
| **Supplemental disclosure of cash flow information:** | | | |
| Conversion of convertible promissory notes, including accrued interest of $923,092 into Series A preferred stock | $ 16,623,092 | $ | $ 16,623,092 |
| Conversion of convertible long-term Pfizer note, including accrued interest of $274,155 into Series A-1 preferred stock | 7,803,000 | | 7,803,000 |
| Initial public offering costs not yet paid | 169,227 | | 169,227 |

*See accompanying notes to the condensed financial statements.*

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**Esperion Therapeutics, Inc.**
**(A Development Stage Company)**

**Notes to the Condensed Financial Statements**

**(Unaudited)**

**1. The Company and Basis of Presentation**

The Company is a biopharmaceutical company focused on the research, development and commercialization of therapies for the treatment of patients with elevated levels of low-density lipoprotein cholesterol (LDL-C) and other cardiometabolic risk factors. ETC-1002, the Company s lead product candidate, is a novel, first in class, orally available, once-daily small molecule therapy designed to target known lipid and carbohydrate metabolic pathways to reduce levels of LDL-C and to avoid side effects associated with existing LDL-C lowering therapies. The Company owns the exclusive worldwide rights to ETC-1002 and its other product candidates.

HDL Therapeutics, Inc. (HDL) was incorporated in the state of Delaware on January 22, 2008. On April 28, 2008, HDL acquired all of the capital stock of Esperion Therapeutics, Inc. (Esperion), a wholly owned subsidiary of Pfizer Inc. On May 5, 2008, Esperion was merged with and into HDL and the Company assumed the name Esperion Therapeutics, Inc. (the Company). Its facilities are located in Plymouth, Michigan.

The Company s primary activities since incorporation have been recruiting personnel, conducting research and development activities, including pre-clinical and clinical testing, performing business and financial planning, and raising capital. Accordingly, the Company is considered to be in development stage.

The Company is subject to the risks associated with a development stage entity, which includes the need to: research, develop, and clinically test potential therapeutic products; obtain regulatory approvals for its products and commercialize them, if approved; expand its management and scientific staff; and finance its operations with an ultimate goal of achieving profitable operations.

The Company has sustained operating losses since inception and expects such losses to continue over the foreseeable future. Management plans to continue to finance operations with a combination of public and private equity issuances, debt arrangements, collaborations and strategic and licensing arrangements. If adequate funds are not available, the Company may not be able to continue the development of its current or future product candidates, or to commercialize its current or future product candidates, if approved.

**Basis of Presentation**

The accompanying condensed financial statements are unaudited and were prepared by the Company in accordance with generally accepted accounting principles in the United States of America (GAAP). In the opinion of management, the Company has made all adjustments, which include only normal recurring adjustments necessary for a fair statement of the Company s financial position and results of operations for the interim periods presented. Certain information and disclosures normally included in the annual financial statements prepared in accordance with GAAP have been condensed or omitted. These condensed financial statements should be read in conjunction with the audited financial statements and accompanying notes for the year ended December 31, 2012 included in the Company s final prospectus dated June 25, 2013 filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the Securities and Exchange Commission on June 26, 2013. The results for the three and nine months ended September 30, 2013 are not necessarily indicative of the results to be expected for a full year, any other interim periods or any future year or period.

**Reverse Stock Split**

On June 11, 2013, in connection with its initial public offering (the IPO), the Company effectuated a 1-for-6.986 reverse stock split of its outstanding common stock, which was approved by the Company s board of directors on June 5, 2013. The reverse stock split resulted in an adjustment to the Series A preferred stock and Series A-1 preferred stock conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. The accompanying financial statements and notes to the financial statements give effect to the reverse stock split for all periods presented. The shares of common stock retained a par value of $0.001 per share. Accordingly, the stockholders deficit reflects the reverse stock split by reclassifying from common stock to Additional paid-in capital in an amount equal to the par value of the decreased shares resulting from the reverse stock split.

**Initial Public Offering**

On July 1, 2013, the Company completed its IPO whereby the Company sold 5,000,000 shares of common stock at a price of $14.00 per share. The shares began trading on the Nasdaq Global Select Market on June 26, 2013. On July 11, 2013, the underwriters exercised their over-allotment option in full and purchased an additional 750,000 shares of common stock at a price of $14.00 per share. The Company received approximately $72.2 million in net proceeds from the IPO, including proceeds from the exercise of the underwriters over-allotment option, net of underwriting discounts and commissions and offering expenses. Upon closing of the IPO, all outstanding shares of preferred stock converted into 9,210,999 shares of common stock; and warrants exercisable for convertible preferred stock were automatically converted into warrants exercisable for 277,690 shares of common stock, resulting in the reclassification of the related convertible preferred stock warrant liability of $2,852,188 to additional paid-in capital (See Note 4).

The following table summarizes the Company s capitalization upon closing of its initial public offering:

| | |
|---|---|
| Total common stock issued as of June 30, 2013 | 396,414 |
| Conversion of Series A preferred stock into common stock upon closing of IPO | 8,244,781 |
| Conversion of Series A-1 preferred stock into common stock upon closing of IPO | 966,218 |
| Sales of common stock through IPO | 5,000,000 |
| Common stock issued as of July 1, 2013 | 14,607,413 |
| Issuance of common stock to underwriters due to exercise of over-allotment | 750,000 |
| Total common stock issued as of July 11, 2013 | 15,357,413 |

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**2. Summary of Significant Accounting Policies**

**Cash and Cash Equivalents**

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

**Investments**

Investments are considered to be available-for-sale and are carried at fair value. Unrealized gains and losses, if any, are reported as a separate component of stockholders deficit. 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 (expense), net. Realized gains and losses, if any, are determined using the specific identification method and in other income (expense), 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 levels of low-density lipoprotein cholesterol and other cardiometabolic risk factors.

**Fair Value of Financial Instruments**

The Company s financial instruments consist principally of cash and cash equivalents, investments, other current assets, accounts payable and accrued liabilities that approximate their carrying 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. Excluding impairment losses recorded on assets held for sale, no other impairment losses have been recorded through September 30, 2013.

**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 pre-clinical studies and trials, non-clinical activities (such as toxicology studies), 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.

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**In-Process Research and Development**

In April 2008, the Company acquired certain tangible research and development assets and intellectual property from Pfizer Inc. (Pfizer). As the acquired in-process research and development had not reached technological feasibility and had no alternative future uses in connection with this asset and intellectual property acquisition and the related purchase price allocation, the Company expensed $85,612 as in-process research and development costs in 2008.

**Accrued Clinical Development Costs**

Outside research costs are a component of research and development expense. These expenses include fees paid to contract 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 operating losses since inception. Accordingly, it is not more likely than not that the Company will realize deferred tax assets and as such, it has recorded a full valuation allowance.

**Warrant Liability**

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 derivative liabilities are recorded on the Company s balance sheet at their fair value on the date of issuance and are marked-to-market on each subsequent reporting period, with the fair value changes recognized in the statement of operations. The warrants are measured using the Black-Scholes option-pricing model subsequent to the pricing of the Company s IPO and a Monte Carlo valuation model for previous periods which are based, in part, upon inputs where there is little or no market data, requiring the Company to develop its own independent assumptions. The Company will continue to adjust the liability for changes in the fair value of these warrants until the earlier of the exercise of the warrants, the expiration of the warrants, or until such time as the warrants are no longer determined to be derivative instruments.

**Stock-Based Compensation**

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

**Recent Accounting Pronouncements**

In February 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2013-02 which is an amendment to the accounting guidance for the presentation of comprehensive income. Under the amended guidance, items that are reclassified to net income from accumulated other comprehensive income in the same reporting period require separate disclosure on the face of the financial statements where net income is presented or within the notes to the financial statements. The adoption of this update did not have a material impact on the Company s financial statements.

In July 2013, the FASB issued ASU 2013-11 which is an amendment to the accounting guidance on income taxes. This guidance provides clarification on the financial statement presentation of an unrecognized benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The amendment will be effective for the Company for interim and annual periods beginning after December 15, 2013, with early adoption permitted. The adoption of this standard is not expected to have a material impact on the Company s financial statements.

**3. Debt**

**Convertible Notes**

In January 2012, the Company issued $6,000,000 of 10% convertible promissory notes for cash. In September and November 2012, the Company issued the aggregate of $9,700,000 of 10% convertible promissory notes that mature on September 4, 2013 for cash. In connection with the September convertible note financing, the Company and the holders of the January 2012 convertible promissory notes agreed to extend the maturity date of the January 2012 notes to September 4, 2013. In February 2013, these convertible promissory notes, with an outstanding principal of $15,700,000 and accrued interest of $923,092, were amended and then converted into 16,623,092 shares of Series A preferred stock, in accordance with their terms and at their conversion price of $1.00 per share, and following such conversion, the notes were cancelled. The holders of the September convertible promissory notes received the benefit of a deemed conversion price of the September convertible promissory notes that were below the estimated fair value of the Series A convertible preferred stock at the time of their issuance. The fair value of this beneficial conversion feature was estimated to be $287,990. The fair value of this beneficial conversion feature was recorded to debt discount and amortized to interest expense using the effective interest method over the term of the convertible promissory notes. As a result of the conversion of the convertible promissory notes into shares of Series A preferred stock on February 12, 2013, the Company recorded the remaining accretion of the beneficial conversion feature of $229,496 as interest expense during the nine months ended September 30, 2013.

In April 2008, the Company acquired all of the capital stock of Esperion from Pfizer in exchange for a non-subordinated convertible note in the original principal amount of $5,000,000. This convertible promissory note had a maturity date of April 28, 2018. The note bore interest at 8.931% annually, payable semiannually on June 30 and December 31 by adding such unpaid interest to the principal of the note, which would thereafter accrue interest. On May 29, 2013 the Company entered into a stock purchase agreement with Pfizer Inc. and sold 6,750,000 shares of Series A-1 preferred stock at a price of $1.1560 per share, which was the fair value at the transaction date. The purchase price was paid through the cancellation of all outstanding indebtedness, including accrued interest, under the Pfizer convertible promissory note, which had an outstanding balance, including accrued interest, of $7,803,000 as of May 29, 2013. The Series A-1 preferred stock issued in connection with this transaction was subsequently converted into 966,218 shares of common stock upon completion of the IPO on July 1, 2013.

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**4. Warrants**

In connection with its various financing transactions, the Company issued warrants to purchase shares of preferred stock which had provisions where the underlying issuance was contingently redeemable based on events outside the Company s control and were recorded as a liability in accordance with ASC 480-10. Warrants classified as derivative liabilities and were recorded on the Company s balance sheet at fair value on the date of issuance and were marked-to-market on each subsequent reporting period, with the fair value changes recognized in the statement of operations. The Company estimated the fair values of the warrants at each reporting period using a Black-Scholes option-pricing model, which is based, in part, upon subjective assumptions including but not limited to stock price volatility, the expected life of the warrants, the risk free interest rate and the fair value of the common stock underlying the warrants. The Company estimates the volatility of its stock based on public company peer group historical volatility that is in line with the expected remaining life of the warrants. The risk free interest rate is based on the U.S. Treasury zero-coupon bond for a maturity similar to the expected remaining life of the warrants. The expected remaining life of the warrants is assumed to be equivalent to their remaining contractual term. In prior periods, a Monte Carlo valuation model was utilized to estimate the fair value of the warrants based on the probability and timing of future financings.

