designs that disappear

# Q3 Quarterly Report on Form 10-Q

**San Diego, California and Sydney, Australia (Thursday, 10 November 2016, AEDT)** – REVA Medical, Inc. (ASX: RVA) ("REVA" or the "Company") is pleased to present the attached Quarterly Report on Form 10-Q, as filed with the U.S. Securities and Exchange Commission today. The Form 10-Q includes the Company's unaudited Financial Statements for the three and nine months ended 30 September 2016 and other required disclosure. The financial statements included in the Form 10-Q were prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and are denominated in United States dollars.

REVA's quarterly briefing call is being held today at 9:00 a.m. AEDT (which is 2:00 p.m. US PST). Ms. Regina Groves, Chief Executive Officer, will host the call, provide an operational update, and discuss the financial results through 30 September 2016. Access details for the call are available on the Company's website under the Investor Relations tab.

## About REVA

REVA is a clinical stage medical device company located in San Diego, California, USA, that is working to commercialize its proprietary bioresorbable scaffolds, as an alternative to metal stents, to treat coronary artery disease. Scaffolds provide restoration of blood flow, support the artery through the healing process, then disappear (or "resorb") from the body over a period of time. This resorption allows the return of natural movement and function of the artery, a result not attainable with permanent metal stents. The Company's *Fantom*® scaffold has been designed to offer an ideal balance of thinness and strength, with distinct ease-of-use features including complete scaffold visibility under x-ray, expansion with one continuous inflation, and no procedural time limitations. REVA will require regulatory approval before it can commercialize *Fantom* or any other product.

### Forward-Looking Statements

*This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management. All statements that are not statements of historical fact, including those statements that address future operating performance and events or developments that we expect or anticipate will occur in the future, are forward-looking statements, such as those statements regarding our ability to obtain regulatory approvals, timely and successfully complete our clinical trials, protect our intellectual property position, commercialize our products if and when approved, develop and commercialize new products, recruit and retain our key personnel, and estimates regarding our capital requirements and financial performance. You should not place undue reliance on forward-looking statements. Although management believes forward-looking statements are reasonable as and when made, forward-looking statements are subject to a number of risks and uncertainties that may cause our actual results to vary materially from those expressed in forward-looking statements, including the risks and uncertainties that are described in the "Risk Factors" section of our Annual Report on Form 10-K filed with the US Securities and Exchange Commission (the "SEC") on March 10, 2016, and as may be updated in our periodic reports thereafter. Any forward-looking statements in this announcement speak only as of the date when made. REVA does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.*

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**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

# FORM 10-Q

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

**For the quarterly period ended September 30, 2016**

**or**

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

**For the transition period from to**

**Commission file number: 000-54192**

# REVA MEDICAL, INC.

*(Exact name of registrant as specified in its charter)*

| **Delaware** | **33-0810505** |
|---|---|
| *(State or other jurisdiction of incorporation or organization)* | *(I.R.S. Employer Identification No.)* |
| **5751 Copley Drive**<br>**San Diego, CA 92111** | **(858) 966-3000** |
| *(Address of principal executive offices, including zip code)* | *(Registrant's telephone number including area code)* |

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

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

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

Large accelerated filer ☐ Accelerated filer ☑ Non-accelerated filer ☐ Smaller reporting company ☐

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

As of November 1, 2016, a total of 42,742,819 shares of the registrant's Common Stock, $0.0001 par value per share, were outstanding.

**REVA MEDICAL, INC.**

**FORM 10-Q — QUARTERLY REPORT**
**For the Quarter Ended September 30, 2016**

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**REFERENCES**

**Corporate Information**

We incorporated in Delaware in October 2010. Our principal executive offices are located at 5751 Copley Drive, San Diego, CA 92111, U.S.A., and our telephone number is (858) 966-3000. Our website address is *www.revamedical.com*. The information on, or accessible through, our website is not part of this report. Unless the context implies otherwise, references in this report and the information incorporated herein by reference to "REVA Medical," "REVA," the "Company," "we," "us," and "our" refer to REVA Medical, Inc.

**Currency**

Unless indicated otherwise in this report, all references to "$" or "dollars" refer to United States dollars, the lawful currency of the United States of America. References to "A$" refer to Australian dollars, the lawful currency of the Commonwealth of Australia.

**Trademarks**

The names *Fantom*® and *ReZolve*® are trademarked by us. All other trademarks, trade names, and service marks appearing in this report are the property of their respective owners. Use or display by us of other parties' trademarks, trade dress, or products is not intended to and does not imply a relationship with, or endorsement or sponsorship of, us by the trademark or trade dress owner.

## PART I. FINANCIAL INFORMATION

### Item 1. Unaudited Consolidated Financial Statements

**REVA Medical, Inc.**
**Consolidated Balance Sheets**
(Unaudited)
(in thousands, except share and per share amounts)

| | December 31, 2015 | September 30, 2016 |
|---|---|---|
| **Assets** | | |
| **Current Assets:** | | |
| Cash and cash equivalents | $ 16,895 | $ 11,553 |
| Prepaid expenses and other current assets | 397 | 202 |
| Total current assets | 17,292 | 11,755 |
| **Non-Current Assets:** | | |
| Property and equipment, net | 2,719 | 2,454 |
| Other non-current assets | 60 | 60 |
| Total non-current assets | 2,779 | 2,514 |
| **Total Assets** | $ 20,071 | $ 14,269 |
| **Liabilities and Stockholders' Deficit** | | |
| **Current Liabilities:** | | |
| Accounts payable | $ 1,054 | $ 883 |
| Accrued expenses and other current liabilities | 2,242 | 2,021 |
| Convertible notes payable | — | $ 113,475 |
| Accrued interest on convertible notes payable | — | 3,673 |
| Total current liabilities | 3,296 | 120,052 |
| **Long-Term Liabilities:** | | |
| Convertible notes payable | 75,365 | — |
| Common stock warrant liability | 19,622 | — |
| Other long-term liabilities | 2,352 | 316 |
| Total long-term liabilities | 97,339 | 316 |
| **Total Liabilities** | 100,635 | 120,368 |
| Commitments and contingencies (Note 7) | | |
| **Stockholders' Deficit** | | |
| Common stock — $0.0001 par value; 100,000,000 shares authorized; 38,155,986 and 42,704,486 shares issued and outstanding at December 31, 2015 and September 30, 2016, respectively | 4 | 4 |
| Class B common stock — $0.0001 par value; 25,000,000 shares authorized; no shares issued or outstanding | — | — |
| Undesignated preferred stock — $0.0001 par value; 5,000,000 shares authorized; no shares issued or outstanding | — | — |
| Additional paid-in capital | 254,572 | 298,333 |
| Accumulated deficit | (335,140) | (404,436) |
| **Total Stockholders' Deficit** | (80,564) | (106,099) |
| **Total Liabilities and Stockholders' Deficit** | $ 20,071 | $ 14,269 |

The accompanying notes are an integral part of these financial statements.

**REVA Medical, Inc.**
**Consolidated Statements of Operations and Comprehensive Loss**
(Unaudited)
(in thousands, except share and per share amounts)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2015 | 2016 | 2015 | 2016 |
| **Operating Expense:** | | | | |
| Research and development | $ 4,404 | $ 4,212 | $ 11,735 | $ 14,165 |
| General and administrative | 1,818 | 1,937 | 4,973 | 6,496 |
| Loss from operations | (6,222) | (6,149) | (16,708) | (20,661) |
| **Other Expense:** | | | | |
| Interest income | 1 | 1 | 7 | 3 |
| Interest expense | (475) | (512) | (1,410) | (1,522) |
| Loss on change in fair value of convertible notes payable and warrant liability | (28,180) | (17,269) | (34,311) | (47,067) |
| Other income (expense) | 8 | (14) | 51 | (49) |
| Other expense | (28,646) | (17,794) | (35,663) | (48,635) |
| **Net Loss and Comprehensive Loss** | $ (34,868) | $ (23,943) | $ (52,371) | $ (69,296) |
| **Net Loss Per Common Share**: | | | | |
| Net loss per share, basic and diluted | $ (1.04) | $ (0.56) | $ (1.56) | $ (1.65) |
| Shares used to compute net loss per share, basic and diluted | 33,647,104 | 42,681,176 | 33,543,151 | 41,909,945 |

The accompanying notes are an integral part of these financial statements.

**REVA Medical, Inc.**
**Consolidated Statements of Cash Flows**
(Unaudited)
(in thousands)

| | Nine Months Ended September 30, 2015 | 2016 |
|---|---|---|
| **Cash Flows from Operating Activities:** | | |
| Net loss | $ (52,371) | $ (69,296) |
| Non-cash adjustments to reconcile net loss to net cash used for operating activities: | | |
| Depreciation and amortization | 811 | 851 |
| Stock-based compensation | 2,368 | 3,754 |
| Interest on convertible notes payable | 1,410 | 1,522 |
| Loss on change in fair value of convertible notes payable and warrant liability | 34,311 | 47,067 |
| Other non-cash expenses | 41 | 15 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | 119 | 195 |
| Accounts payable | 36 | (133) |
| Accrued expenses and other current liabilities | (490) | (236) |
| Other long-term liabilities | (119) | 115 |
| Net cash used for operating activities | (13,884) | (16,146) |
| **Cash Flows from Investing Activities:** | | |
| Purchases of property and equipment | (754) | (624) |
| Maturities of investments | 498 | — |
| Net cash used for investing activities | (256) | (624) |
| **Cash Flows from Financing Activities:** | | |
| Proceeds from issuances of common stock | 221 | 11,428 |
| Costs of issuing convertible notes payable and warrants | (50) | — |
| Net cash provided by financing activities | 171 | 11,428 |
| Net decrease in cash and cash equivalents | (13,969) | (5,342) |
| Cash and cash equivalents at beginning of period | 25,814 | 16,895 |
| **Cash and Cash Equivalents at End of Period** | $ 11,845 | $ 11,553 |
| | | |
| **Supplemental Non-Cash Information:** | | |
| Property and equipment in accounts payable at end of period | $ 36 | $ 12 |
| Warrant liability transferred to equity upon exercise | $ — | $ 28,579 |

The accompanying notes are an integral part of these financial statements.

## 1. Background and Basis of Presentation

***Background*:** REVA Medical, Inc. ("REVA" or the "Company") was incorporated in California in 1998 under the name MD3, Inc. In March 2002, we changed our name to REVA Medical, Inc. In October 2010, we reincorporated in Delaware. We established a non-operating wholly owned subsidiary, REVA Germany GmbH, in 2007. In these notes the terms "us," "we," or "our" refer to REVA and our consolidated subsidiary unless context dictates otherwise.