Upon the closing of the Company s IPO, all warrants exercisable for 1,940,000 shares of Series A preferred stock, at an exercise price of $1.00 per share, were automatically converted into warrants exercisable for 277,690 shares of common stock, at an exercise price of $6.99 per share. As a result, the Company concluded the warrants outstanding no longer met the criteria to be classified as derivative liabilities and were reclassified to additional paid-in capital at fair value on the date of reclassification. The 277,690 warrants outstanding as of September 30, 2013 expire in February 2018.

**5. Commitments and contingencies**

In August 2013, the Company entered into the second amendment to the operating lease agreement for its current office and laboratory facility in Plymouth, MI which extended the expiration date of the initial term from October 2, 2013 to April 30, 2014.

**6. Investments**

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

| | September 30, 2013 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
| **Cash equivalents:** | | | | |
| Money Market Funds | $ 13,355,283 | $ | $ | $ 13,355,283 |
| **Investments:** | | | | |
| U.S. treasury notes | 6,083,969 | 2,993 | | 6,086,962 |
| U.S. government agency securities | 7,387,319 | 3,135 | (139) | 7,390,315 |
| Total | $ 26,826,571 | $ 6,128 | $ (139) | $ 26,832,560 |

| | December 31, 2012 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
| **Cash equivalents:** | | | | |
| Money Market Funds | $ 6,357,542 | | | $ 6,357,542 |
| Total | $ 6,357,542 | $ | $ | $ 6,357,542 |

There were no unrealized gains or losses on investments reclassified from accumulated other comprehensive income to other income (expense) in the Statement of Operations during the nine months ended September 30, 2013.

**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. |

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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 |
|---|---|---|---|---|
| **September 30, 2013** | | | | |
| Assets: | | | | |
| Money market funds | $ 13,355,283 | $ 13,355,283 | $ | $ |
| Available for sale securities: | | | | |
| U.S. treasury notes | 6,086,962 | 6,086,962 | | |
| U.S. government agency securities | 7,390,315 | | 7,390,315 | |
| | | | | |
| Total assets at fair value | $ 26,832,560 | $ 19,442,245 | $ 7,390,315 | $ |
| | | | | |
| **December 31, 2012** | | | | |
| Assets: | | | | |
| Money market funds | $ 6,357,542 | $ 6,357,542 | $ | $ |
| Total assets at fair value | $ 6,357,542 | $ 6,357,542 | $ | $ |
| Liabilities: | | | | |
| Warrants | $ 265,323 | $ | $ | $ 265,323 |
| Total liabilities at fair value | $ 265,323 | $ | $ | $ 265,323 |

There were no transfers between Levels 1, 2 or 3 during the nine months ended September 30, 2013 or September 30, 2012.

The following table summarizes the changes in the fair value of the Company s Level 3 warrant liabilities the nine month period ended September 30, 2013:

| | Warrant Liability |
|---|---|
| Level 3 Liabilities: | |
| As of December 31, 2012 | $ 265,323 |
| Change in fair value | 2,586,865 |
| Reclassification of warrants liabilities to additional paid-in capital in conjunction with the conversion of the convertible preferred stock into common stock upon the closing of the Company s IPO | (2,852,188) |
| As of September 30, 2013 | $ |

**Fair Value Measurements on a Nonrecurring Basis**

In addition to items that are measured at fair value on a recurring basis, the Company also measures assets held for sale at the lower of its carrying amount or fair value on a nonrecurring basis. During the nine months ended September 30, 2013, the Company recognized an impairment loss of $27,000 based on recent purchase offers. The Company recognized $214,393 of impairment expense related to the assets held for sale in the period from inception through September 30, 2013. The fair value of assets held for sale was estimated using a market approach, considering the estimated fair value for other comparable equipment which are Level 3 inputs.

**8. Convertible Preferred Stock and Stockholders Deficit**

On April 19, 2013, the Company issued and sold an aggregate of 17,000,000 shares of Series A preferred stock at a price of $1.00 per share for proceeds of $16,880,463, which is net of issuance costs of $119,537, to funds affiliated with Longitude Capital and certain existing investors. Each share of Series A preferred stock issued in the financing was convertible into 0.143 shares of common stock as of June 30, 2013. Upon the closing of the financing, Patrick Enright of Longitude Capital became a member of the board of directors.

On May 29, 2013, the Company entered into a stock purchase agreement with Pfizer Inc. and issued and sold 6,750,000 shares of Series A-1 preferred stock at a price of $1.1560 per share. The purchase price was paid through the cancellation of all outstanding indebtedness, including accrued interest, under the Pfizer convertible promissory note, which had an aggregate balance, including accrued interest, of $7,803,000 as of May 29, 2013. Each share of Series A-1 preferred stock issued in the agreement was convertible into 0.124 shares of common stock as of June 30, 2013.

Upon the closing of the Company s IPO on July 1, 2013, all of the outstanding shares of convertible preferred stock were converted into 9,210,999 shares of common stock. As of September 30, 2013, the Company did not have any convertible preferred stock issued or outstanding.

**9. Stock Compensation**

**2013 Stock Option and Incentive Plan**

On June 7, 2013, the Company s stockholders approved the 2013 Stock Option and Incentive Plan (the 2013 Plan), which became effective on June 25, 2013. The number of shares of stock reserved and available for issuance under the 2013 Plan is the sum of (i) 1,100,000, plus (ii) 54,129 shares originally reserved under the Company s 2008 Incentive Stock Option and Restricted Stock Plan (the 2008 Plan) that became available for issuance under the 2013 Plan upon completion of the Company s initial public offering, plus (iii) the shares underlying any awards granted under the 2008 Plan that are forfeited, canceled, held back upon the exercise of an option or settlement of an award to cover the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of stock or otherwise terminated (other than be exercise). Additionally, on January 1, 2014 and each January 1 thereafter, the number of shares reserved and available for issuance under the 2013 Plan shall be cumulatively increased by two and a half percent of the number of shares issued and outstanding on the immediately preceding December 31 or such lesser number of shares as determined by the plan administrator.

The following table summarizes the activity relating to the Company s options to purchase common stock for the nine months ended September 30, 2013:

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| | Number of Options | Weighted-Average Price Per Share | Weighted-Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding at December 31, 2012 | 211,500 | $ 1.43 | 7.5 | $ 141,389 |
| Granted | 1,116,549 | $ 10.34 | | |
| Forfeited or expired | (12,212) | $ 2.03 | | |
| Exercised | (49,936) | $ 2.47 | | |
| Outstanding at September 30, 2013 | 1,265,901 | $ 9.24 | 9.07 | $ 12,177,504 |

The following table summarizes information about the Company s stock option plan as of September 30, 2013:

| | Number of Options | Weighted-Average Price Per Share | Weighted-Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Vested and expected to vest at September 30, 2013 | 1,200,274 | $ 9.12 | 9.04 | $ 11,690,025 |
| Exercisable at September 30, 2013 | 559,481 | $ 2.21 | 8.34 | $ 9,317,579 |

As of September 30, 2013, there was approximately $6,886,306 of unrecognized compensation cost related to unvested options, adjusted for forfeitures, which will be recognized over a weighted-average period of approximately 3.6 years.

**10. Income Taxes**

There was no provision for income taxes for the three or nine months ended September 30, 2013 and 2012 because the Company has incurred operating losses since inception. At September 30, 2013, the Company has concluded that it is more likely than not that the Company will not realize the benefit of its deferred tax assets due to its history of losses. Accordingly, the net deferred tax assets have been fully reserved.

**11. Net Loss Per Common Share**

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, convertible preferred stock, convertible debt, warrants for preferred stock and stock options are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive. Interest expense for convertible debt that is dilutive is added back to net income in the calculation of diluted net loss per share.

The shares outstanding at the end of the respective periods presented below, after giving effect for the 1-for-6.986 reverse stock split, were excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

| | September 30, 2013 | December 31, 2012 |
|---|---|---|
| Convertible preferred stock | | 3,431,865 |
| Warrants for common stock | 277,690 | 277,690 |
| Common shares under option | 1,265,901 | 211,500 |
| Unvested restricted stock | 22,190 | |
| Convertible debt | | 3,430,723 |
| Total potential dilutive shares | 1,565,781 | 7,351,778 |

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**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 final prospectus filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the Securities Act), with the Securities and Exchange Commission (the SEC) on June 26, 2013.*

***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 ETC-1002, to be materially different from any future results, performance or achievements, including in relation to the clinical development of ETC-1002, 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 discussed in the section titled Risk Factors included in Item 1A of Part II of this Quarterly Report on Form 10-Q. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance.*

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

**Overview**

***Corporate Overview***

We are a biopharmaceutical company focused on the research, development and commercialization of therapies for the treatment of patients with elevated levels of LDL-C and other cardiometabolic risk factors. ETC-1002, our lead product candidate, is a novel, first in class, orally

available, once-daily LDL-C lowering small molecule therapy designed to avoid the side effects associated with existing LDL-C lowering therapies. We own the exclusive worldwide rights to ETC-1002 and our other product candidates.

We were incorporated in Delaware in January 2008 and commenced our operations in April 2008. Since our inception, we have devoted substantially all of our resources to developing ETC-1002 and our other product candidates, business planning, raising capital and providing general and administrative support for these operations. We have funded our operations primarily through the issuance of preferred stock, our initial public offering of common stock, which we closed in July 2013, convertible promissory notes and warrants to purchase shares of preferred stock.

On July 1, 2013, we completed the initial public offering, or IPO, of our common stock pursuant to a registration statement on Form S-1. In the IPO, we sold an aggregate of 5,000,000 shares of common stock under the registration statement at a public offering price of $14.00 per share. Net proceeds from the IPO were approximately $62.7 million, after deducting underwriting discounts and commissions and offering expenses. Upon the closing of the IPO, all outstanding shares of our preferred stock were converted into 9,210,999 shares of common stock. Additionally, as part of the IPO, we granted the underwriters a 30-day option to purchase up to 750,000 additional shares of common stock at the IPO price to cover over-allotments, if any. On July 11, 2013, the underwriters exercised this option in full. As a result of this exercise, we received an additional $9.5 million in proceeds, net of underwriting discounts and commissions and offering expenses.

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We are a development stage company and do not have any products approved for sale. To date, we have not generated any revenue. We have never been profitable and, from inception to September 30, 2013, our losses from operations have been $51.7 million. Our net losses were $5.2 million and $3.4 million for the three months ended September 30, 2013 and 2012, respectively, and $16.4 million and $9.0 million for the nine months ended September 30, 2013 and 2012, respectively. Substantially all of our net losses resulted from costs incurred in connection with research and development programs, general and administrative costs associated with our operations and the mark-to-market of our liability classified warrants. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, including, among others:

- conducting additional clinical studies of ETC-1002 to complete its development;
- seeking regulatory approval for ETC-1002;
- commercializing ETC-1002; and
- operating as a public company.

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

***Product Overview***

ETC-1002, our lead product candidate, is a novel, first in class, orally available, once-daily LDL-C lowering small molecule therapy designed to target known lipid and carbohydrate metabolic pathways to lower levels of LDL-C and to avoid side effects associated with existing LDL-C lowering therapies. We acquired the rights to ETC-1002 from Pfizer in 2008. We own the exclusive worldwide rights to ETC-1002 and we are not obligated to make any royalty or milestone payments to Pfizer.

In 2011, we incurred $4.6 million in expenses related to our Phase 1b Multiple Dose Tolerance clinical trial (ETC-1002-004), our Phase 2a Proof-of-Concept clinical study in Patients with Hypercholesterolemia (ETC-1002-003) which reported top-line results in March 2012, and our Phase 2a Proof-of-Concept clinical study in patients with Hypercholesterolemia and Type 2 Diabetes (ETC-1002-005) which reported top-line results in January 2013.

In 2012, we incurred $5.8 million in expenses related to our Phase 2a Proof-of-Concept clinical study in Patients with Hypercholesterolemia and Type 2 Diabetes (ETC-1002-005) and our Phase 2a Proof-of-Concept clinical study in Patients with Hypercholesterolemia and a History of Statin Intolerance (ETC-1002-006) which reported top-line results in June 2013, and our Phase 2a clinical study in Patients with Hypercholesterolemia taking 10 mg of atorvastatin ( ETC-1002-007) which reported top-line results in September 2013.

During the nine months ended September 30, 2013, we incurred $7.0 million in expenses related to our Phase 2a Proof-of-Concept clinical study in Patients with Hypercholesterolemia and Type 2 Diabetes (ETC-1002-005), our Phase 2a Proof-of-Concept clinical study in Patients with Hypercholesterolemia and a History of Statin Intolerance (ETC-1002-006), our Phase 2a clinical study in Patients with Hypercholesterolemia taking 10 mg of atorvastatin (ETC-1002-007) and our Phase 2b clinical study in Patients with Hypercholesterolemia and a History of either Statin Intolerance or Statin Tolerance (ETC-1002-008).

We also have two other early-stage programs in pre-clinical development. We licensed one of these candidates from The Cleveland Clinic Foundation, or CCF, and are obligated to make certain royalty and milestone payments (consisting of cash and common stock) to CCF, including a minimum annual cash payment of $50,000 during years when a milestone payment is not met. No milestone or royalty payments will be due to any third-party in connection with the development and commercialization of our other pre-clinical product candidate, ESP41091.

***Clinical Developments***

*ETC-1002-007 Phase 2a Proof of Concept Clinical Study in Patients with Hypercholesterolemia taking 10 mg of Atorvastatin*

ETC-1002-007 was an eight-week Phase 2a clinical study in 58 patients, who were dosed with ETC-1002 or placebo, across six participating clinical recruitment sites in the United States. The primary objective of this clinical study was to evaluate the safety and tolerability of ETC-1002 when added to atorvastatin 10 mg/day in patients with hypercholesterolemia, and to test the effects of ETC-1002 on the pharmacokinetics of atorvastatin and its active metabolites. After completing a lipid-lowering therapy wash out period of four weeks, patients were placed on atorvastatin (10 mg) for four weeks to achieve steady state plasma levels of atorvastatin. Patients were then randomized in a 3:1 ratio of active ETC-1002 treatment to placebo for eight weeks (42 patients received ETC-1002 and 16 patients received placebo). During this clinical study, patients were dosed up to eight weeks in a forced titration schema of 60 mg, 120 mg, 180 mg and 240 mg doses of ETC-1002 for two weeks each.

Top-line results of the ETC-1002-007 study were reported in September 2013. The study demonstrated that ETC-1002 achieved incremental LDL-C lowering of 22 percent at eight weeks, compared with 0 percent in the placebo group. ETC-1002 was well tolerated over eight weeks of treatment when added to a statin, no serious adverse events were reported and there was a weak pharmacokinetic interaction of atorvastatin with ETC-1002.

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*ETC-1002-008 Phase 2b Clinical Study in Patients with or without Statin Intolerance and Hypercholesterolemia*

In October 2013, we initiated our Phase 2b clinical study in Patients with or without Statin Intolerance and Hypercholesterolemia (ETC-1002-008), the first clinical study in our Phase 2b program. The ETC-1002-008 study is a 12-week Phase 2b study for the treatment of elevated LDL-C levels in approximately 322 patients who are either statin intolerant or statin tolerant. The goals of this study are to compare the LDL-C lowering efficacy of ETC-1002 with ezetimibe and to demonstrate comparable tolerability to ezetimibe, a common therapy for statin intolerant patients with hypercholesterolemia. Patients enrolled in the ETC-1002-008 study will complete a four week placebo run-in period and will then be randomized to one of five arms: 1) 120 mg dose of ETC-1002, 2) 180 mg dose of ETC-1002, 3) an active comparator, 10 mg dose of ezetimibe (a common treatment for statin intolerant patients), 4) a combination of 120 mg of ETC-1002 and ezetimibe, or 5) a combination of 180 mg of ETC-1002 and ezetimibe. This Phase 2b clinical study has a parallel dose design and a 12-week duration. The primary objective is to assess the LDL-C lowering efficacy of ETC-1002 monotherapy versus ezetimibe monotherapy in patients with elevated LDL-C levels with or without statin intolerance. In addition, the study will assess the LDL-C lowering efficacy of ETC-1002 in combination with ezetimibe versus ezetimibe monotherapy. We expect to complete the study by the end of 2014.

**Financial Operations Overview**

***Revenue***

To date, we have not generated any revenue, other than grant income. In the future, we may generate revenue from the sale of ETC-1002 or our other product candidates. If we fail to complete the development of ETC-1002 or our 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 preclinical and clinical studies. Our research and development expenses consist primarily of costs incurred in connection with the development of ETC-1002, which include:

- expenses incurred under agreements with consultants, contract research organizations, or CROs, and investigative sites that conduct our pre-clinical and clinical studies;

- the cost of acquiring, developing and manufacturing clinical study materials;

- employee-related expenses, including salaries, benefits, stock-based compensation and travel expenses;

- allocated expenses for rent and maintenance of facilities, insurance and other supplies; and

- costs related to compliance with regulatory requirements.

We expense research and development costs as incurred. To date, substantially all of our research and development work has been related to ETC-1002. Costs for certain development activities, such as clinical studies, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors. Our direct research and development expenses consist principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical studies. We do not allocate acquiring and manufacturing clinical study materials, salaries, stock-based compensation, employee benefits or other indirect costs related to our research and development function to specific programs.

Our research and development expenses are expected to increase in the foreseeable future. Costs associated with ETC-1002 will increase as we continue to conduct our Phase 2b clinical studies and initiate our Phase 3 clinical studies. We cannot determine with certainty the duration and completion costs associated with the ongoing or future clinical studies of ETC-1002. Also, we cannot conclude with certainty if, or when, we will generate revenue from the commercialization and sale of ETC-1002 or our other product candidates for which we obtain regulatory approval, if ever. We may never succeed in obtaining regulatory approval for any of our product candidates, including ETC-1002. The duration, costs and timing associated with the development and commercialization of ETC-1002 and our other product candidates 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 ETC-1002, or if we experience significant delays in enrollment in any of our clinical studies, we could be required to expend significant additional financial resources and time on the completion of clinical development or post-commercialization clinical studies of ETC-1002.

***General and Administrative Expenses***

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

We anticipate that our general and administrative expenses will increase in the future in connection with the continued research and development and commercialization of ETC-1002, increases in our headcount, expansion of our information technology infrastructure, increased legal, compliance, accounting and investor and public relations expenses associated with being a public company.

***Interest Expense***

Interest expense consists primarily of non-cash interest costs associated with our convertible promissory notes.

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***Stock-Based Compensation***

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

**Warrant Liability**

Our previously outstanding warrants to purchase shares of preferred stock had provisions by which the underlying issuance is contingently redeemable based on events outside of our control and were recorded as a liability in accordance with ASC 480-10. Warrants classified as derivative liabilities are recorded on our balance sheet at fair value on the date of issuance and are marked-to-market on each subsequent reporting period. Non-cash changes in the fair value at each reporting period are recognized in the statement of operations. Upon the closing of our IPO on July 1, 2013, all warrants exercisable for shares of preferred stock became exercisable for shares of common stock and, as a result, the warrants no longer met the criteria to be classified as derivative liabilities and were reclassified to additional paid-in capital at fair value.

**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, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. We evaluate our estimates and judgments on an ongoing basis, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, contractual milestones and other various factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in more detail in Note 2 to our financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

**Results of Operations**

***Comparison of the Three Months Ended September 30, 2013 and 2012***

The following table summarizes our results of operations for the three months ended September 30, 2013 and 2012:

| | Three Months Ended September 30, 2013 | 2012 | Change |
|---|---|---|---|
| | (in thousands) | | |
| **Operating Expenses:** | | | |
| Research and development | $ 3,483 | $ 2,456 | $ 1,027 |
| General and administrative | 1,924 | 534 | 1,390 |
| **Loss from operations** | (5,407) | (2,990) | (2,417) |
| Other income (expense): | | | |
| Interest expense | | (361) | 361 |
| Other income (expense), net | 168 | | 168 |
| **Net loss** | $ (5,239) | $ (3,351) | $ (1,888) |

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***Research and development expenses***

Research and development expenses for the three months ended September 30, 2013 were $3.5 million, compared to $2.5 million for the three months ended September 30, 2012, an increase of $1.0 million. The increase in research and development expenses is primarily related to the further clinical development of ETC-1002 in our Phase 2 clinical program.

***General and administrative expenses***

General and administrative expenses for the three months ended September 30, 2013 were $1.9 million, compared to $0.5 million for the three months ended September 30, 2012, an increase of $1.4 million. The increase in general and administrative expenses was primarily attributable to costs to support public company operations, increases in our headcount, which includes increased stock-based compensation expense, and other costs to support our growing organization.

***Interest expense***

We incurred no non-cash interest expense for the three months ended September 30, 2013 compared to $0.4 million for the three months ended September 30, 2012. The decrease in interest expense was primarily related the conversion of the Pfizer convertible promissory note on May 29, 2013 and the convertible promissory notes on February 11, 2013.

***Other income (expense), net***

Other income (expense), net for the three months ended September 30, 2013 was income of approximately $168,000 compared to no income for the three months ended September 30, 2012, a $168,000 increase in income. This increase was primarily related to gains on the sale of assets and an increase in interest income earned on our cash and cash equivalents.

***Comparison of the Nine Months Ended September 30, 2013 and 2012***

The following table summarizes our results of operations for the nine months ended September 30, 2013 and 2012:

| | Nine Months Ended September 30, | | |
|---|---|---|---|
| | 2013 | 2012 | Change |
| | (in thousands) | | |

| | | | |
|---|---|---|---|
| **Operating Expenses:** | | | |
| Research and development | $ 8,676 | $ 6,344 | $ 2,332 |
| General and administrative | 4,347 | 1,700 | 2,647 |
| **Loss from operations** | (13,023) | (8,044) | (4,979) |
| Other income (expense): | | | |
| Interest expense | (936) | (925) | (11) |
| Change in fair value of warrant liability | (2,587) | | (2,587) |
| Other income (expense), net | 147 | 3 | 144 |
| **Net loss** | $ (16,399) | $ (8,966) | $ (7,433) |

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***Research and development expenses***

Research and development expenses for the nine months ended September 30, 2013 were $8.7 million, compared to $6.3 million for the nine months ended September 30, 2012, an increase of $2.4 million. The increase in research and development expenses primarily related to the further clinical development of ETC-1002 in our Phase 2 clinical program.

***General and administrative expenses***

General and administrative expenses for the nine months ended September 30, 2013 were $4.3 million, compared to $1.7 million for the nine months ended September 30, 2012, an increase of $2.6 million. The increase in general and administrative expenses was primarily attributable to costs to support public company operations, increases in our headcount, which includes increased stock-based compensation expense, and other costs to support our growing organization.