We do not yet have a product available for sale. We have submitted an application for CE Marking of our *Fantom* scaffold product, which, if approved, would allow us to commercialize *Fantom* in Europe and other countries that recognize the CE Mark. *Fantom* is a drug-eluting bioresorbable stent used to treat vascular disease in humans. This stent was introduced in humans in December 2014 and has been implanted subsequently in 247 patients in eight countries outside the United States. We used the data from 117 of these patients at a six-month time point in our CE Mark application, which we completed submission of in early August 2016.

In December 2010 we completed an initial public offering (the "IPO") of our common stock in Australia and registered with the U.S. Securities and Exchange Commission ("SEC") and, consequently, became an SEC filer. Our stock is traded in the form of CHESS Depositary Interests ("CDIs") on the Australian Securities Exchange ("ASX"); each share of our common stock is equivalent to ten CDIs. Our trading symbol is "RVA.AX." Under an agreement with the current holders of our convertible notes, we intend to pursue a listing of our common stock on NASDAQ or another exchange approved by our noteholders, with the intention to be accepted for listing no later than June 30, 2017.

***Basis of Presentation*:** We have prepared the accompanying consolidated financial statements in accordance with U.S. generally accepted accounting principles ("GAAP") and the rules and regulations of the SEC for reporting of interim financial information and, therefore, certain information and footnote disclosures normally included in annual financial statements have been omitted. Accordingly, these interim financial statements should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations contained in this report and with the audited financial statements and accompanying footnotes included in our Annual Report on Form 10-K ("Form 10-K") for the year ended December 31, 2015.

Our consolidated financial statements include the accounts of REVA and our wholly owned subsidiary. All intercompany transactions and balances, if any, have been eliminated in consolidation.

These interim consolidated financial statements are unaudited; the consolidated balance sheet as of December 31, 2015 was derived from the Company's audited financial statements included in our Form 10-K for the year ended December 31, 2015.

The interim financial statements have been prepared on the same basis as our annual financial statements and, in our opinion, all adjustments, consisting only of normal recurring accruals, considered necessary for a fair statement of the results of these interim periods have been included.

The results of operations for the three-month and nine-month periods ended September 30, 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016 or for any other interim period.

***Liquidity*:** We have experienced recurring losses and negative cash flows from operating activities since our inception and, as of September 30, 2016, we had an accumulated deficit of $404,436,000 and current liabilities of $120,052,000. While we anticipate initiating commercial operations by mid-2017, until we generate revenue, and at a level to support our cost structure, we expect to continue to incur substantial operating losses and net cash outflows. We had cash of $11,553,000 at September 30, 2016, which reflects the receipt of $11,407,000 in cash proceeds from warrant exercises on February 12, 2016. Based on our current operating plans and projections, we believe this cash balance will be sufficient to fund our operating and capital needs into, and possibly through, the first fiscal quarter of 2017. These conditions, combined with the uncertainty of the timing of receipt of future financings, if any, raise substantial doubt about our ability to continue as a going concern.

**1. Background and Basis of Presentation** (continued)

***Liquidity (continued)*:** A total of $117,148,000 of the current liabilities as of September 30, 2016 relate to our convertible notes payable (the "Notes"), which contain a one-time option for cash redemption at face value, plus accrued interest, on June 30, 2017, if the Notes are not otherwise converted or redeemed prior to that time. As discussed in Note 3 below, the Notes automatically convert to equity if and when we achieve the three conditions to automatic conversion. While we believe we would be able to cause the conversion of the Notes to equity prior to June 30, 2017, if the noteholders were to exercise their one-time option to request cash redemption on June 30, 2017, there can be no assurance that we will be successful prior to June 30, 2017 in triggering the automatic conversion of the Notes. Because we believe the Notes will be converted to equity prior to the time we would be requested to redeem their $25,000,000 face value, plus accrued interest, we do not currently anticipate requiring additional capital to redeem them.

Although we currently have no set financing plans, until we can sustain positive cash flows from our operations, we intend to fund our future needs by raising additional capital through equity or debt issuances. There can be no assurance that we will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to us. If we are unable to raise sufficient additional capital, we may be compelled to reduce the scope of our operations and planned capital expenditures or sell certain assets, including intellectual property assets.

Even if we do attain revenue, we may never become profitable and even if we do attain profitable operations, we may not be able to sustain that profitability or positive cash flows on a recurring basis.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

***Use of Estimates*:** In order to prepare our financial statements in conformity with GAAP, we are required to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Our most significant estimates relate to, or have related to, the fair value of our convertible notes payable, the fair value of our warrant liability, our operating expense accruals, including clinical study expenses, and our stock-based compensation. Actual results could differ from our estimates.

**2. Fair Value Measurements**

We measure the fair value of our financial and non-financial assets and liabilities at each reporting date in accordance with the fair value hierarchy according to GAAP, which requires that fair value measurements be classified and disclosed in one of the following three categories:

Level 1 – Quoted market prices for identical assets or liabilities in active markets at the measurement date;

Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities in active or non-active markets, or other inputs that can be corroborated by observable market data for substantially the full term of an asset or liability; and,

Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of an asset or liability, including management's best estimate of the factors that market participants would use in pricing an asset or liability at the measurement date.

**2. Fair Value Measurements** (continued)

We carry our convertible notes payable and, until February 12, 2016 when the warrants were exercised in full, our common stock warrant liability at fair value. We carry our other financial instruments at amortized cost, which we consider to be reasonable estimates of their respective fair values due to their short-term nature and, therefore, fair value information is not provided in the following table; these other financial instruments include cash and cash equivalents, accounts payable, and accrued expenses. Utilizing the lowest level inputs available under the measurement hierarchy, the fair values of our measured financial instruments, which consist only of liabilities, are as follows:

| | Level 3 (in thousands) |
|---|---|
| ***Fair Value of Liabilities at December 31, 2015:*** | |
| Convertible notes payable | $ 75,365 |
| Common stock warrant liability | 19,622 |
| | $ 94,987 |
| ***Fair Value of Liabilities at September 30, 2016:*** | |
| Convertible notes payable | $ 113,475 |
| Common stock warrant liability | — |
| | $ 113,475 |

We had no Level 1 or Level 2 financial instruments through September 30, 2016.

Our Level 3 financial liabilities, which are recurring, consist of convertible notes payable (the "Notes") and, until they were exercised in full, warrants for the purchase of common stock, all of which were issued in November 2014. The fair values of the Notes were determined utilizing a least squares Monte Carlo simulation model and valuation of the warrants was determined utilizing a Black-Scholes valuation model. Both models require use of unobservable inputs that are determined by management, with the assistance of independent experts. These inputs represent our best estimates, but involve certain inherent uncertainties. We used the market value of the underlying stock, a life equal to the contractual life of the financial instrument, incremental borrowing rates and bond yields that correspond to instruments of similar credit worthiness and the instrument's remaining life, an estimate of volatility based on the historical prices of our trading securities, and we made assumptions as to our abilities to test and commercialize our product(s), to obtain future financings when and if needed, and to comply with the terms and conditions of our Notes.

A summary of the assumptions used to value the Notes and warrants is as follows:

| | December 31, 2015 | September 30, 2016 |
|---|---|---|
| Market price per share of common stock | $6.26 | $9.73 |
| Risk-free interest rate | 1.07% | 1.53% |
| Expected volatility of common stock | 70.0% | 70.0% |
| Expected life – years | 3.87 | 3.12 |
| Bond yield of equivalent securities | 29.1% | 26.5% |

A significant change in the market price per share, expected volatility, or bond yield of equivalent securities, in isolation, would result in significantly higher or lower fair value measurements. In combination, changes in these inputs could result in a significantly higher or lower fair value measurement if the input changes were to be aligned, or could result in a minimally higher or lower fair value measurement if the input changes were of a compensating nature.

**2. Fair Value Measurements** (continued)

We recorded a total of $28,180,000 and $17,269,000 in unrealized losses during the three-month periods and a total of $34,311,000 and $47,067,000 in unrealized losses during the nine-month periods ended September 30, 2015 and 2016, respectively, that arose from the change in fair value on our Level 3 financial liabilities. Our Level 3 fair value activity through September 30, 2016 is as follows:

| | Level 3 (in thousands) |
|---|---|
| ***Balance at December 31, 2015*** | $ 94,987 |
| ***Losses from Change in Fair Value:*** | |
| Convertible notes payable | 23,807 |
| Common stock warrant liability | 8,957 |
| ***Transfer to additional paid-in capital upon exercise of warrants*** | (28,579) |
| ***Balance at March 31, 2016*** | 99,172 |
| ***Gain from Change in Fair Value:*** | |
| Convertible notes payable | (2,966) |
| ***Balance at June 30, 2016*** | 96,206 |
| ***Loss from Change in Fair Value:*** | |
| Convertible notes payable | 17,269 |
| ***Balance at September 30, 2016*** | $ 113,475 |

**3. Convertible Notes Payable and Warrants to Purchase Common Stock**

In November 2014, we issued 250 convertible notes payable, each with a face value of $100,000, for total cash proceeds of $25,000,000. The Notes are convertible into 11,506,155 shares of common stock, which is a conversion rate of $2.17275 per share. The Notes are convertible at any time at the holders' election; the Notes automatically convert in the case where we have received CE Mark approval of our *Fantom* product, sustained a market trading price of at least A$0.60 per CDI for 20 consecutive trading days, and listed our securities for trading on NASDAQ or another stock exchange that is acceptable to the noteholders. The Notes mature on November 14, 2019, if not converted or redeemed earlier. Interest accrues on the Notes at the rate of 7.54 percent per annum, compounded annually, and is payable upon redemption or maturity; accrued interest is not payable or convertible upon conversion of the Notes. Effective March 22, 2016 upon an amendment to the Notes and approved by our shareholders, the Notes provide the holders a one-time option for cash redemption on June 30, 2017, if not previously converted or redeemed, for the face value plus accrued interest.

Following an analysis of the embedded and derivative features of the Notes upon their issuance in 2014, and a projection of the volatility of their effective interest rates under the cost method, we made an irrevocable election to utilize fair value accounting for the Notes. Management believed the fair value method of accounting would provide a more appropriate presentation of these liabilities than would be provided under the cost method. The fair values of the Notes as of December 31, 2015 and September 30, 2016 were calculated to be $50,365,000 and $88,475,000, respectively, higher than the unpaid principal balance of the Notes of $25,000,000. The increases of $19,760,000 and $38,110,000 in the fair value of the Notes during the nine months ended September 30, 2015 and 2016, respectively, were recorded as losses in the consolidated statement of operations.