***Interest expense***

Non-cash interest expense for the nine months ended September 30, 2013 was $0.9 million, compared to $0.9 million for the nine months ended September 30, 2012. Interest expense during the nine months of 2013 was primarily related to our issuance of convertible promissory notes in January, September and November 2012, which had a 10% interest rate before being converted into an aggregate of 16,623,092 shares of Series A preferred stock in February 2013 as well as the accrued interest on the 8.931% convertible promissory note issued to Pfizer, which was subsequently converted into 6,750,000 shares of Series A-1 preferred stock on May 29, 2013.

***Change in fair value of warrant liability***

The outstanding warrants to purchase 277,690 shares of our common stock required liability classification and mark-to-market accounting at each reporting period in accordance with ASC 480-10 prior to the completion of our initial public offering (IPO). The fair values of the warrants were determined using the Black Scholes valuation model and resulted in the recognition of a loss of approximately $2.6 million related to the change in fair values for the nine months ended September 30, 2013. Subsequent to our IPO, the warrants were reclassified to equity as they no longer met the criteria for classification as derivative liabilities.

***Other income (expense), net***

Other income (expense), net for the nine months ended September 30, 2013 was an expense of approximately $147,000 compared to income of approximately $3,000 for the nine months ended September 30, 2012, a $144,000 increase in income. This increase was primarily related to gains on the sale of assets and an increase in interest income earned on our cash and cash equivalents.

**Liquidity and Capital Resources**

We have funded our operations since inception through the sale of common stock in our IPO, private placements of preferred stock, convertible promissory notes and warrants to purchase shares of preferred stock. To date, we have not generated any revenue, and we anticipate that we will continue to incur losses for the foreseeable future.

In July 2013, we completed our IPO pursuant to a registration statement on Form S-1. In the IPO, we issued and sold an aggregate of 5,750,000 shares of common stock, including the underwriters exercise in full of their over-allotment option, under the registration statement at a public offering price of $14.00 per share. Net proceeds were approximately $72.2 million, after deducting underwriting discounts and commissions and offering expenses.

As of September 30, 2013, our primary sources of liquidity were our cash and cash equivalents and investments, which totaled $71.9 million and $ 13.5 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:

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| | Nine Months Ended September 30, | |
|---|---|---|
| | 2013 | 2012 |
| | (in thousands) | |
| Cash (used in) operating activities | $ (10,583) | $ (8,439) |
| Cash provided by (used in) investing activities | (13,348) | (3) |
| Cash provided by financing activities | 89,315 | 10,036 |
| **Net increase (decrease) in cash and cash equivalents** | $ 65,384 | $ 1,594 |

***Operating Activities***

We have incurred, and expect to continue to incur, significant costs in the areas of research and development, regulatory and other clinical study costs, associated with our development of ETC-1002.

Net cash used in operating activities totaled $10.6 million and $8.4 million for the nine months ended September 30, 2013 and 2012, respectively. The primary use of our cash was to fund the development of ETC-1002, adjusted for non-cash expenses, such as depreciation and amortization, interest expense, stock-based compensation expense, mark-to-market of our warrant liability and changes in working capital.

***Investing Activities***

Net cash used in investing activities of $13.3 million for the nine months ended September 30, 2013 consisted primarily of our purchase of highly liquid, interest bearing investment-grade and government securities. Net cash used in investing activities of approximately $3,000 for the nine months ended September 30, 2012 consisted primarily of property and equipment purchases, partially off-set by our sale of certain assets.

***Financing Activities***

Net cash provided by financing activities of $89.3 million for the nine months ended September 30, 2013 related primarily to the net proceeds of our IPO in July 2013 and the issuance and sale of 17,000,000 shares of our Series A preferred stock at a price of $1.00 per share in April 2013. Net cash provided by financing activities of $10.0 million for the nine months ended September 30, 2012 consisted primarily of the issuance of convertible promissory notes.

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

ETC-1002 is currently in Phase 2b clinical development, and we expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We expect that our existing cash and cash equivalents and available-for-sale investments will enable us to fund our operating expenses and capital expenditure requirements through at least the end of 2015 and that we will likely need to raise additional capital thereafter to continue to fund the further development of ETC-1002 and our operations. We expect to announce top-line results from our

Phase 2b ETC-1002-008 clinical study by the end of 2014 and to have an end-of-Phase 2 meeting with the FDA in the first quarter of 2015. 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 ETC-1002, and the extent to which we may enter into collaborations with pharmaceutical partners regarding the development and commercialization of ETC-1002, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development and commercialization of ETC-1002. Our future funding requirements will depend on many factors, including, but not limited to:

- our ability to successfully develop and commercialize ETC-1002 and our other product candidates;

- the costs, timing and outcomes of our ongoing and planned clinical studies of ETC-1002;

- the time and cost necessary to obtain regulatory approvals for ETC-1002, if at all;

- our ability to establish a sales, marketing and distribution infrastructure to commercialize ETC-1002 in the United States and abroad or our ability to establish any future collaboration or commercialization arrangements on favorable terms, if at all;

- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and

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- the implementation of operational and financial information technology.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams or ETC-1002 or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or through collaborations, strategic alliances or licensing arrangements when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market ETC-1002 that we would otherwise prefer to develop and market ourselves.

**Contractual Obligations and Commitments**

We lease office and laboratory space in Plymouth, MI under an operating lease agreement that was originally scheduled to expire on October 2, 2013. We have options to renew this lease for two additional five-year terms. On August 26, 2013, we entered into an amendment to the lease to extend the expiration date of the initial term from October 2, 2013 to April 30, 2014.

The following table summarizes our future minimum lease obligations as of December 31, 2012:

| | Total | Less than 1 Year | 1-3 Years | 3-5 Years | More than 5 Years |
|---|---|---|---|---|---|
| | | | (in thousands) | | |
| Operating leases | $ 287 | $ 287 | $ | $ | $ |
| Total | $ 287 | $ 287 | $ | $ | $ |

We are also party to a license agreement pursuant to which we are obligated to make future minimum annual payments of $50,000 in years during which milestone payments are not triggered under the agreement. In addition, we are also contractually obligated to issue up to an aggregate of 11,451 shares of common stock upon various milestones set forth in the agreement.

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

**Off-Balance Sheet Arrangements**

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

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**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

We had cash and cash equivalents and available-for-sale investments of approximately $85.4 million and $6.5 million at September 30, 2013 and December 31, 2012, 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 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.

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 or nine months ended September 30, 2013 and 2012.

**Item 4. Controls and Procedures**

***Evaluation of Disclosure Controls and Procedures***

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities and Exchange Act of 1934 is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC s rules and forms and (2) accumulated and communicated to our management, including our President and Chief Executive Officer, who is our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of September 30, 2013, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer has concluded based upon the evaluation described above that, as of September 30, 2013, 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.

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**PART II OTHER INFORMATION**

**Item 1A. Risk Factors**

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q and in our other public filings before making an investment decision. Our business, prospects, financial condition, or operating results could be harmed by any of these risks, as well as other risks not currently known to us or that we currently consider immaterial. If any such risks or uncertainties actually occur, our business, financial condition or operating results could differ materially from the plans, projections and other forward-looking statements included in the section titled Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this report and in our other public filings. The trading price of our common stock could decline due to any of these risks, and as a result, you may lose all or part of your investment.*

**Risks Related to our Business and the Clinical Development and Commercialization of ETC-1002**

***We depend almost entirely on the success of one product candidate, ETC-1002, which is still in Phase 2 clinical development. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, ETC-1002.***

We currently have only one product candidate, ETC-1002, in clinical development, and our business depends almost entirely on its successful clinical development, regulatory approvals and commercialization. We currently have no drug products for sale and may never be able to develop marketable drug products. ETC-1002, which is currently in Phase 2 clinical studies, will require substantial additional clinical development, testing, and regulatory approvals before we are permitted to commence its commercialization. Our other product candidates are still in pre-clinical development stages. None of our product candidates have advanced into a pivotal study, and it may be years before such studies are initiated, if ever. The clinical studies of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through pre-clinical testing and clinical studies that the product candidate is safe and effective for use in each target indication. This process can take many years and may include post-marketing studies and surveillance, including a Risk Evaluation and Mitigation Strategy, or REMS program, which will require the expenditure of substantial resources beyond the proceeds we raised in our initial public offering. Of the large number of drugs in development in the United States, only a small percentage successfully complete the FDA or any other foreign regulatory approval process and are commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development and clinical programs, we cannot assure you that ETC-1002 or any other of our product candidates will be successfully developed or commercialized.

We are not permitted to market ETC-1002 in the United States until we receive approval of a New Drug Application, or NDA, from the FDA, or in any foreign countries until we receive the requisite approval from such countries. As a condition to submitting an NDA to the FDA for ETC-1002 to treat patients with hypercholesterolemia, we currently expect to complete two Phase 2b clinical studies, two pivotal Phase 3 clinical studies and one long-term safety study. We have not commenced any of these clinical studies. Obtaining approval of an NDA is a complex, lengthy, expensive and uncertain process, and the FDA may delay, limit or deny approval of ETC-1002 for many reasons, including, among others:

- we may not be able to demonstrate that ETC-1002 is safe and effective in treating hypercholesterolemia to the satisfaction of the FDA;

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

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- the FDA may disagree with the number, design, size, conduct or implementation of our clinical studies;

- the FDA may require that we conduct additional clinical studies, such as a cardiovascular outcomes trial;

- the FDA may not release its partial clinical hold on ETC-1002 to permit us to conduct a clinical study for more than six months;

- the FDA or an applicable foreign regulatory agency may not approve the formulation, specifications or labeling of ETC-1002;

- the clinical research organizations, or CROs, that we retain to conduct our clinical studies may take actions outside of our control that materially adversely impact our clinical studies;

- the FDA may find the data from pre-clinical studies and clinical studies insufficient to demonstrate that ETC-1002 s clinical and other benefits outweigh its safety risks;

- the FDA may disagree with our interpretation of data from our pre-clinical studies and clinical studies;

- the FDA may not accept data generated at our clinical study sites;

- if our NDA, if and when submitted, is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional pre-clinical studies or clinical studies, limitations in approved labeling or distribution and use restrictions;

- the FDA may require the development of a REMS as a condition of approval or post-approval;

- the FDA or the applicable foreign regulatory agency may not approve the manufacturing processes or facilities of third-party manufacturers with which we contract; or

- the FDA may change its approval policies or adopt new regulations.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market ETC-1002. Moreover, because our business is almost entirely dependent upon this one product candidate, any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

***Failures or delays in the commencement or completion of our Phase 2b or pivotal Phase 3 clinical studies of ETC-1002 could result in increased costs to us and could delay, prevent or limit our ability to generate revenue and continue our business.***

We only recently initiated our Phase 2b clinical studies in October 2013 and have not commenced our pivotal Phase 3 clinical studies. Successful completion of such clinical studies is a prerequisite to submitting an NDA to the FDA and, consequently, the ultimate approval and commercial marketing of ETC-1002. We do not know whether our Phase 2b clinical studies will be completed on schedule, if at all, or whether our pivotal Phase 3 clinical studies will begin or be completed on schedule, if at all, as the commencement and completion of clinical studies can be delayed or prevented for a number of reasons, including, among others:

- the FDA may deny permission to proceed with Phase 3 clinical trials, including not releasing its partial clinical hold on ETC-1002 to permit us to conduct a clinical study for more than six months, or may place a clinical study on hold;

- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs and study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;

- inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical studies;

- difficulties or delays obtaining institutional review board, or IRB, approval to conduct a clinical study at a prospective site or sites;

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- challenges in recruiting and enrolling patients to participate in clinical studies or in a cardiovascular outcomes study, if one were to be required, including the size and nature of the patient population, the proximity of patients to clinical sites, eligibility criteria for the clinical study, the nature of the clinical study protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical study programs for similar indications;

- severe or unexpected drug-related side effects experienced by patients in a clinical study, including instances of muscle pain or weakness or other side effects previously identified in our completed clinical studies;

- reports from pre-clinical or clinical testing of other cardiometabolic therapies that raise safety or efficacy concerns; and

- difficulties retaining patients who have enrolled in a clinical study but may be prone to withdraw due to rigors of the study, lack of efficacy, side effects, personal issues or loss of interest.

Clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical study may be suspended or terminated by us, the FDA, the IRBs at the sites where the IRBs are overseeing a clinical study, a data safety monitoring board, or DSMB, overseeing the clinical study at issue or other regulatory authorities due to a number of factors, including, among others:

- failure to conduct the clinical study in accordance with regulatory requirements or our clinical protocols;

- inspection of the clinical study operations or study sites by the FDA or other regulatory authorities that reveals deficiencies or violations that require us to undertake corrective action, including the imposition of a clinical hold;

- unforeseen safety issues, including any that could be identified in our ongoing pre-clinical carcinogenicity studies, adverse side effects or lack of effectiveness;

- changes in government regulations or administrative actions;

- problems with clinical supply materials; and

- lack of adequate funding to continue the clinical study.

***Positive results from Phase 1 and Phase 2a clinical studies of ETC-1002 are not necessarily predictive of the results of our Phase 2b and planned Phase 3 clinical studies of ETC-1002. If we cannot replicate the positive results from our Phase 1 and Phase 2a clinical studies of ETC-1002 in our Phase 2b and Phase 3 clinical studies, we may be unable to successfully develop, obtain regulatory approval for and commercialize ETC-1002.***

Even if we are able to complete our Phase 2b and planned pivotal Phase 3 clinical studies of ETC-1002 according to our current development timeline, the positive results from our Phase 1 and Phase 2a clinical studies of ETC-1002 may not be replicated in our Phase 2b or pivotal Phase 3 clinical study results. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical studies after achieving positive results in early stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, pre-clinical findings made while clinical studies were underway or safety or efficacy observations made in clinical studies, including previously unreported adverse events. Our Phase 2b clinical studies will evaluate the safety and efficacy of ETC-1002 in statin-intolerant patients and as an add-on to existing statin treatments. We expect that our Phase 3 clinical studies will evaluate the safety and efficacy of ETC-1002 in these same patient populations. Nevertheless, the results from our Phase 2a clinical studies for ETC-1002, including ETC-1002-006 and ETC-1002-007, may not be predictive of the results we may obtain in our Phase 2b or Phase 3 clinical studies of ETC-1002. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in pre-clinical studies and clinical studies nonetheless failed to obtain FDA approval. If we fail to-obtain positive results in our Phase 2b and Phase 3 clinical studies of ETC-1002, the development timeline and regulatory approval and commercialization prospects for our leading product candidate, and, correspondingly, our business and financial prospects, would be materially adversely affected.

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

Although we believe that the net proceeds from our initial public offering will be sufficient to fund our operations through the completion of our currently anticipated Phase 2b clinical studies and end of Phase 2 meeting with the FDA, we will likely need to raise additional capital thereafter to continue to fund the further development of ETC-1002 and our operations. We expect to announce top-line results from our latest currently anticipated Phase 2b clinical studies in the fourth quarter of 2014 and to have our end of Phase 2 meeting with the FDA in the first quarter of 2015. Our future capital requirements may be substantial and will depend on many factors including:

- the scope, size, rate of progress, results and costs of initiating and completing our Phase 2b clinical studies of ETC-1002 and our operating costs incurred as we conduct these studies and through our planned end of Phase 2 meeting with the FDA, for which we currently estimate that we will use substantially all of the net proceeds from our initial public offering;

- the scope, size, rate of progress, results and costs of initiating and completing our Phase 3 clinical program of ETC-1002, which currently includes two pivotal Phase 3 clinical studies and one long-term safety study, for which we only plan on using net proceeds from our initial public offering to the extent they are available;

- the cost, timing and outcome of our efforts to obtain marketing approval for ETC-1002 in the United States, including to fund the preparation and filing of an NDA with the FDA for ETC-1002 and to satisfy related FDA requirements;

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

- the costs associated with commercializing ETC-1002 or any future product candidates if we receive marketing approval, including the cost and timing of developing sales and marketing capabilities or entering into strategic collaborations to market and sell ETC-1002 or any future product candidates;

- the cost of manufacturing ETC-1002 or any future product candidates and any products we successfully commercialize; and

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

Changing circumstances may cause us to consume capital significantly faster than we currently anticipate. Because the outcome of any clinical study is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval and commercialization of ETC-1002 and any future product candidates. Additional financing may not be available when we need it or

may not be available on terms that are favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If adequate funds are unavailable to us on a timely basis, or at all, we may not be able to continue the development of ETC-1002 or any future product candidate, or to commercialize ETC-1002 or any future product candidate, if approved, unless we find a partner.

***We are a development stage biopharmaceutical company with a limited operating history and have not generated any revenue from product sales. We have incurred significant operating losses since our inception, and anticipate that we will incur continued losses for the foreseeable future.***

We are a development stage company with a limited operating history on which to base your investment decision. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We were incorporated in January 2008. Our operations to date have been limited primarily to organizing and staffing our company and conducting research and development activities for ETC-1002. We have never generated any revenue from product sales. We have not obtained regulatory approvals for any of our product candidates. As such, we are subject to all the risks described in this prospectus incident to the development, regulatory approval and commercialization of new pharmaceutical products and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors.

Since our inception, we have focused substantially all of our efforts and financial resources on developing ETC-1002, which is currently in Phase 2 clinical development. We have funded our operations to date through proceeds from sales of common stock, preferred stock and convertible debt and have incurred losses in each year since our inception. Our net losses were $16.4 million for the nine months ended September 30, 2013, $11.7 million for the year ended December 31, 2012 and $10.8 million for the year ended December 31, 2011. As of September 30, 2013, we had an accumulated deficit of $58.4 million. Substantially all of our operating losses resulted from costs incurred

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in connection with our development program and from general and administrative costs associated with our operations. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders equity and working capital. We expect our research and development expenses to significantly increase in connection with our additional clinical studies of ETC-1002 and development of any other product candidates we may choose to pursue. In addition, if we obtain marketing approval for ETC-1002, we will also incur significant sales, marketing and outsourced manufacturing expenses. As a newly public company, we will incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

***Changes in regulatory requirements, FDA guidance or unanticipated events during our Phase 2b or Phase 3 clinical studies of ETC-1002 may occur, which may result in changes to clinical study protocols or additional clinical study requirements, such as the initiation or completion of a cardiovascular outcomes trial, which could result in increased costs to us and could delay our development timeline.***

Changes in regulatory requirements, FDA guidance or unanticipated events during our clinical studies may force us to amend clinical study protocols or the FDA may impose additional clinical study requirements. Amendments to our clinical study protocols would require resubmission to the FDA and IRBs for review and approval, which may adversely impact the cost, timing and/or successful completion of a clinical study. If we experience delays completing or if we terminate any of our Phase 2b or Phase 3 clinical studies, or if we are required to conduct additional clinical studies, such as a cardiovascular outcomes trial, the commercial prospects for ETC-1002 may be harmed and our ability to generate product revenue will be delayed. If the FDA requires us to conduct a cardiovascular outcomes trial, we may not be able to identify and enroll the requisite number of patients in that study. Even if we are successful in enrolling patients in a cardiovascular outcomes study, we may not ultimately be able to demonstrate that lowering LDL-C levels using ETC-1002 provides patients with an incremental lowering of cardiovascular disease risks and our failure to do so may delay or prejudice our ability to obtain FDA approval for ETC-1002. Our current development timeline for ETC-1002 does not contemplate the completion of a cardiovascular outcomes trial. Any such study, if required, would be costly and time-consuming and, regardless of the outcome, would adversely affect our development timeline and financial condition.

***Even if we receive marketing approval for ETC-1002, we may still face future development and regulatory difficulties.***

Even if we receive marketing approval for ETC-1002, regulatory authorities may still impose significant restrictions on ETC-1002 s indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies, such as a cardiovascular outcomes trial. ETC-1002 will also be subject to ongoing FDA requirements governing the packaging, storage, labeling, advertising and promotion of the product, recordkeeping and submission of safety updates and other post-marketing information. The FDA has significant post-marketing authority, including, for example, the authority to require labeling changes based on new safety information and to require post-marketing studies or clinical studies to evaluate serious safety risks related to the use of a drug product. The FDA also has the authority to require, as part of an NDA or post-approval, the submission of a REMS. Any REMS required by the FDA may lead to increased costs to assure compliance with post-approval regulatory requirements and potential requirements or restrictions on the sale of approved products, all of which could lead to lower sales volume and revenue.

Manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practices and other regulations. If we or a regulatory agency discover problems with ETC-1002, such as adverse events of unanticipated severity or frequency, or problems with the facility where ETC-1002 is manufactured, a regulatory agency may impose restrictions on ETC-1002, the manufacturer or us, including requiring withdrawal of ETC-1002 from the market or suspension of manufacturing. If we, ETC-1002 or the manufacturing facilities for ETC-1002 fail to comply with applicable regulatory

requirements, a regulatory agency may, among other things:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw marketing approval;
- suspend any ongoing clinical studies;
- refuse to approve pending applications or supplements to applications submitted by us;

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- suspend or impose restrictions on operations, including costly new manufacturing requirements; or

- seize or detain products, refuse to permit the import or export of products, or request that we initiate a product recall.

***Even if we receive marketing approval for ETC-1002 in the United States, we may never receive regulatory approval to market ETC-1002 outside of the United States.***

We have not yet selected any markets outside of the United States where we intend to seek regulatory approval to market ETC-1002. In order to market any product outside of the United States, however, we must establish and comply with the numerous and varying efficacy, safety and other regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ from that required to obtain FDA approval. The marketing approval processes in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. In particular, in many countries outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others. Failure to obtain marketing approval in other countries or any delay or other setback in obtaining such approval would impair our ability to commercialize ETC-1002 in such foreign markets. Any such impairment would reduce the size of our potential market, which could have a material adverse impact on our business, results of operations and prospects.