In connection with the issuance of the Notes in November 2014, we issued warrants to the noteholders to purchase up to 8,750,000 shares of common stock. In October 2015, a total of 4,375,000 warrants were exercised for $9,506,000 cash proceeds and on February 12, 2016 the remaining 4,375,000 warrants were exercised for $11,407,000 cash proceeds. The fair value of the warrants on the February 12, 2016 exercise date was calculated to be $28,579,000. The increases of $14,551,000 and $8,957,000 in fair value of the warrant liability during the nine months ended September 30, 2015 and the period from December 31, 2015 to February 12, 2016, respectively, were recorded as losses in the consolidated statement of operations.

## 4. Balance Sheet Details

***Property and Equipment and Accrued Expenses*:** Components of our property and equipment and accrued expenses and other current liabilities are as follows:

| | December 31, 2015 | September 30, 2016 |
|---|---|---|
| | (in thousands) | |
| ***Property and Equipment:*** | | |
| Furniture, office equipment, and software | $ 650 | $ 661 |
| Laboratory equipment | 5,952 | 6,503 |
| Leasehold improvements | 2,386 | 2,407 |
| | 8,988 | 9,571 |
| Accumulated depreciation and amortization | (6,269) | (7,117) |
| | $ 2,719 | $ 2,454 |
| ***Accrued Expenses and Other Current Liabilities:*** | | |
| Accrued salaries and other employee costs | $ 1,311 | $ 1,064 |
| Accrued operating expenses | 745 | 766 |
| Accrued use taxes and other | 186 | 191 |
| | $ 2,242 | $ 2,021 |

## 5. Income Taxes

We have reported tax net operating losses since our inception through September 30, 2016; therefore, no provision for income taxes has been recorded since our inception. The net operating tax loss carryforwards arising from our net losses may be available to offset future taxable income for income tax purposes; however, under Internal Revenue Code ("IRC") Sections 382 and 383, use of the net operating tax loss carryforwards, as well as our research tax credit carryforwards, may be limited based on cumulative changes in ownership. We have established a valuation allowance against our net deferred tax assets due to the uncertainty surrounding the realization of those assets and we, therefore, have no deferred asset or liability balance for any reporting period. We periodically evaluate the recoverability of the deferred tax assets and, when it is determined that it is more-likely-than-not that the deferred tax assets are realizable, the valuation allowance will be reduced. Due to our valuation allowance, future changes in our unrecognized tax benefits will not impact our effective tax rate.

## 6. Stock-Based Compensation

***The Plan*:** Our 2010 Equity Incentive Plan, as amended (the "Plan"), provides for grants of incentive and non-qualified stock options for purchase of our common stock at a price per share equal to the closing market price on the date of grant and for awards of restricted stock units and restricted stock, for which there is no consideration payable by the recipient. The number of shares reserved for issuance under the Plan may be increased annually by up to three percent of the outstanding stock of the Company and on January 1, 2016, an additional 550,000 shares were reserved for issuance under the Plan. An aggregate of 8,262,445 shares are reserved for issuance under the Plan as of September 30, 2016. All stock issuances under the Plan are made with new shares from our authorized but unissued common stock. The term of grants and awards under the Plan may not exceed ten years.

**6. Stock-Based Compensation** (continued)

Employees, non-employee directors, and consultants are eligible to participate in the Plan. For purposes of determining stock-based compensation expense, we include non-employee directors with employees; we account for consultant compensation expense separately. Option activity under the Plan is as follows:

| | Options Outstanding | Weighted Average Exercise Price |
|---|---|---|
| ***Balance at December 31, 2014*** | 4,243,425 | $7.01 |
| Granted | 2,152,500 | $4.50 |
| Cancelled | (232,292) | $2.85 |
| Exercised | (251,208) | $2.27 |
| ***Balance at December 31, 2015*** | 5,912,425 | $6.46 |
| Granted | 570,100 | $8.22 |
| Cancelled | (31,834) | $4.00 |
| Exercised | (13,500) | $1.56 |
| ***Balance at September 30, 2016*** | 6,437,191 | $6.64 |

Vesting periods of stock and unit awards and option grants are determined by the Company's board of directors. The majority of options granted by the Company vest over four years, with 25 percent vesting on the one-year anniversary of the vesting commencement date and 75 percent vesting in equal monthly installments thereafter. A majority of those options are exercisable at any time but, if exercised, are subject to a lapsing right of repurchase by us at the exercise price until fully vested. During March 2015, we granted a total of 316,000 options that vest based on certain performance milestones of the Company. We estimated the vesting term for each performance objective on the date of grant, and on each reporting date thereafter, based on our internal timelines and operating projections. Our estimates of vesting ranged from approximately nine to 30 months at the grant date in March 2015; we estimated the remaining vesting term to be 20 months as of December 31, 2015 and to be 15 months as of September 30, 2016. A total of 65 percent of these options had vested as of September 30, 2016; unvested options of 12,250 were cancelled during the three months ended September 30, 2016 resulting in reversal of $13,000 in compensation expense that had been recorded during the three months ended June 30, 2016.

During July 2012, January 2013, and May 2013 we awarded 33,000 shares, 40,000 shares, and 47,500 shares, respectively, of restricted stock; 25 percent of each award vests on each annual anniversary date of the award. Through September 30, 2016, none of the restricted stock had been cancelled.

During March 2015, we awarded 824,200 restricted stock units ("RSUs") to employees. These RSUs vest based on certain performance milestones of the Company. We estimated the vesting term for each performance objective on the award date, and on each reporting date thereafter, based on our internal timelines and operating projections. Our estimates of vesting ranged from approximately 21 to 30 months at the award date in March 2015; we estimated the remaining weighted average vesting term to be 22.9 months as of December 31, 2015 and to be 10.1 months as of September 30, 2016. None of these RSUs had vested as of September 30, 2016; a total of 118,000 of these RSUs were cancelled during the three months ended September 30, 2016 resulting in reversal of $327,000 in compensation expense that had been recorded between the date of their issuance in March 2015 and June 30, 2016.

During May 2015, we awarded 160,000 RSUs to employee and non-employee directors; these RSUs vested on May 24, 2016. During May 2016, we awarded 35,200 RSUs and during July 2016 we awarded 12,600 RSUs to non-employee directors; these RSUs vest on the earlier of May 25, 2017 or one day prior to our 2017 annual stockholder meeting. Each RSU entitles the recipient to one share of our common stock upon vesting. Through September 30, 2016, none of these RSUs had been cancelled.

No tax benefits arising from stock-based compensation have been recognized in the consolidated statements of operations and comprehensive loss through September 30, 2016.

**6. Stock-Based Compensation** (continued)

***Grants and Awards to Employees*:** We account for option grants, restricted stock awards, and RSU awards to employees based on their estimated fair values on the date of grant or award, with the resulting stock-based compensation recorded over the requisite service period on a straight-line basis. For the options and RSUs that vest upon performance milestones, we estimate the probability that the performance milestones will be met and record the related stock-based compensation expense. During the three months ended March 31, 2016, we determined that two of the three performance targets for our performance-based awards continued to be probable of being achieved and, therefore, we recorded straight-line quarterly expense of $344,000 for those awards only. During the three months ended June 30, 2016, we determined that all three of the performance targets were probable of being achieved, and, therefore, recorded cumulative expense of $583,000 for the third performance target, as well as straight-line quarterly expense of $308,000 for all performance-based awards, during the second quarter of 2016. We continued to believe all three performance targets were probable of being achieved through September 30, 2016 and recorded straight-line quarterly expense of $229,000 for the awards during the three months ended September 30, 2016. Stock-based compensation arising from employee options and awards under the Plan is as follows:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2015 | 2016 | 2015 | 2016 |
| | (in thousands) | | (in thousands) | |
| ***Employee Stock-Based Compensation:*** | | | | |
| Research and development expense | $ 448 | $ (104) | $ 1,162 | $ 1,060 |
| General and administrative expense | 535 | 788 | 1,179 | 2,654 |
| | $ 983 | $ 684 | $ 2,341 | $ 3,714 |

The fair value of restricted stock and RSU awards is equal to the closing market price of our common stock on the date of award. The fair value of options granted was estimated on the date of grant using the following weighted-average assumptions:

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2015 | 2016 |
| Risk-free interest rate | 1.82% | 1.56% |
| Expected volatility of common stock | 55.6% | 57.6% |
| Expected life in years | 6.16 | 6.13 |
| Dividend yield | 0% | 0% |

The assumed risk-free interest rate was based on the implied yield on a U.S. Treasury zero-coupon issue with a remaining term equal to the expected life of the option. The assumed volatility was calculated based on the historical market prices of a selected group of publicly traded companies considered to be our peers; we use peer group data due to the fact that we have limited historical trading data but adjusted the 2016 volatility upward by approximately ten percent to allow us to move toward using our trading history, which is more volatile than our peer group. For options that vest based on passage of time, the expected option life was calculated using the simplified method under the accounting standard for stock compensation and a ten-year option expiration; we use the simplified method because we do not yet have adequate history as a public company to establish a reasonable expected life. For options that vest based on performance achievements, the expected life was calculated based on the requisite service periods estimated by management and a ten-year option expiration. The expected dividend yield of zero reflects that we have not paid cash dividends since inception and do not intend to pay cash dividends in the foreseeable future. The options granted to employees during the nine months ended September 30, 2016 had a weighted average grant date fair value of $4.48.

The aggregate intrinsic value of options exercised during the nine months ended September 30, 2015 and 2016 was $417,000 and $92,000, respectively.

**6. Stock-Based Compensation** (continued)

***Stock Options to Consultants*:** We account for stock options granted to consultants at their fair value. Under this method, the fair value is estimated at each reporting date during the vesting period using the Black-Scholes option-pricing model. The resulting stock-based compensation expense, or income if the fair value declines in a reporting period, is recorded over the consultant's service period. Fully vested options to purchase 7,500 shares of common stock were granted to consultants during the nine months ended September 30, 2016; no options were granted to consultants during the nine months ended September 30, 2015. Stock-based compensation expense arising from consultant options granted under the Plan is as follows:

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2015 | 2016 |
| | (in thousands) | |
| ***Consultant Stock-Based Compensation:*** | | |
| Research and development expense | $ — | $ 40 |
| General and administrative expense | 27 | — |
| | $ 27 | $ 40 |

We did not record any stock-based compensation expense during the three month periods ended September 30, 2015 and 2016 for consultant options.

The fair value of the options granted to consultants during the nine months ended September 30, 2016 was estimated to be $5.30 per share based on weighted-average assumptions of a risk-free interest rate of 2.02 percent, volatility of 57.4 percent, an option life of ten years, and a dividend yield of zero percent. The assumed risk-free interest rate was based on the implied yield on a U.S. Treasury zero-coupon issue with a remaining term equal to the expected life of the option. The assumed volatility was calculated from the historical market prices of a selected group of publicly traded companies considered to be our peers; we use peer group data due to the fact that we have limited historical trading data. The expected option life is the remaining term of the option. The expected dividend yield of zero reflects that we have not paid cash dividends since inception and do not intend to pay cash dividends in the foreseeable future. There were no unvested consultant options at either September 30, 2015 or September 30, 2016.

**7. Commitments and Contingencies**

We have licensed certain patents and other intellectual property rights related to the composition and coating of our bioresorbable stent and our other biomaterial products. Terms of these licenses include provisions for royalty payments on any future sales of products, if any, utilizing this technology, with provisions for minimum royalties once product sales begin. The amount of royalties varies depending upon type of product, use of product, stage of product, location of sale, and ultimate sales volume, and ranges from a minimum of approximately $25 per unit to a maximum of approximately $100 per unit sold, with license provisions for escalating minimum royalties that could be as high as $2.2 million per year. Additionally, in the event we sublicense the technology and receive certain milestone payments, the licenses require that up to 40 percent of the milestone amount be paid to the licensors. Additional terms of the technology licenses include annual licensing payments of $175,000 until the underlying technology has been commercialized. Terms of the licenses also include other payments to occur during commercialization that could total $950,000, payment of $350,000 upon a change in control of ownership, payments of up to $300,000 annually to extend filing periods related to certain technology (of which, payments totaling up to $250,000 per year during the years 2016, 2017, and 2018 may be deferred to January 1, 2019), and payment of patent filing, maintenance, and defense fees. The license terms remain in effect until the last patent expires.

## 8. Net Loss Per Common Share

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method and the if-converted method, as applicable. For purpose of this calculation, common stock options and restricted stock subject to forfeiture are considered to be common stock equivalents; common share equivalents are included in the calculation of diluted net loss per share only when their effect is dilutive.

The following weighted average shares were excluded from the computations of diluted net loss per share because including them would have been antidilutive.

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2015 | 2016 | 2015 | 2016 |
| ***Weighted Average Shares Excluded from EPS:*** | | | | |
| Options to purchase common stock | 4,466,191 | 6,462,165 | 4,425,491 | 6,354,540 |
| Unvested restricted stock | 53,435 | 23,310 | 64,869 | 34,769 |
| Restricted stock units | 984,200 | 862,848 | 696,356 | 926,018 |
| Warrants to purchase common stock | 8,750,000 | — | 8,750,000 | 670,620 |
| Common share equivalents of convertible notes | 11,506,156 | 11,506,156 | 11,506,156 | 11,506,156 |
| | 25,759,982 | 18,854,479 | 25,442,872 | 19,492,103 |

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

*You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our unaudited consolidated financial statements and related notes thereto included in this Quarterly Report on Form 10-Q and with our consolidated financial statements and the related notes thereto that are contained in our Annual Report on Form 10-K for the year ended December 31, 2015. In addition to historical information, the following discussion and analysis includes forward-looking statements that involve risks, uncertainties, and assumptions. Forward-looking statements are all statements other than statements of historical facts, such as those statements regarding the projections and timing surrounding our plans to complete clinical and regulatory evaluations, receive regulatory approvals and commence commercial sales, develop pipeline products, incur losses from operations, and assess and obtain future financings for operating and capital requirements.*

*We caution readers that forward-looking statements are not guarantees of future performance and actual results and the timing of events could differ materially from those anticipated by these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" in our Form 10-K for the year ended December 31, 2015. Investors are cautioned that many of the assumptions on which our forward-looking statements are based are likely to change after our forward-looking statements are made. Further, we may make changes to our business plans that could or will affect our results. We caution investors that we do not intend to update our forward-looking statements more frequently than quarterly, notwithstanding any changes in our assumptions, changes in our business plans, our actual experience, or other changes, and we undertake no obligation to update any forward-looking statements.*

**Overview**

We are a pre-revenue stage medical device company working toward commercialization of our proprietary technologies to provide minimally invasive medical devices for treating conditions in humans. We are in the later stages of developing and clinically testing bioresorbable drug-eluting coronary stents, which we call "scaffolds" because they are not permanent devices like metal stents that are commonly used today. In clinical use, a scaffold is implanted by an interventional cardiologist during a minimally invasive surgery. It is delivered to a coronary artery location with a balloon catheter system, whereupon it is deployed to restore blood flow through the artery and medicate the artery to prevent further blocking, or "restenosis." Our scaffolds are made from our proprietary bioresorbable polymer and have been designed to offer unique features that include full x-ray visibility, low profile, standard clinical delivery, and a wide expansion range. Our scaffolds also contain standard features of relevant sizing, robust strength during the healing period, and controlled and safe resorption. Due to their unique features and ease of clinical use, we believe our products will enable us to compete effectively in the stent marketplace.

Our scaffold products have not yet been approved for sale and will require regulatory approval before they can generate sales. In addition to the clinical trials we are currently conducting, we have invested significant time and funds in development, having performed scientific research, engineering development, and testing in laboratory and preclinical studies. We have developed, tested, and selected the polymer formulation, tested and selected the anti-restenotic drug and coating process, created and iterated the device design, and identified and implemented methods and processes to produce and test the scaffold. We designed and performed extensive preclinical tests that ranged from bench and engineering studies to in vitro and in vivo laboratory studies. In 2007, we enrolled patients in a small human clinical study that proved the viability of the technology while confirming the areas needing further development. We have been developing and advancing our scaffolds in both design and polymer composition since that study and have undertaken significant testing that has shown the viability of the technology across various models, including enrollment of 165 patients in two clinical trials between 2011 and 2014.

We began enrolling patients in a pivotal clinical trial of our *Fantom* scaffold in March 2015 and completed full enrollment in March 2016 with two sets of patients. We enrolled 117 patients in Cohort A of the trial and 123 patients in Cohort B, for total trial enrollment of 240 patients. Patients in Cohort A have completed imaging assessments at a six-month time point and we used the data from these patients in our application for European CE Marking, the regulatory approval that would allow us to sell in Europe and other countries that recognize the CE Mark. We completed submission of this application in early August 2016. Patients in Cohort B are undergoing imaging assessments at a nine-month time point, with such assessments scheduled to be completed in January 2017; data from this second set of patients will be used for market support and other commercial purposes. All patients will be followed for five years unless they otherwise exit the study.

We have been preparing our manufacturing capabilities for commercialization and have been planning our sales, marketing, and distribution strategies. We will continue to work on our manufacturing scale-up and expand our capabilities to allow for such things as additional scaffold sizes during the remainder of 2016. We will additionally be preparing our systems and back-office needs for commercialization during the remainder of 2016 and continue to evaluate how best to implement our commercialization strategies.

When, and if, we receive CE Mark approval, we intend to be in a position to roll-out our commercialization strategies. While our *Fantom* scaffold could be approved for sale in late 2016 or early 2017, our efforts to generate substantial revenue and achieve positive cash flows from our operations may take several years, even if our clinical results are favorable.

During the course of our product development and testing, we have invented, co-invented, and licensed a portfolio of proprietary technologies. Our design-related technologies have been invented by our employees and consultants and our materials-related technologies have been either invented by our employees or licensed from, or co-invented with, Rutgers, The State University of New Jersey. We consider our patent portfolio to be significant and have invested considerable time and funds to develop and maintain it. Our goal is to continue to perform feasibility tests on additional technologies in our patent portfolio as our resources allow and, if feasibility is proven, determine a course of development for additional products.

We perform all of our research and development activities from one location in San Diego, California. As of September 30, 2016, we had 59 employees, a majority of whom are degreed professionals and five of whom are PhDs. We leverage our internal expertise with contract research and preclinical laboratories, outside catheter manufacturing, and other outside services as needed. We have three clean rooms and multiple engineering and chemistry labs at our facility, in addition to our corporate and administrative office. We are ISO certified to the medical device standard 13485:2012 and intend to maintain the certification to support our commercialization plans.

In November 2014, we completed a financing to provide ongoing capital for our operations, including the *Fantom* clinical trial and application for CE Mark. This financing comprised the issuance of 250 senior unsecured convertible notes (the "Notes"), each with a face value of $100,000 and a five-year maturity, and warrants to purchase 8,750,000 shares of our common stock. We received cash proceeds of $25.0 million from the Notes in November 2014 and we received $20.9 million cash proceeds from the exercise of the 8,750,000 warrants between October 2015 and February 2016. In February 2016, we entered into an amendment to the Convertible Note Deed dated September 25, 2014 (the "Note Deed") that governs the Notes. The amendment, which was approved by our stockholders on March 22, 2016, provided two modifications. The first modification extended the date of an optional redemption right of the noteholders to June 30, 2017; the prior optional redemption date had been January 14, 2017. The second modification added a third condition, being that the Company list its common stock on the NASDAQ stock exchange (or another exchange approved by the noteholders), before the Notes will automatically convert into common stock. The prior conditions to an automatic conversion of the Notes were the receipt of a CE Mark on *Fantom* combined with a market trading price of the Company's securities of at least A$0.60 per CDI for 20 or more consecutive trading days.

Because we have not yet developed a product to a saleable stage, we have not generated any product or other revenues. Our development efforts have been funded with a variety of capital received from angel investors, venture capitalists, strategic partners, hedge funds, the proceeds from our IPO in 2010, issuance of the convertible notes in November 2014, and the proceeds from the warrant exercises through February 2016. As of September 30, 2016, we had approximately $11.6 million in cash available for operations, which we believe will be sufficient to fund our operating and capital needs into, and possibly through, the first fiscal quarter of 2017. We have incurred substantial losses since our inception; as of September 30, 2016, we had accumulated a deficit of approximately $404.4 million and we had approximately $120.1 million of current liabilities. These conditions, combined with the uncertainty of the timing of receipt of future financings, if any, raise substantial doubt about our ability to continue as a going concern.