***Even if we receive marketing approval for ETC-1002, it may not achieve broad market acceptance, which would limit the revenue that we generate from its sales.***

The commercial success of ETC-1002, if approved by the FDA or other regulatory authorities, will depend upon the awareness and acceptance of ETC-1002 among the medical community, including physicians, patients and healthcare payors. Market acceptance of ETC-1002, if approved, will depend on a number of factors, including, among others:

- ETC-1002 s demonstrated ability to treat statin intolerant patients with hypercholesterolemia and, if required by any applicable regulatory authority in connection with the approval for this or any other indication, to provide patients with incremental cardiovascular disease benefits, as compared with other available therapies;

- the relative convenience and ease of administration of ETC-1002, including as compared with other treatments for patients with hypercholesterolemia;

- the prevalence and severity of any adverse side effects such as muscle pain or weakness;

- limitations or warnings contained in the labeling approved for ETC-1002 by the FDA;

- availability of alternative treatments, including a number of competitive LDL-C lowering therapies already approved or expected to be commercially launched in the near future;

- pricing and cost effectiveness;

- the effectiveness of our sales and marketing strategies;

- our ability to increase awareness of ETC-1002 through marketing efforts;

- our ability to obtain sufficient third-party coverage or reimbursement; and

- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If ETC-1002 is approved but does not achieve an adequate level of acceptance by patients, physicians and payors, we may not generate sufficient revenue from ETC-1002 to become or remain profitable. Before granting reimbursement approval, healthcare payors may require us to demonstrate that, in addition to lowering elevated LDL-C levels, ETC-1002 also provides incremental cardiovascular disease benefits to patients. Our efforts to educate the medical community and third-party payors about the benefits of ETC-1002 may require significant resources and may never be successful.

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***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell ETC-1002, we may not be able to generate any revenue.***

We do not currently have an infrastructure for the sales, marketing and distribution of pharmaceutical products. In order to market ETC-1002, if approved by the FDA or any other regulatory body, we must build our sales, marketing, managerial, and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, or if we are unable to do so on commercially reasonable terms, our business, results of operations, financial condition and prospects will be materially adversely affected.

***Even if we obtain marketing approval for ETC-1002, physicians and patients using other LDL-C lowering therapies may choose not to switch to our product.***

Physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective, safe or convenient treatments enter the market. In addition, patients often acclimate to the brand or type of therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of reimbursement for existing therapies. If physicians or patients are reluctant to switch from existing therapies to ETC-1002, if approved, our operating results and financial condition would be materially adversely affected.

***Guidelines and recommendations published by various organizations may adversely affect the use or commercial viability of ETC-1002, if approved.***

Government agencies issue regulations and guidelines directly applicable to us and to ETC-1002, including guidelines generally relating to therapeutically significant LDL-C levels. In addition, professional societies, practice management groups, private health or science foundations and other organizations involved in the research, treatment and prevention of various diseases from time to time publish guidelines or recommendations to the medical and patient communities. These various sorts of recommendations may relate to such matters as product usage and use of related or competing therapies. For example, organizations such as the American Heart Association have made recommendations about therapies in the cardiovascular therapeutics market. Changes to these existing recommendations or other guidelines advocating alternative therapies could result in decreased use of ETC-1002, if approved, which would adversely affect our results of operations.

***Even if approved, reimbursement policies could limit our ability to sell ETC-1002.***

Market acceptance and sales of ETC-1002 will depend on reimbursement policies and may be affected by healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels for those medications. Cost containment is a primary concern in the U.S. healthcare industry and elsewhere. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that reimbursement will be available for ETC-1002 and, if reimbursement is available, the level of such reimbursement. Reimbursement may impact the demand for, or the price of, ETC-1002. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize ETC-1002.

In some foreign countries, particularly in Canada and European countries, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or pricing approval in some countries, we may be required to conduct a clinical study that compares the cost-effectiveness of ETC-1002 with other available therapies. If reimbursement for ETC-1002 is unavailable in any country in which we seek reimbursement, if it is limited in scope or amount, if it is conditioned upon our completion of additional clinical studies, or if pricing is set at unsatisfactory levels, our operating results could be materially adversely affected.

***Our product development programs for candidates other than ETC-1002 may require substantial financial resources and may ultimately be unsuccessful.***

In addition to the development of ETC-1002, we may pursue the development of our other two early-stage development programs. Neither of our other potential product candidates has commenced any clinical studies, and there are a number of FDA requirements that we must satisfy before we can commence such clinical studies. Satisfaction of these requirements will entail substantial time, effort and financial resources. We may never satisfy these requirements. Any time, effort and financial resources we expend on our other two early-stage development programs may adversely affect our ability to continue development and commercialization of ETC-1002, and we may never commence clinical studies of such development programs despite expending significant resources in pursuit of their

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development. If we do commence clinical studies of our other potential product candidates, such product candidates may never be approved by the FDA.

***Recent federal legislation will increase pressure to reduce prices of pharmaceutical products paid for by Medicare, which could materially adversely affect our revenue, if any, and our results of operations.***

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the scope of coverage and the price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may cause a similar reduction in payments from private payors. This legislation may pose an even greater risk to ETC-1002 than some other pharmaceutical products because a significant portion of the target patient population for ETC-1002 would likely be over 65 years of age and, therefore, many such patients will be covered by Medicare.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the PPACA, became law in the United States. The goal of the PPACA is to reduce the cost of healthcare and substantially change the way healthcare is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, the PPACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of ETC-1002, if approved, or any of our future products. In 2012, members of the U.S. Congress and some state legislatures sought to overturn certain provisions of the PPACA including those concerning the mandatory purchase of insurance. However, on June 28, 2012, the United States Supreme Court upheld the constitutionality of these provisions. Members of the U.S. Congress have since proposed a number of legislative initiatives, including possible repeal of the PPACA. We cannot predict the outcome or impact of current proposals or whether new proposals will be made or adopted, when they may be adopted or what impact they may have on us if they are adopted.

Finally, the availability of generic LDL-C lowering treatments may also substantially reduce the likelihood of reimbursement for branded counterparts or other competitive LDL-C lowering therapies, such as ETC-1002 if it is approved for commercial distribution. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed.

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

We may face competition for ETC-1002, if approved, from cheaper LDL-C lowering therapies sourced from foreign countries that have placed price controls on pharmaceutical products. The MMA contains provisions that may change U.S. importation laws and expand pharmacists and wholesalers ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. These changes to U.S. importation laws will not take effect unless and until the Secretary of Health and Human Services certifies that

the changes will pose no additional risk to the public s health and safety and will result in a significant reduction in the cost of products to consumers. The Secretary of Health and Human Services has so far declined to approve a reimportation plan. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop, including ETC-1002, and adversely affect our future revenues and prospects for profitability.

***The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found to have improperly promoted off-label uses, we may become subject to significant liability.***

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as ETC-1002 if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or other regulatory agencies as reflected in the product s approved labeling. If we receive marketing approval for ETC-1002 as a therapy for lowering LDL-C levels in statin intolerant patients with hypercholesterolemia, the first indication we intend to pursue, physicians may nevertheless prescribe ETC-1002 to their patients in a manner that is inconsistent with the approved label, potentially including as a therapy in addition to statins. If we are found to have promoted such off-label uses, we may become subject to significant liability.

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The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of ETC-1002, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

***Our market is subject to intense competition. If we are unable to compete effectively, our opportunity to generate revenue from the sale of ETC-1002, if approved, will be materially adversely affected.***

The LDL-C lowering therapies market is highly competitive and dynamic and dominated by the sale of statin treatments, including the cheaper generic versions of statins. We estimate that the total statin monotherapy and fixed combination market, including generic drugs, accounted for 69% of U.S. sales in the LDL-C lowering market in 2012. Our success will depend, in part, on our ability to obtain a share of the market, initially, for patients who are statin intolerant. Potential competitors in North America, Europe and elsewhere include major pharmaceutical companies, specialty pharmaceutical companies, biotechnology firms, universities and other research institutions and government agencies. Other pharmaceutical companies may develop LDL-C lowering therapies for statin intolerant patients that compete with ETC-1002, if approved, that do not infringe the claims of our patents, pending patent applications or other proprietary rights, which could materially adversely affect our business and results of operations.

Low-density lipoprotein cholesterol (LDL-C) lowering therapies currently on the market that would compete with ETC-1002 include the following:

- Statins, such as Crestor® (rosuvastatin) and Lipitor® (atorvastatin), including their cheaper generic versions;

- Cholesterol absorption inhibitors, such as Zetia® (ezetimibe), a monotherapy marketed by Merck & Co., and Welchol® (colesevelam), a bile acid sequestrant marketed by Daiichi Sankyo Inc.;

- MTP inhibitors, such as JUXTAPID® (lomitapide), marketed by Aegerion Pharmaceuticals, Inc.;

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

- Combination therapies, such as Vytorin® (ezetimibe and simvastatin) and Liptruzet® (ezetimibe and atorvastatin), marketed by Merck & Co., Inc.; and

- Other lipid-lowering monotherapies, such as Tricor® (fenofibrate) and Niaspan® (niacin extended release), and combination therapies, such as Advicor® (niacin extended release and lovastatin) and Simcor® (niacin and simvastatin), both of which are marketed by AbbVie, Inc.

Several other pharmaceutical companies have other LDL-C lowering therapies in development that may be approved for marketing in the United States or outside of the United States. Based on publicly available information, we believe the current therapies in development that would compete with ETC-1002 include:

- PCSK9 inhibitors, such as SAR236553/REGN727, a therapy in Phase 3 clinical testing being developed by Sanofi and Regeneron Pharmaceuticals, Inc., and AMG-145, a separate therapy in Phase 3 development being developed by Amgen Inc.; and

- CETP inhibitors, such as MK-0859, a therapy in Phase 3 clinical testing being developed by Merck, and LY2484595, a therapy in Phase 3 clinical testing being developed by Eli Lilly & Company.

Many of our potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience discovering and developing drug candidates, obtaining FDA and other marketing approvals of products and commercializing those products. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval for drugs and achieving widespread market acceptance. Our competitors drugs may be more effective, or more effectively marketed and sold, than ETC-1002, if approved, and may render ETC-1002 obsolete or non-competitive before we can recover the expenses of developing and commercializing it. If approved, ETC-1002 may also compete with unapproved and off-label LDL-C lowering treatments, and following the expiration of additional patents covering the LDL-C lowering market, we may also face additional competition from the entry of new generic drugs. We anticipate that we will encounter intense and increasing competition as new drugs enter the market and advanced technologies become available.

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

The use of ETC-1002 in clinical studies and the sale of ETC-1002, if approved, exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with ETC-1002. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, including as a result of interactions with alcohol or other drugs, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we become subject to product liability claims and cannot successfully defend ourselves against them, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in, among other things:

- withdrawal of patients from our clinical studies;
- substantial monetary awards to patients or other claimants;
- decreased demand for ETC-1002 or any future product candidates following marketing approval, if obtained;
- damage to our reputation and exposure to adverse publicity;
- increased FDA warnings on product labels;
- litigation costs;
- distraction of management s attention from our primary business;
- loss of revenue; and
- the inability to successfully commercialize ETC-1002 or any future product candidates, if approved.

We maintain product liability insurance coverage for our clinical studies with a $5 million annual aggregate coverage limit. Nevertheless, our insurance coverage may be insufficient to reimburse us for any expenses or losses we may suffer. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses, including if insurance coverage becomes increasingly expensive. If and when we obtain marketing approval for ETC-1002, we intend to expand our insurance coverage to include the sale of commercial products; however, we may not be able to obtain this product liability insurance on commercially reasonable terms. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial, particularly in light of the size of our business and financial resources. A product liability claim or series of claims brought against us could cause our stock price to decline and, if we are unsuccessful in defending such a claim or claims and the resulting judgments exceed our insurance coverage, our financial condition, business and prospects could be materially adversely affected.

***We are subject to healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of ETC-1002, if approved. Our future arrangements with third-party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute ETC-1002, if we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

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

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

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

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

- The federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.

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

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

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

***Our internal computer systems, or those of our third-party clinical research organizations or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our ETC-1002 development programs.***

Despite the implementation of security measures, our internal computer systems and those of our third-party clinical research organizations and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical study data for ETC-1002 could result in delays in our regulatory approval efforts and significantly increase our costs to recover or

reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of ETC-1002 could be delayed.

**Risks Related to our Intellectual Property**

***If we are unable to adequately protect our proprietary technology or maintain issued patents which are sufficient to protect ETC-1002, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects.***

Our commercial success will depend in part on our success obtaining and maintaining issued patents and other intellectual property rights in the United States and elsewhere and protecting our proprietary technology. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

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As of September 30, 2013, Esperion s patent estate, including patents we own or license from third parties, on a worldwide basis, included approximately 16 issued United States patents and 5 pending United States patent applications and 6 issued patents and 25 pending patent applications in other foreign jurisdictions. Of our worldwide patents and pending applications, only a subset relates to our small molecule program which includes our lead product candidate, ETC-1002. ETC-1002 is claimed in U.S. Patent No. 7,335,799 that is scheduled to expire in December 2025, which includes 711 days of patent term adjustment, and may be eligible for a patent term extension period of up to 5 years. U.S. Patent No. 8,497,301 claims a method of treatment using ETC-1002. We also have a pending U.S. patent application claiming methods of treatment using ETC-1002. There are currently three issued patents and four pending applications in countries outside the United States that relate to ETC-1002.

A second subset of this portfolio relates to our early-stage product candidate ESP41091. ESP41091 is claimed in U.S. Patent Nos. 7,119,221 and 7,405,226. Various methods of treatment using ESP41091 are claimed in U.S. Patent Nos. 8,153,690 and 8,309,604 and in at least one other pending application in the United States. There are currently two issued patents and four pending applications in countries outside the United States that relate to ESP41091.

Our 4WF patent portfolio currently consists of 19 issued patents and pending patent applications in the United States and other foreign jurisdictions regarding apolipoprotein mixtures, dimeric oxidation-resistant apolipoprotein variants and oxidant resistant apolipoprotein A1 variants and mimetic peptides thereof.

We cannot assure you that any of our patents have, or that any of our pending patent applications will mature into issued patents that will include, claims with a scope sufficient to protect ETC-1002 or our other product candidates. Others have developed technologies that may be related or competitive to our approach, and may have filed or may file patent applications and may have received or may receive patents that may overlap or conflict with our patent applications, either by claiming the same methods or formulations or by claiming subject matter that could dominate our patent position. The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions, and, therefore, the issuance, scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated, or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, *ex parte* reexamination, *inter partes* review and post-grant review proceedings, supplemental examination and may be challenged in district court. Patents granted in certain other countries may be subjected to opposition or comparable proceedings lodged in various national and regional patent offices. These proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, re-examination, opposition, post-grant review, *inter partes* review, supplemental examination or revocation proceedings may be costly. Thus, any patents that we may own or exclusively license may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third-party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize ETC-1002.

Furthermore, the issuance of a patent, while presumed valid and enforceable, is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, vendors, former employees and current employees. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. If these developments were to occur, they could have a material adverse effect on our sales.

Our ability to enforce our patent rights depends on our ability to detect infringement. It is difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor s or

potential competitor s product. Any litigation to enforce or defend our patent rights, if any, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If, in any proceeding, a court invalidated or found unenforceable our patents covering ETC-1002, our financial position and results of operations would be materially and adversely impacted. In addition, if a court found that valid, enforceable patents held by third parties covered ETC-1002, our financial position and results of operations would also be materially and adversely impacted.

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

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- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect ETC-1002;

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

- we will be able to successfully commercialize ETC-1002, if approved, before our relevant patents expire;

- we were the first to make the inventions covered by each of our patents and pending patent applications;

- we were the first to file patent applications for these inventions;

- others will not develop similar or alternative technologies that do not infringe our patents;

- any of our patents will be valid and enforceable;

- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;

- we will develop additional proprietary technologies or product candidates that are separately patentable; or

- that our commercial activities or products will not infringe upon the patents of others.

We rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors.

***If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished.***

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, contract manufacturers, vendors and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, we cannot guarantee that we have executed these agreements with each party that may have or have had access to our trade secrets.

Moreover, because we acquired certain rights to our lead product candidate from Pfizer, we must rely on Pfizer s practices, and those of its predecessors, with regard to parties that may have had access to our trade secrets related thereto before our incorporation. Any party with whom we or they have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they disclose such trade secrets, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position would be harmed.

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***We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing ETC-1002, if approved.***

Our success will depend in part on our ability to operate without infringing the intellectual property and proprietary rights of third parties. We cannot assure you that our business, products and methods do not or will not infringe the patents or other intellectual property rights of third parties.

The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may allege that ETC-1002 or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. Any claim relating to intellectual property infringement that is successfully asserted against us may require us to pay substantial damages, including treble damages and attorney s fees if we are found to be willfully infringing another party s patents, for past use of the asserted intellectual property and royalties and other consideration going forward if we are forced to take a license. In addition, if any such claim were successfully asserted against us and we could not obtain such a license, we may be forced to stop or delay developing, manufacturing, selling or otherwise commercializing ETC-1002.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign our products. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease developing, selling or otherwise commercializing ETC-1002;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all; and
- redesign, or rename in the case of trademark claims, ETC-1002 to avoid infringing the intellectual property rights of third parties, which may not be possible and, even if possible, could be costly and time-consuming.

Any of these risks coming to fruition could have a material adverse effect on our business, results of operations, financial condition and prospects.

***Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.***

The United States has recently enacted and is currently implementing the America Invents Act of 2011, wide-ranging patent reform legislation. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the United States Patent and Trademark Office, or the U.S. PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

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***We could become dependent on licensed intellectual property. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing ETC-1002 or our other product candidates, if approved.***

In the future, we may enter into license(s) to third-party intellectual property that are necessary or useful to our business. Such license agreement(s) will likely impose various obligations upon us, and our licensor(s) have or may have the right to terminate the license thereunder in the event of a material breach or, in some cases, at will. Future licensor(s) may allege that we have breached our license agreement with them or decide to terminate our license at will, and accordingly seek to terminate our license. If successful, this could result in our loss of the right to use the licensed intellectual property, which could materially adversely affect our ability to develop and commercialize a product candidate or product, if approved, as well as harm our competitive business position and our business prospects.

***We do not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.***

Filing, prosecuting and defending patents on product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

***We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

Our employees have been previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we are not aware of any claims currently pending against us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of the former employers of our employees. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to

commercialize ETC-1002, which would materially adversely affect our commercial development efforts.

**Risks Related to our Dependence on Third Parties**

***We will be unable to directly control all aspects of our clinical studies due to our reliance on CROs and other third parties that assist us in conducting clinical studies.***

We will rely on CROs to conduct our Phase 2b and Phase 3 clinical studies for ETC-1002. As a result, we will have less direct control over the conduct, timing and completion of these clinical studies and the management of data developed through the clinical studies than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or

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

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

Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording, and reporting the results of clinical studies to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical study participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements.

Problems with the timeliness or quality of the work of any CRO may lead us to seek to terminate our relationship with any such CRO and use an alternative service provider. Making this change may be costly and may delay our clinical studies, and contractual restrictions may make such a change difficult or impossible to effect. If we must replace any CRO that is conducting our clinical studies, our clinical studies may have to be suspended until we find another CRO that offers comparable services. The time that it takes us to find alternative organizations may cause a delay in the commercialization of ETC-1002 or may cause us to incur significant expenses to replicate data that may be lost. Although we do not believe that any CRO on which we may rely will offer services that are not available elsewhere, it may be difficult to find a replacement organization that can conduct our clinical studies in an acceptable manner and at an acceptable cost. Any delay in or inability to complete our clinical studies could significantly compromise our ability to secure regulatory approval of ETC-1002 and preclude our ability to commercialize ETC-1002, thereby limiting or preventing our ability to generate revenue from its sales.

***We rely completely on third-party suppliers to manufacture our clinical drug supplies for ETC-1002, and we intend to rely on third parties to produce commercial supplies of ETC-1002 and pre-clinical, clinical and commercial supplies of any future product candidate.***

We do not currently have, nor do we plan to acquire, the infrastructure or capability to internally manufacture our clinical drug supply of ETC-1002, or any future product candidates, for use in the conduct of our pre-clinical studies and clinical studies, and we lack the internal resources and the capability to manufacture any product candidates on a clinical or commercial scale. The facilities used by our contract manufacturers to manufacture the active pharmaceutical ingredient and final drug for ETC-1002, or any future product candidates, must be approved by the FDA and other comparable foreign regulatory agencies pursuant to inspections that would be conducted after we submit our NDA or relevant foreign regulatory submission to the applicable regulatory agency.

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

***If we do not establish successful collaborations, we may have to alter our development and commercialization plans for ETC-1002.***

Our drug development programs and commercialization plans for ETC-1002 will require substantial additional cash to fund expenses. We may develop and initially commercialize ETC-1002 in the United States without a partner. However, in order to pursue the broader statin resistant market in the United States, we may also enter into a partnership or co-promotion arrangement with an established pharmaceutical company that has a larger sales force and we may enter into collaborative arrangements to develop and commercialize ETC-1002 outside of the United States. We will face significant competition in seeking appropriate collaborators and these collaboration agreements are complex and time-consuming to negotiate. We may not be able to negotiate collaborations on acceptable terms, or at all. If that were to occur, we may have to curtail the development or delay commercialization of ETC-1002 in certain geographies, reduce the scope of our sales or marketing activities, reduce the scope of our commercialization plans, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities outside of the United States on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all.

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***If a collaborative partner terminates or fails to perform its obligations under an agreement with us, the commercialization of ETC-1002 could be delayed or terminated.***

We are not currently party to any collaborative arrangements for the commercialization of ETC-1002 or similar arrangements, although we may pursue such arrangements before any commercialization of ETC-1002 outside of the United States or to further commercialize ETC-1002 in the broader statin resistant market in the United States, if approved. If we are successful in entering into collaborative arrangements for the commercialization of ETC-1002 or similar arrangements and any of our collaborative partners does not devote sufficient time and resources to a collaboration arrangement with us, we may not realize the potential commercial benefits of the arrangement, and our results of operations may be materially adversely affected. In addition, if any such future collaboration partner were to breach or terminate its arrangements with us, the commercialization of ETC-1002 could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue commercialization of ETC-1002 on our own in such locations.

Much of the potential revenue from future collaborations may consist of contingent payments, such as payments for achieving regulatory milestones or royalties payable on sales of drugs. The milestone and royalty revenue that we may receive under these collaborations will depend upon our collaborators ability to successfully develop, introduce, market and sell new products. In addition, collaborators may decide to enter into arrangements with third parties to commercialize products developed under collaborations using our technologies, which could reduce the milestone and royalty revenue that we may receive, if any. Future collaboration partners may fail to develop or effectively commercialize products using our products or technologies because they:

- decide not to devote the necessary resources due to internal constraints, such as limited personnel with the requisite expertise, limited cash resources or specialized equipment limitations, or the belief that other drug development programs may have a higher likelihood of obtaining marketing approval or may potentially generate a greater return on investment;

- decide to pursue other technologies or develop other product candidates, either on their own or in collaboration with others, including our competitors, to treat the same diseases targeted by our own collaborative programs;

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

- cannot obtain the necessary marketing approvals.