We expect our losses to continue as we complete our clinical studies and prepare for commercialization during the remainder of this year; if we are able to obtain regulatory approval, we expect to commence product sales in 2017. In order to successfully transition to profitable operations, we will need to achieve a level of revenues and product margins to support the Company's cost structure. Until such time as we generate positive cash flow, we plan to continue to fund our operating and capital needs by utilizing our current cash balances and by raising additional capital through equity or debt financings, or through strategic or other transactions. We continue to evaluate our financing options, assess market conditions, and explore viable paths for capital. We intend to secure additional capital on a timeframe that coincides with our cash needs. Also during the remainder of 2016 and into 2017, we intend to pursue listing of our common stock on NASDAQ, or another exchange approved by our noteholders, with the intention to be accepted for listing no later than June 30, 2017.

Our company was founded in California in June 1998 and named MD3, Inc. We changed our name to REVA Medical, Inc. in March 2002. We reincorporated from the State of California to the State of Delaware in October 2010; as a result, the rights of our stockholders are governed by the Delaware General Corporation Law. We formed a wholly owned subsidiary in Germany in 2007 to facilitate our clinical trials and our planned commercialization of products; we have not used this subsidiary yet for any operating activities.

**Key Components of our Results of Operations**

We are still in a pre-revenue stage and our activities are focused on the clinical study and manufacturing process refinements of our bioresorbable coronary scaffold with the goal of commercially selling it. We also are currently performing a small amount of research and tests to determine the feasibility of other product possibilities. Consequently, our operating results primarily consist of research and development expenses, which include the costs to perform clinical trials, general and administrative expenses, and other expenses that are largely the costs underlying the convertible notes and warrants that we issued in November 2014.

***Research and Development Expenses*:** Our research and development expenses arise from internal and external costs. Our internal costs primarily consist of employee salaries and benefits, facility and other overhead expenses, and engineering and other supplies that we use in our labs for prototyping, testing, and producing our scaffolds and other product possibilities. Our external costs primarily consist of contract research, engineering consulting, polymer consulting, polymer lasing costs, catheter system and anti-restenotic drug purchases, preclinical and clinical study expenses, regulatory consulting, and license fees paid for the technology underlying our polymer materials. All research and development costs are expensed when incurred.

Historically, our research and development expenses have represented between 70 and 75 percent of our total operating expenses; they represented 70 percent of total operating expenses for the year ended December 31, 2015 and 69 percent for the nine months ended September 30, 2016. We expect our research and development expenses to increase during the remainder of 2016 and the first quarter of 2017 as we continue to assess the patients enrolled in the clinical trial of *Fantom*, consider and initiate follow-on clinical trials, prepare our product and processes for commercialization, which will include development of final manufacturing processes and equipment, and as we research the feasibility of developing additional products from technology in our intellectual property portfolio.

***General and Administrative Expenses*:** Our general and administrative expenses consist primarily of salaries and benefits for our executive officers and administrative staff, corporate office and other overhead expenses, legal expenses including patent filing and maintenance costs, audit and tax fees, investor relations and other public company costs, and travel expenses. Although our patent portfolio is one of our most valuable assets, we record legal costs related to patent development, filing, and maintenance as expense when the costs are incurred since the underlying technology associated with these assets is purchased or incurred in connection with our research and development efforts and the future realizable value cannot be determined.

Historically, our general and administrative expenses have represented between 25 and 30 percent of our total operating expenses; they represented 30 percent of total operating expenses for the year ended December 31, 2015 and 31 percent for the nine months ended September 30, 2016. We anticipate continuing to invest in patents at similar levels as we have in the past. Additionally, we anticipate that we will expand our corporate infrastructure in late 2016 and early 2017 to continue to support the needs of being a public company and to prepare for commercial sales of our products, which will increase our general and administrative expenses accordingly. We also expect to begin to incur sales and marketing expenses beginning in late 2016 as we prepare for product sales in the event we receive CE Marking.

***Other Income and Expense*:** Through October 2014, our other income and expense was relatively immaterial and primarily comprised interest income on investments and gains and losses from foreign currency fluctuations. Following our issuance of the Notes and warrants in November 2014, the components of other income and expense also include interest expense on the Notes and losses related to the changes in fair values of both the Notes and warrants. We recorded the Notes and warrants at fair value upon issuance and we remeasure their fair values at each reporting date. If those fair values change, we record a corresponding gain (upon a decrease in fair value) or loss (upon an increase in fair value) in the consolidated statement of operations.

Since issuing the Notes and warrants, due to a variety of factors including the successful enrollment of patients in the clinical trial of *Fantom* and positive clinical results from those patients, the addition of a new Chief Executive Officer in September 2015 and a Senior Vice President of Operations in January 2016, and an increase in the market trading price of our common stock of approximately 190 percent since January 1, 2015, the value of the Notes and warrants (during the time they remained outstanding) increased significantly. We recorded a $56.8 million loss on the increase in value during the year ended December 31, 2015 and a $47.1 million loss during the nine months ended September 30, 2016. Since all the warrants were exercised and none remained outstanding after February 12, 2016, we will not record further changes in their fair value. Until the Notes are either converted into common stock or repaid, we expect our other income and expense to fluctuate, possibly by a significant amount, by future gains or losses on changes in their fair value. Also, we will continue to accrue and record interest expense on the Notes at the rate of 7.54 percent per annum until they are either converted or repaid. We do not expect any material changes in interest income or foreign currency gains or losses during the remainder of 2016.

**Critical Accounting Policies and Estimates**

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States. In preparing our financial statements and related disclosures, we are required to use estimates, assumptions, and judgments that affect the reported amounts of assets, liabilities, stockholders' equity, expenses, and the presentation and disclosures related to those items. We base our estimates and assumptions on historical experience and other factors that we believe are reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis; changes in our estimates and assumptions are reasonably likely to occur from period to period. Additionally, actual results could differ significantly from the estimates we make. To the extent there are material changes in our estimates or material differences between our estimates and our actual results, our future financial statement presentation, financial condition, results of operations, and cash flows will be affected.

We believe the following accounting policies involve a greater degree of judgment and complexity than any other of our accounting policies and, therefore, are the most critical to understanding and evaluating our consolidated financial condition and results of operations. Our other key accounting policies are less subjective and, therefore, are not included here.

***Research and Development Costs*:** We expense research and development costs as incurred. Our preclinical and clinical study costs are incurred on a contract basis and generally span a period from a few months to longer than a year. We record costs incurred under these contracts as the work occurs and make payments according to contractual terms. Until a contract is completed, we estimate the amount of work performed and accrue for estimated costs that have been incurred but not paid. As actual costs become known, we adjust our accruals. Until such time as we commence another large clinical trial, we expect our clinical expense accruals to decrease from recent levels since we have reached the primary measurement for a majority of the patients in our *Fantom* trial. We will continue to make estimates of work performed throughout the term of our clinical trials, each of which is expected to be five years or longer. If our estimates are inaccurate, possible material changes to our accruals could be required, which could materially affect our results of operations within any fiscal period. To date, there have been no material changes in our research and development expense estimates, including our estimates for accrued clinical costs.

***Stock-Based Compensation:*** We recognize stock-based compensation expense in connection with stock option grants, restricted stock awards, and restricted stock unit ("RSU") awards to employees, directors, and consultants. We have granted options, restricted stock, and RSUs that vest based on the passage of time and, in March 2015, we granted options and RSUs that vest based on achievement of performance milestones.

For employees and directors, we determine the amount of compensation expense by estimating an award's fair value on the date of award, with the resulting stock-based compensation recorded over the vesting period, which ranges from one to four years, on a straight-line basis. For stock options and RSUs that vest upon performance achievements, we record only the compensation expense for the performance targets that are probable of being achieved and we record such expense on a straight-line basis over the vesting period. During the three months ended March 31, 2016, we determined that two of the three performance targets for our performance-based awards were probable of being achieved and, therefore, recorded straight-line quarterly expense of $344,000 for those awards only. During the three months ended June 30, 2016, we determined that all three performance targets were probable of being achieved, and, therefore, recorded cumulative expense of $583,000 for the third performance target, as well as straight-line quarterly expense of $308,000 for all the performance-based awards, during the second quarter of 2016. We recorded straight-line quarterly expense of $229,000 for the awards during the third quarter of 2016; however, unvested awards were cancelled during the third quarter that resulted in reversal of $340,000 compensation expense that had been recorded in previous quarters.

All stock-based compensation expense is recorded as either research and development or general and administrative expense based on a recipient's work classification. For stock options, we estimate the fair value by using the Black-Scholes option pricing model. For the model inputs, we use the fair value of the underlying common stock, a risk-free interest rate that corresponds to the expected life of the option, an expected option life ranging between 5.50 and 6.25 years, and an estimate of volatility based on the market trading prices of comparative peer companies. The fair value of restricted stock and RSUs awarded is equal to the closing market price of our common stock on the date of award. Additionally, we reduce the amount of recorded compensation expense to allow for potential forfeitures of the options; the forfeiture rate is based on our actual historical forfeitures and has ranged from approximately 2.1 percent to 3.4 percent.

We occasionally grant options to consultants; as of September 30, 2016, no consultant options remained subject to vesting. When we grant or have unvested consultant options, we estimate the fair value at date of grant and at each subsequent accounting date until vesting is complete and record compensation expense based on the fair value during the service period of the consultant. We estimate the fair value by using the Black-Scholes option pricing model with the same approach to inputs and assumptions as we use to estimate the fair value of options granted to employees, except we use the remaining term as the expected life of the option.

As a result of our use of estimates for the fair value calculations and the performance-based achievement probabilities, if factors change and we use different assumptions, the amount of our stock-based compensation expense could fluctuate materially in the future. Also, we may increase the level of awards for options, restricted stock, and/or RSUs as we expand our workforce and prepare for commercialization, which could result in an increase of our stock-based compensation in the future.

***Notes Payable*:** We analyze notes payable as of their issue date to determine their classification, issue discounts or premiums, and embedded or derivative features, if any. If embedded or derivative features exist, such as a right to convert notes into common stock, we evaluate the features in accordance with accounting guidance for derivative securities, determine whether such features would give rise to separate accounting, and, if they do, make an election to account for the notes at cost or at fair value.

We elected to account for the convertible notes we issued in November 2014 at fair value, which does not require separate accounting for derivative features. On the issue date of convertible notes, we record the difference, if any, between the issue price of the notes and their fair value as a gain or loss in the consolidated statement of operations. Until such time as the notes are converted into common stock or repaid, we accrue interest on the notes at the stated interest rate. We additionally remeasure the fair value of the notes at each reporting date and record a gain (upon decrease in fair value) or loss (upon an increase in fair value) for any change in fair value. Through September 30, 2015, the fair values were determined using a binomial valuation model; we moved to a least squares Monte Carlo simulation model thereafter as it was considered better aligned with the inputs to, and the features of, our Notes. This change in models did not have a material effect on the fair value of the Notes. These valuations require the use of subjective assumptions, including unobservable inputs that are supported by little or no market activity. The assumptions represent our best estimates, but involve certain inherent uncertainties. Inputs to the model include the market value of the underlying stock, a life equal to the contractual life of the notes, incremental borrowing rates that correspond to debt with similar credit worthiness, estimated volatility based on the historical prices of our trading securities, and we make assumptions as to our abilities to test and commercialize our product(s), to obtain future financings when and if needed, and to comply with the terms and conditions of the notes. Since the determination of fair value is complex and involves the use of subjective assumptions, if our assumptions, estimates, or modeling approaches change and we use different assumptions or methods, our fair values could be materially different in the future.

***Common Stock Warrants*:** We record the fair value of warrants we issue for the purchase of common stock as a liability whenever they call for issuance of registered shares upon exercise, a condition that we may not be able to accommodate and which may result in a net settlement of the warrants. Prior to the final exercises of the warrants we issued in November 2014, their fair value was assessed at each reporting date. A binomial valuation model was used through September 30, 2015 since two exercise prices were possible; we moved to a Black-Scholes valuation model to determine the value beginning in October 2015 because Company conditions had been met that resulted in a fixed exercise price. This change in models did not have a material effect on the fair value of the warrants. Inputs to the valuation models are of the same nature as those used for our Notes. Any change in fair value is recorded as a gain (upon a decrease in fair value) or loss (upon an increase in fair value) in the consolidated statement of operations. Since all the warrants were exercised by February 12, 2016 and none remained outstanding thereafter, we will not record future changes in their fair value.

**Results of Operations**

During the first nine months of 2015, our operating activities focused on testing and preparing our *Fantom* scaffold for clinical trials and enrolling patients in the clinical trial; we initiated enrollment of patients in the pivotal trial in March 2015 and completed enrollment of 110 patients by September 30, 2015.

During 2016, our operating activities have consisted of continuing enrollments in the trial, which were completed in March 2016 with a total of 240 patients enrolled, performing follow-up assessments of the patients, collecting the related clinical data to support the CE Mark submission that we completed in early August 2016, and continuing to refine our manufacturing processes in preparation for the commercialization of *Fantom* that is planned for the first half of 2017.

***Comparison of the Three Months Ended September 30, 2015 and 2016***

Our operating results for the three-month periods indicated are as follows (dollars in thousands):

| | Three Months Ended September 30, | | Change | |
|---|---|---|---|---|
| | 2015 | 2016 | $ | % |
| Research and development expense | $ 4,404 | $ 4,212 | $ (192) | (4%) |
| General and administrative expense | $ 1,818 | $ 1,937 | $ 119 | 7% |
| Interest expense | $ 475 | $ 512 | $ 37 | 8% |
| Loss on change in fair values of convertible notes and warrant liability | $ (28,180) | $ (17,269) | $ 10,911 | (39%) |
| Other income (expense) | $ 9 | $ (13) | $ (22) | (244%) |

Research and development expense decreased $192,000, or four percent, for the three months ended September 30, 2016 compared to the three months ended September 30, 2015. This decrease primarily comprises reductions in personnel costs, clinical costs, and preclinical costs, which were offset by increases in materials, related testing and quality costs, and technology license fees. Personnel costs decreased $237,000 between the comparative quarters; a $552,000 decrease in stock compensation expense was offset by a $315,000 increase in salaries and other personnel costs. The decrease in stock compensation includes $398,000 from the cancellation of unvested employee awards upon employment termination and $94,000 due to completion of vesting service periods or achievement of performance-vesting milestones that had no corresponding replacement awards. Salary expense increased $290,000 due to an approximate 15 percent increase in headcount between the comparative periods and accrual of $75,000 for incentive bonuses in the third quarter of 2016 where there had been no incentive program in 2015. Clinical costs decreased $275,000 in the third quarter of 2016 as compared to the third quarter of 2015; the clinical trial initiated in March 2015 completed enrollment in March 2016 and patient follow-up assessment activity during the third quarter of 2016 was comparatively less than the enrollment period due to the timing of scheduled assessments. Preclinical study costs decreased $234,000 between comparative quarters due to the timing of tests and analysis of testing results; a majority of preclinical tests for *Fantom* concluded during the first quarter of 2016. Direct material, quality, and testing costs, including purchased catheters and polymer lasing costs, increased $462,000 between the comparative quarters due to the increased product needs as we continued process improvements during the third quarter of 2016. We incurred $100,000 more in the third quarter of 2016 for non-stent intellectual property than we had in the prior year under the terms of our license agreement with Rutgers University. The remainder of the change in research and development expenses between quarters resulted from individually immaterial changes in lab supplies, engineering and other outside services, depreciation, and facilities expenses.

General and administrative expense increased $119,000, or seven percent, for the three months ended September 30, 2016 compared to the three months ended September 30, 2015, primarily a result of a net $88,000 increase in personnel costs. Stock-based compensation increased $253,000 between the comparative quarters; a $353,000 increase in stock compensation arising from option grants made to our Chief Executive Officer in September 2015 and February 2016 was offset by decreases resulting from other employees' completion of vesting service periods or achievement of performance-vesting milestones. Additionally, we accrued $100,000 for incentive bonuses in the third quarter of 2016, where there had been no incentive program in 2015. Offsetting the increases, a non-recurring severance accrual of $210,000 recorded in the third quarter of 2015 was not repeated in 2016. The remainder of the change in general and administrative expenses between periods was due to individually immaterial changes in travel and entertainment expenses, investor relations costs, marketing and tradeshow costs, office supplies, facilities costs, audit and legal fees, board of directors fees and costs, depreciation, insurance, and other overhead expenses.

Our other non-operating expenses during the third quarters of 2015 and 2016 primarily arose from our convertible notes and warrants. We accrued a comparable amount of interest expense, which compounds annually, on the Notes each quarter. The losses recorded on the change in fair values of the Notes and warrants between comparative quarters reflects the timing of factors driving value, including an increase in the market trading price of our common stock of approximately $2.00 per share during the third quarter of 2015 compared to an increase of approximately $1.54 per share during the third quarter of 2016 (an increase in value results in a non-cash accounting loss). Additionally, the warrants exercised in October 2015 and February 2016 had contributed to the change in value during the third quarter of 2015, whereas, the warrants did not contribute to the change during the third quarter of 2016 as none were outstanding. The decrease in other income (expenses) arose from exchange rate losses occurring during the third quarter of 2016, compared to gains recorded during the third quarter of 2015, based on the relative strength of the U.S. dollar in those periods compared to the Australian and European currencies in which we make our clinical trial payments.

***Comparison of the Nine Months Ended September 30, 2015 and 2016***

Our operating results for the nine-month periods indicated are as follows (dollars in thousands):

| | Nine Months Ended September 30, | | Change | |
|---|---|---|---|---|
| | 2015 | 2016 | $ | % |
| Research and development expense | $ 11,735 | $ 14,165 | $ 2,430 | 21% |
| General and administrative expense | $ 4,973 | $ 6,496 | $ 1,523 | 31% |
| Interest expense | $ 1,410 | $ 1,522 | $ 112 | 8% |
| Loss on change in fair values of convertible notes and warrant liability | $ 34,311 | $ 47,067 | $ 12,756 | 37% |
| Other income (expense) | $ 58 | $ (46) | $ (104) | (179%) |

Research and development expense increased $2,430,000, or 21 percent, for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015. A combination of items contributed to this increase. Personnel costs, including benefits and stock-based compensation, increased $971,000 between the comparative periods primarily due to an approximate $950,000 increase in salaries; headcount increased by approximately 16 percent between the comparative periods and we accrued $365,000 for incentive bonuses in 2016 where there had been no incentive program in 2015. Direct material costs, including purchased catheters and polymer lasing costs, increased $931,000 between the comparative periods due to the increased product needs for clinical enrollments and our continuation of process improvement efforts in 2016. Our quality, testing costs, and engineering service costs increased $376,000 through the third quarter of 2016 as compared to 2015 as we performed design and process verifications in support of our CE Mark application. Clinical costs increased $196,000 in 2016 as compared to 2015; the *Fantom* clinical trial was initiated in March 2015 with moderate patient enrollment activity through September 30, 2015 compared to significant enrollment and follow-up assessment activity in 2016. Offsetting the increases, preclinical study costs decreased $137,000 between the comparative periods due to the timing of tests and analysis of testing results, a portion of which were used in our CE Mark application. The remainder of the change in research and development expenses between periods resulted from individually immaterial changes in lab supplies, technology license fees, depreciation, and facilities expenses.

General and administrative expense increased $1,523,000, or 31 percent, for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015, primarily a result of a $1,418,000 increase in personnel and recruiting costs. Stock-based compensation increased $1,448,000 between the comparative periods, primarily due to a $1,013,000 increase in stock compensation arising from option grants made to our Chief Executive Officer in September 2015 and February 2016, an increase of $339,000 from equity grants made to our board of directors in May 2015 and May 2016, and an increase of $208,000 from the performance-based equity grants made in March 2015. Additionally, we accrued $300,000 for incentive bonuses in 2016, where there had been no incentive program in 2015. Offsetting the increases, a non-recurring severance accrual of $210,000 recorded in the third quarter of 2015 was not repeated in 2016. Also, recruiting costs of $168,000 recorded in 2015, primarily related to the search for a Chief Executive Officer, were not repeated in 2016. The remainder of the change in general and administrative expenses between periods was due to individually immaterial changes in travel and entertainment expenses, investor relations costs, marketing and tradeshow costs, office supplies, facilities costs, audit and legal fees, board of directors fees and costs, depreciation, and other overhead expenses.

Our other non-operating expenses during the first three quarters of 2015 and 2016 primarily arose from our convertible notes and warrants. We accrued a comparable amount of interest expense, which compounds annually, on the Notes each period. The increase in losses recorded on the change in fair values of the Notes and warrants between comparative periods reflects the timing of factors driving value, including increases in the market trading price of our common stock of approximately $2.27 per share during the first three quarters of 2015 compared to approximately $3.47 per share during the first three quarters of 2016 (an increase in value results in a non-cash accounting loss). Additionally, the warrants exercised in October 2015 and February 2016 had contributed to the change in value during 2015, whereas, the warrants contributed to the change only during the period they were outstanding in 2016. The decrease in other income (expense) arose from exchange rate losses occurring during 2016, compared to gains recorded during 2015, based on the relative strength of the U.S. dollar in those periods compared to the Australian and European currencies in which we make our clinical trial payments.