Competition may negatively impact a partner s focus on and commitment to ETC-1002 and, as a result, could delay or otherwise negatively affect the commercialization of ETC-1002 outside of the United States or in the broader statin resistant market in the United States. If future collaboration partners fail to develop or effectively commercialize ETC-1002 for any of these reasons, our sales of ETC-1002, if approved, may be limited, which would have a material adverse effect on our operating results and financial condition.

**Risks Related to General Business, Employee Matters and Managing Growth**

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

In connection with being a newly public company, we expect to increase our number of employees and the scope of our operations. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure; give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of ETC-1002. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize ETC-1002, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

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***Our future success depends on our ability to retain both our founder, Executive Chairman and Chief Scientific Officer and our President and Chief Executive Officer, and to attract, retain and motivate qualified personnel.***

We are highly dependent on Dr. Roger S. Newton, our founder, Executive Chairman and Chief Scientific Officer, and Tim M. Mayleben, our President and Chief Executive Officer. We have entered into employment agreements with Dr. Newton and Mr. Mayleben, but any employee may terminate his or her employment with us. Although we do not have any reason to believe that we will lose the services of either Dr. Newton or Mr. Mayleben in the foreseeable future, the loss of the services of either individual might impede the achievement of our research, development and commercialization objectives. We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Recruiting and retaining qualified scientific personnel and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific personnel from universities and research institutions. Failure to succeed in clinical studies may make it more challenging to recruit and retain qualified scientific personnel.

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

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

***Our employees may engage in misconduct or other improper activities, including violating applicable regulatory standards and requirements or engaging in insider trading, which could significantly harm our business.***

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA and applicable non-U.S. regulators, provide accurate information to the FDA and applicable non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of, including trading on, information obtained in the course of clinical studies, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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

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

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**Risks Related to our Financial Position and Capital Requirements**

***We have not generated any revenue from ETC-1002 and may never be profitable.***

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our lead product candidate, ETC-1002, and we do not know when, or if, we will generate any revenue. We do not expect to generate significant revenue unless and until we obtain marketing approval of, and begin to sell, ETC-1002. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- initiate and successfully complete our Phase 2b clinical studies that meet their clinical endpoints;

- initiate and successfully complete our Phase 3 clinical program;

- initiate and successfully complete all safety studies required to obtain U.S. and foreign marketing approval for ETC-1002 as a treatment for patients with hypercholesterolemia;

- commercialize ETC-1002, if approved, by developing a sales force or entering into collaborations with third parties; and

- achieve market acceptance of ETC-1002 in the medical community and with third-party payors.

Absent our entering into a collaboration or partnership agreement, we expect to incur significant sales and marketing costs as we prepare to commercialize ETC-1002. Even if we initiate and successfully complete our Phase 3 clinical program of ETC-1002, which includes two pivotal Phase 3 clinical studies and one long-term safety study, which each meet their clinical endpoints and ETC-1002 is approved for commercial sale, and despite expending these costs, ETC-1002 may not be a commercially successful drug. We may not achieve profitability soon after generating product sales, if ever. If we are unable to generate product revenue, we will not become profitable and may be unable to continue operations without continued funding.

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

We may seek additional capital through a combination of private and public equity offerings, debt financings, collaborations and strategic and licensing arrangements. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable

into common stock, your ownership interest in our company will be diluted. In addition, the terms of any such securities may include liquidation or other preferences that materially adversely affect your rights as a stockholder. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic partnerships and licensing arrangements with third parties, we may have to relinquish valuable rights to ETC-1002, our intellectual property, future revenue streams or grant licenses on terms that are not favorable to us.

***Our recurring operating losses have raised substantial doubt regarding our ability to continue as a going concern.***

We have a limited operating history and have not commercialized any products or generated any revenue since our inception. We have incurred operating losses in each year since our inception. Our recurring operating losses raise substantial doubt about our ability to continue as a going concern. As a result, for the fiscal year ended December 31, 2012, our independent registered public accounting firm has issued its report on our financial statements and has expressed substantial doubt about our ability to continue as a going concern. We have no current source of revenue to sustain our present activities, and we do not expect to generate revenue until and unless the FDA or other applicable regulatory authorities approve ETC-1002 and we successfully commercialize ETC-1002. Accordingly, our ability to continue as a going concern will require us to obtain additional financing to fund our operations. Uncertainty surrounding our ability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees.

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***Our ability to use our net operating loss carry forwards may be subject to limitation.***

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, changes in our ownership may limit the amount of our net operating loss carryforwards that could be utilized annually to offset our future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards before they expire. The closing of our initial public offering, together with private placements and other transactions that have occurred since our inception, may trigger such an ownership change pursuant to Section 382. Any such limitation, whether as the result of our initial public offering, prior private placements, sales of our common stock by our existing stockholders or additional sales of our common stock by us after our initial public offering, could have a material adverse effect on our results of operations in future years. We have not completed a study to assess whether an ownership change for purposes of Section 382 has occurred, or whether there have been multiple ownership changes since our inception, due to the significant costs and complexities associated with such study.

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

As a public company, we are required to comply with applicable provisions of the Sarbanes-Oxley Act of 2002, as well as other rules and regulations promulgated by the SEC and the NASDAQ Stock Market LLC, or NASDAQ, which results in significant initial and continuing legal, accounting, administrative and other costs and expenses. The listing requirements of The NASDAQ Global Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel need to devote a substantial amount of time to ensure that we comply with all of these requirements.

We are subject to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, and the related rules of the SEC that generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with the second annual report that we will be required to file with the SEC, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if before such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting.

We are in the early stages of the costly and challenging process of evaluating and testing our internal controls for the purpose of providing the reports required by these rules. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, we are required to timely file accurate quarterly and annual reports with the SEC under the Securities Exchange Act of 1934, or the Exchange Act, as amended. In order to report our results of operations and financial statements on an accurate and timely basis, we depend on CROs to provide timely and accurate

notice of their costs to us. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The NASDAQ Global Market or other adverse consequences that would materially harm our business.

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

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

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

- plans for, progress of or results from clinical efficacy or safety studies of ETC-1002;
- the failure of the FDA to approve ETC-1002;
- announcements of new products, technologies, commercial relationships, acquisitions or other events by us or our competitors;
- the success or failure of other LDL-C lowering therapies;
- regulatory or legal developments in the United States and other countries;
- failure of ETC-1002, if approved, to achieve commercial success;
- fluctuations in stock market prices and trading volumes of similar companies;
- general market conditions and overall fluctuations in U.S. equity markets;
- variations in our quarterly operating results;

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

- changes in accounting principles;

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

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

- additions or departures of key personnel;

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

- other risks and uncertainties described in these risk factors.

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

***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. If we were to be sued, it could result in substantial costs and a diversion of management s attention and resources, which could harm our business.

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

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

***We are an emerging growth company, and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.***

We are an emerging growth company, as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

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

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

***We do not intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.***

We have never declared or paid any cash dividend on our common stock and do not currently intend to do so in the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which you purchased them.

***Future sales of our common stock may cause our stock price to decline.***

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

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

**Unregistered Sales of Equity Securities**

During the quarter ended September 30, 2013 we granted stock options to certain employees, consultants and directors to purchase an aggregate of 571,000 shares of our common stock at a weighted-average exercise price of $17.13 per share. We deemed these grants of stock options as exempt pursuant to Section 4(2) of the Securities Act or in reliance on Rule 701 of the Securities Act as offers and sales of securities under compensatory benefit plans and contracts relating to compensation in compliance with Rule 701. Each of the recipients of securities in any transaction exempt from registration either received or had adequate access, through employment, business or other relationships, to information about us.

**Use of Proceeds from Initial Public Offering of Common Stock**

On July 1, 2013, we closed the sale of 5,000,000 shares of common stock to the public at an initial public offering price of $14.00 per share. On July 11, 2013, the underwriters exercised their over-allotment option in full, pursuant to which we sold an additional 750,000 shares of common stock at a price of $14.00 per share. The offer and sale of the shares in the IPO was registered under the Securities Act pursuant to registration statements on Form S-1 (File No. 333-188595), which was filed with the SEC on May 14, 2013 and amended subsequently and declared effective on June 25, 2013, and Form S-1MEF (File No. 333-189590), which was filed with the SEC on June 25, 2013 and declared effective on June 25, 2013. Following the sale of the shares in connection with the closing of our IPO, the offering terminated. The offering did not terminate before all the securities registered in the registration statements were sold. The underwriters of the offering were Credit Suisse Securities (USA) LLC and Citigroup Global Markets Inc. acted as joint book-running managers for the offering and as representatives of the underwriters. JMP Securities LLC and Stifel, Nicolaus & Company, Incorporated acting as co-managers for the offering.

We raised approximately $72.2 million in net proceeds after deducting underwriting discounts and commissions of approximately $5.6 million and other offering expenses of approximately $2.7 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

To date, we have not yet used the net proceeds from our IPO. We invested the funds received in cash equivalents and other short-term investments in accordance with our investment policy. None of such payments were direct or indirect payments to any of our directors or officers (or their associates), to persons owning ten percent or more of our common stock or to any other affiliates. As described in our final prospectus filed with the SEC on June 26, 2013 pursuant to Rule 424(b) under the Securities Act, we expect to use the net proceeds from our IPO to fund the clinical development of ETC-1002 through the completion of our currently anticipated Phase 2b clinical studies and end of Phase 2 meeting with the FDA, as well as for working capital and general corporate purposes, including funding the costs of operating as a public company. We currently expect to have our end of Phase 2 meeting with the FDA in the first quarter of 2015.

**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.

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**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.

November 6, 2013 By: /s/ Tim M. Mayleben
Tim M. Mayleben
*President and Chief Executive Officer*

*(Principal Executive Officer and Principal Financial Officer)*

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**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 | 3.1 | 6/12/2013 | 333-188595 |
| 3.2 | Amended and Restated By-Laws of the Registrant. | S-1/A | 3.2 | 6/12/2013 | 333-188595 |
| 4.1 | Specimen Common Stock Certificate of the Registrant. | S-1/A | 4.1 | 6/12/2013 | 333-188595 |
| 10.1 | Transitional Services and Letter Agreement by and between Esperion Therapeutics, Inc. and Troy A. Ignelzi, effective August 8, 2013. | 10-Q | 10.1 | 8/12/2013 | 001-35986 |
| 10.2 | Second Amendment to Lease, dated August 26, 2013, between the Registrant and the Michigan Land Bank Fast Track Authority. | 8-K | 10.1 | 8/27/2013 | 001-35986 |
| 31.1* | Certification of Principal Executive Officer and Principal Financial Officer pursuant to Exchange Act rules 13a-14 or 15d-14. | | | | |
| 32.1* | Certification of Principal Executive Officer and Principal Financial Officer pursuant to Exchange Act rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350. | | | | |
| 101.INS** | XBRL Instance Document. | | | | |
| 101.SCH** | XBRL Taxonomy Extension Schema Document. | | | | |
| 101.CAL** | XBRL Taxonomy Extension Calculation Document. | | | | |
| 101.DEF** | XBRL Taxonomy Extension Definition Linkbase Document. | | | | |
| 101.LAB** | XBRL Taxonomy Extension Labels Linkbase Document. | | | | |
| 101.PRE** | XBRL Taxonomy Extension Presentation Link Document. | | | | |

* Filed herewith.

** Attached as Exhibit 101 to this report are documents formatted in XBRL (Extensible Business Reporting Language). Pursuant to Rule 406T of Regulation S-T, the interactive data file is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is otherwise not subject to liability under these sections.