**Liquidity and Capital Resources**

***Sources of Liquidity***

We are completing the clinical testing phase of product development and have submitted an application for regulatory approval to commercially sell our *Fantom* scaffold under a European CE Marking. If and when approved, *Fantom* would be our first commercial product; we have not commercialized any products or generated any revenue since our inception in June 1998. Our future operating and capital requirements will depend on many factors, including the timing and achievement of regulatory approval of *Fantom* or any other product, growth of revenue, amount of intellectual property and technology expenditures, number and size of future clinical trials, extent of new product development, and the timing of repayment of our convertible notes, should they become due and payable. We do not anticipate having a product available for sale and being able to generate revenue unless, and until, we successfully receive CE Marking or other regulatory approval and begin selling, or licensing, one of our products, which we do not anticipate will occur before the second quarter of 2017 at the earliest. We anticipate that we will continue to incur substantial net losses and cash outflows through at least the remainder of this year and into 2017 as we complete current and initiate new clinical trials, expand our corporate infrastructure, and prepare for the commercial launch of our products.

Our development, clinical, and operating activities have been funded with a variety of capital received from angel investors, venture capitalists, strategic partners, hedge funds, our IPO in 2010, issuance of convertible notes in November 2014, and the cash proceeds from warrant exercises in October 2015 and February 2016. Since our inception through September 30, 2016, we have received approximately $175.6 million in equity proceeds and $53.5 million from issuance of notes payable ($28.5 million of the notes payable were converted to common stock upon our IPO in 2010).

In November 2014, we completed a financing to provide ongoing capital for our operations, including the *Fantom* clinical trial and application for CE Mark. This financing comprised the issuance of 250 senior unsecured convertible notes (the "Notes"), each with a face value of $100,000 and a five-year maturity, and warrants to purchase 8,750,000 shares of our common stock. We received cash proceeds of $25.0 million from the Notes in November 2014 and we received $20.9 million cash proceeds from the exercise of the warrants between October 2015 and February 2016. In February 2016, we entered into an amendment to the Note Deed that governs the Notes. The amendment, which was approved by our stockholders on March 22, 2016, provided two modifications. The first modification extended the date of an optional redemption right of the noteholders to June 30, 2017; the prior optional redemption date had been January 14, 2017. The second modification added a third condition, being that the Company list its common stock on the NASDAQ stock exchange (or another exchange approved by the noteholders), before the Notes will automatically convert into common stock. The prior conditions to an automatic conversion of the Notes were the receipt of a CE Mark on *Fantom* combined with a market trading price of the Company's securities of at least A$0.60 per CDI for 20 or more consecutive trading days.

As of September 30, 2016, we had approximately $11.6 million in cash available for operations, which we believe will be sufficient to fund our operating and capital needs into, and possibly through, the first fiscal quarter of 2017. We have incurred substantial losses since our inception; as of September 30, 2016, we had accumulated a deficit of approximately $404.4 million and had current liabilities of approximately $120.1 million. A total of $117.1 million of the current liabilities relate to our convertible notes payable, which contain the one-time option for cash redemption at face value, plus accrued interest, on June 30, 2017, if the notes are not otherwise converted or redeemed prior to that time. These conditions, combined with the uncertainty of the timing of receipt of future financings, if any, raise substantial doubt about our ability to continue as a going concern.

As a result of our intentions to list our securities on NASDAQ, combined with our efforts to receive CE Marking of our *Fantom* scaffold product, we believe we would be able to cause the automatic conversion of our Notes into equity prior to the time we would be required to redeem their $25.0 million face value, plus accrued interest, if the noteholders were to exercise their one-time option to request cash redemption on June 30, 2017. We, therefore, do not currently anticipate requiring additional capital to redeem the Notes. There can be no assurance, however, that we will be successful prior to June 30, 2017 in triggering the automatic conversion of the Notes.

We expect our losses to continue as we complete our clinical studies, await regulatory approval of our application for CE Mark, and prepare for commercialization during the remainder of this year; if we receive regulatory approval, we expect to commence product sales in 2017. In order to successfully transition to profitable operations, we will need to achieve a level of revenues and product margins to support the Company's cost structure. Until such time as we generate positive cash flow, we plan to continue to fund our operating and capital needs by utilizing our current cash balances and by raising additional capital through equity or debt financings, or through strategic or other transactions.

We continue to evaluate our financing options, assess market conditions, and explore viable paths for raising capital. We intend to secure additional capital on a timeframe that coincides with our cash needs.

Also during the remainder of 2016, we intend to pursue listing of our common stock on NASDAQ, or another exchange approved by our noteholders, with the intention to be accepted for listing by June 30, 2017. As a result of our intentions to list our securities on NASDAQ, combined with our efforts to receive CE Marking of our *Fantom* scaffold product, we believe we would be able to cause our Notes to be converted to equity prior to the time we would be required to redeem their $25.0 million face value, plus accrued interest, if the noteholders were to exercise their one-time right to request cash redemption on June 30, 2017. We, therefore, do not currently anticipate requiring additional capital to redeem the Notes. There can be no assurance, however, that we will be successful prior to June 30, 2017 in triggering the automatic conversion of the Notes.

***Cash Flows***

Our cash flows for the periods indicated are as follows:

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2015 | 2016 |
| | (in thousands) | |
| Net cash used for operating activities | $ (13,884) | $ (16,146) |
| Net cash used for investing activities | $ (256) | $ (624) |
| Net cash provided by financing activities | $ 171 | $ 11,428 |
| Net decrease in cash and cash equivalents | $ (13,969) | $ (5,342) |

***Net Cash Flow from Operating Activities***

Net cash used for operating activities during the first nine months of 2015 primarily reflects the loss from operations of $16,708,000 and the changes in operating assets and liabilities of $454,000. These items were offset by non-cash expenses of $2,368,000 for stock-based compensation, $811,000 of depreciation and amortization, and $41,000 of other non-cash expense. The accrued interest on convertible notes and the loss on change in fair value of convertible notes and warrant liability were non-cash items that had no effect on cash flows.

Net cash used for operating activities during the first nine months of 2016 primarily reflects the loss from operations of $20,661,000 and the changes in operating assets and liabilities of $59,000. These items were offset by non-cash expenses of $3,754,000 for stock-based compensation, $851,000 of depreciation and amortization, and $15,000 of other non-cash expense. The accrued interest on convertible notes and the loss on change in fair value of convertible notes and warrant liability were non-cash items that had no effect on cash flows.

***Net Cash Flow from Investing Activities***

Net cash used for investing activities during the first nine months of 2015 consisted of $754,000 for the purchase of lab and other equipment, offset by $498,000 received upon the maturity of certificates of deposit.

Cash used for investing activities during the first nine months of 2016 consisted of the purchase of lab and other equipment.

***Net Cash Flow from Financing Activities***

Cash provided by financing activities during the first nine months of 2015 resulted from $221,000 in proceeds from the issuance of common stock upon exercise of employee stock options, offset by payment of $50,000 in issuance costs from the financing completed in November 2014.

Cash provided by financing activities during the first nine months of 2016 consisted of $11,407,000 in proceeds from the issuance of common stock upon the exercise of 4,375,000 warrants that had been issued in 2014 and $21,000 in proceeds from the issuance of common stock upon the exercise of employee stock options.

***Operating Capital and Capital Expenditure Requirements***

We are completing clinical testing, performing product verification, and have applied for approval to commercially sell our *Fantom* scaffold under a European CE Marking. We have not previously commercialized any product or generated revenue. If we receive regulatory approval, *Fantom* would be our first commercial product; we anticipate we could begin commercial sales in the first half of 2017. We have incurred substantial losses since our inception and anticipate that we will continue to incur substantial net losses and cash outflows through the remainder of 2016 and into 2017 as we continue current and initiate new clinical trials, expand our corporate infrastructure, prepare to commercially manufacture and sell our products, and collect cash from sales of our product(s).

Until we commercialize a product and reach a sales volume to generate positive cash flow, we plan to fund our operating and capital needs with our current cash resources and by raising additional capital through equity or debt financings, or through strategic or other transactions. As of September 30, 2016, we had $11,553,000 in cash available for operations. We believe these cash resources will be sufficient to fund our operating and capital needs into, and possibly through, the first fiscal quarter of 2017. We are currently evaluating our financing options and working to arrange a capital raise in order to secure additional capital on a timeframe that coincides with our cash needs. Until we secure additional capital, and given our cash resources as of September 30, 2016, there is substantial doubt about our ability to continue as a going concern.

Additionally, we intend to pursue listing of our common stock on NASDAQ, or another exchange approved by our noteholders, with the intention to be accepted for listing no later than June 30, 2017. As a result of our intentions to list our securities on NASDAQ, combined with our efforts to receive CE Marking of our *Fantom* scaffold product, we believe our outstanding convertible notes can be converted to equity prior to the time we would be required to redeem their $25,000,000 face value, plus accrued interest, if the noteholders were to exercise their one-time right to request cash redemption on June 30, 2017. We, therefore, do not currently anticipate requiring additional capital to redeem the convertible notes.

Assuming success in our current capital raising efforts and successful approval of our product for commercial sales, we may still need to secure additional capital prior to the time we are able to maintain our operations from our cash inflows. This needed additional capital may not be available on reasonable terms, if at all. Additionally, we may be limited under the terms of the Notes as to the type, quantity, timing, or other aspects of a financing, unless the noteholders agree. Any financing, even one to which the noteholders agree, may result in additional dilution to our current securityholders, could have rights senior to those of our common stock, and/or could contain provisions that would restrict our operations. If we are unable to raise additional capital as and when needed, we may be compelled to sell certain assets, including intellectual property assets. Even if we are able to raise additional capital and commercialize our products, we may never become profitable, or if we do attain profitable operations, we may not be able to sustain profitability and cash flows on a recurring basis.

Because of the numerous risks and uncertainties associated with developing, testing, and commercializing medical devices, such as our bioresorbable scaffolds, we are unable to estimate the exact amounts, or timing, of capital outlays and operating expenditures necessary to complete our ongoing clinical trials and other testing, successfully deliver a commercial product to market, and collect on trade receivables. Our ongoing funding requirements will depend on many factors, including, but not limited to:

- the time and effort it will take to successfully complete our clinical trials and analyze patient data;
- the requirements, cost, and timing of regulatory approvals;
- the time and effort required to refine and scale-up manufacturing processes and the cost of establishing commercial supplies of our products;
- the cost and timing of establishing sales, marketing, and distribution capabilities;
- the scope of research and development for any of our other product opportunities and the terms and timing of any collaborative, licensing, or other arrangements that we may establish; and,
- the cost of filing and prosecuting patentable technologies and defending and enforcing our patent and other intellectual property rights and the effect of competing technological and market developments.

Our ongoing capital requirements will also depend on the extent to which we acquire or invest in businesses, products, and technologies; we currently have no commitments or agreements relating to any of these types of transactions. We believe our current San Diego facility has the capacity to produce the quantities of *Fantom* that will be needed for our initial commercial sales and, therefore, do not have any plans for facility expansion at this time.

**Contractual Obligations, Commitments, and Contingencies**

The following table summarizes our outstanding contractual obligations, other than our convertible notes payable and accrued interest payable thereon, as of September 30, 2016:

| | Payments Due by Period | | |
|---|---|---|---|
| | < 1 Year | 1 to 3 Years | Total |
| | (in thousands) | | |
| ***Contractual Obligations:*** | | | |
| Operating lease obligations | $ 705 | $ 242 | $ 947 |
| Purchase obligations | 227 | 17 | 244 |
| | $ 932 | $ 259 | $ 1,191 |

**Off-Balance Sheet Arrangements**

Not applicable.

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

There have been no material changes in our market risks during the quarter ended September 30, 2016.

**Interest Rate Sensitivity**

As of September 30, 2016, we had no investments and our convertible notes payable bear interest at a fixed rate; therefore, we do not believe we have any current material exposure to changes in interest rates.

**Foreign Currency Risk**

To date, our purchases from foreign suppliers have been minimal. While the amounts we incur to the hospitals and doctors that conduct our clinical trials, which are denominated primarily in the currencies of Australia and the European Union, have increased during the first nine months of 2016, we do not expect these cost increases to continue for the remainder of 2016. Our German subsidiary is non-operational and its functional currency is the Euro; accordingly, the effects of exchange rate fluctuations on the net assets are accounted for as translation gains or losses, a component of Comprehensive Loss. These translation adjustments have been immaterial through September 30, 2016. We do not enter into foreign currency hedging transactions. We believe we currently have minimal exposure to foreign currency rate fluctuations.

**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 Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized, and reported correctly within the time period specified in the SEC's rules and forms.

Our management, including our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2016, the end of the period covered by this Quarterly Report on Form 10-Q.

As a result of the restatement of our June 30, 2016 financial statements, which was filed with the SEC on November 8, 2016, and our initial assessment of classification as of September 30, 2016 of our convertible notes payable, management reassessed the effectiveness of our disclosure controls and procedures for both reporting periods and identified a material weakness in our controls over the accounting and reporting for infrequent, unusual, or complex technical accounting issues, as described below. Our management concluded, therefore, that our disclosure controls and procedures were not effective during the period covered by this report. The material weakness was the result of design and operating deficiencies within our internal control over financial reporting.

A "material weakness" in internal control over financial reporting is a deficiency, or a combination of deficiencies, in internal control such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis by the company's internal controls.

The matter involving internal controls and procedures that our management considered to be a material weakness involves the sufficiency of Company personnel with accounting technical knowledge and expertise related to disclosure of infrequent, unusual, or complex accounting matters. Specifically, a control failure occurred that allowed for misapplication of Accounting Standards Codification ("ASC") 470-10, "Debt – Overall" in the classification of securities that contain a "due on demand" provision and we did not adequately assess the balance sheet classification of the Company's convertible notes payable as of June 30, 2016. While we also did not initially assess the correct balance sheet classification of the convertible notes payable as of September 30, 2016, we corrected the classification prior to the date of filing this Quarterly Report on Form 10-Q.

***Remediation Plan***

In connection with, and as a result of, the material weakness identified, we are implementing additional technical accounting review procedures, to be performed by an external qualified technical accounting resource, to help evaluate new or existing infrequent, unusual, or complex technical accounting issues. Additionally, we have implemented additional review procedures related to the classification of our convertible notes. Management believes that these additional controls will remediate the material weakness discussed above; however, no assurance can be given that these changes will remediate the material weakness until such time that the controls have operated for a sufficient period of time and their operating effectiveness has been tested.

**Changes in Internal Control Over Financial Reporting**

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act), except as described above, during the quarter ended September 30, 2016 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings

We may from time to time become subject to various claims and legal actions during the ordinary course of our business. We are not party to any legal proceedings at the date of filing of this Quarterly Report on Form 10-Q.

### Item 1A. Risk Factors

Our business is subject to various risks, including those described in Item 1A "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, which we strongly encourage you to review. In addition to the risks described therein, we identified the following Risk Factor.

***Failure to maintain effective internal control over our financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could cause our financial reports to be inaccurate***

We are required pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404") to maintain internal control over financial reporting and to assess and report on the effectiveness of those controls. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Our management concluded that our disclosure controls and procedures over financial reporting were ineffective as of June 30, 2016 and September 30, 2016, and identified a material weakness in our controls over the accounting and reporting for infrequent, unusual, or complex technical accounting issues. While management believes the Company has added and enhanced internal controls that will remediate the material weakness, there is no assurance that the changes will remediate the identified material weakness or that the controls will prevent or detect future material weaknesses.

If we are not able to maintain effective internal control over financial reporting, our financial statements, including related disclosures, may be inaccurate, which could have a material adverse effect on our business.

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

**Unregistered Sales of Equity Securities**

None.

**Use of Proceeds from Registered Securities**

Not applicable.

### Item 3. Defaults upon Senior Securities

None.

### Item 4. Mine Safety Disclosures

Not applicable.

### Item 5. Other Information

Not applicable.

### Item 6. Exhibits

The exhibits listed in the accompanying Index to Exhibits are filed or incorporated by reference as part of this Quarterly Report on Form 10-Q.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Quarterly Report on Form 10-Q to be signed on its behalf by the undersigned, thereunto duly authorized.

REVA Medical, Inc.

Date: November 9, 2016

/s/ Regina E. Groves
Regina E. Groves
Chief Executive Officer
*(Principal Executive Officer)*

Date: November 9, 2016

/s/ Katrina L. Thompson
Katrina L. Thompson
Chief Financial Officer and Secretary
*(Principal Financial Officer and Principal Accounting Officer)*

## INDEX TO EXHIBITS

| Exhibit Number | Description of Exhibits | Filed with this Form 10-Q | Incorporated by Reference | | |
|---|---|---|---|---|---|
| | | | Form | File No. | Date Filed |
| 3.1 | Amended and Restated Certificate of Incorporation | | S-1/A | 333-168852 | 10/22/2010 |
| 3.2 | Amended and Restated Bylaws | | S-1/A | 333-168852 | 10/22/2010 |
| 3.3 | Amendment No. 1 to the Amended and Restated Bylaws | | 8-K | 000-54192 | 9/12/2014 |
| 4.1 | Form of Stock Certificate | | S-1/A | 333-168852 | 11/12/2010 |
| 4.2 | Form of Amended and Restated Investors' Rights Agreement, by and among REVA Medical, Inc. and the holders of our common stock and convertible notes set forth therein | | DEF14A | 000-54192 | 10/14/2014 |
| 4.3 | Convertible Note Deed dated September 25, 2014, by and between REVA Medical, Inc., Goldman Sachs International, and Senrigan Master Fund | | DEF14A | 000-54192 | 10/14/2014 |
| 4.4 | First Amendment to Convertible Note Deed, dated February 11, 2016, by and among REVA Medical, Inc., Goldman Sachs International, and Senrigan Master Fund | | DEF14A | 000-54192 | 3/9/2016 |
| 10.1 | Amendment #3 to Exclusive License Agreement #2 between Rutgers, The State University of New Jersey and REVA Medical, Inc. dated July 1, 2010 * | X | | | |
| 31.1 | Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended | X | | | |
| 31.2 | Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended | X | | | |
| 32.1 ** | Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350 | X | | | |
| 99.1 | Section 13 of the ASX Settlement Rules | | S-1/A | 333-168852 | 10/22/2010 |
| 101.INS | XBRL Instance Document | X | | | |
| 101.SCH | XBRL Taxonomy Extension Schema Document | X | | | |
| 101.CAL | XBRL Taxonomy Calculation Linkbase Document | X | | | |
| 101.DEF | XBRL Taxonomy Definition Linkbase Document | X | | | |
| 101.LAB | XBRL Taxonomy Label Linkbase Document | X | | | |
| 101.PRE | XBRL Taxonomy Presentation Linkbase Document | X | | | |

* Registrant has requested confidential treatment with respect to certain portions of this exhibit.

** These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of REVA Medical, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**EXHIBIT 10.1**

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETED ASTERISKS [***], HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**



**AMENDMENT #3**

**TO EXCLUSIVE LICENSE AGREEMENT # 2**

WHEREAS Reva Medical Inc. ("REVA") and Rutgers, The State University of New Jersey ("Rutgers"), referred to collectively herein as "the Parties", entered into an EXCLUSIVE LICENSE AGREEMENT NUMBER 2 ("License #2) effective July 1, 2010; and,

WHEREAS Section 6.3 (i)(b) of License #2, as amended by the signed Request for Extension letter dated July 1, 2014, requires REVA to file an application with the USFDA or a comparable agency in another Major Market Country no later than the end of 2015; and

WHEREAS Section 6.3 (ii) (b), as amended by Amendment #2, requires REVA to Pay Rutgers an annual amount of $[***] in order to extend REVA's rights in the field of Non-Stent Products for as long as the necessary regulatory filing for Non-Stent Product has not been effected;

THEREFORE, the Parties hereby mutually agree to amend License #2 as of **August 31, 2016** as follows:

1. Section 6.3 (i)(b) will be replaced with the following:

   **"Licensee or its Sublicensees will submit a complete application to either an appropriate regulatory body in the European Community or to the USFDA for a CE Marking or a Pre-Market Approval for at least one Coronary Stent Product, not later than by September 1, 2016."**

2. The following language will be added at the end of the first paragraph of Section 6.3 (ii)(b):

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission.

**"Starting on June 30, 2016, for each annual filing extension desired by Licensee, Licensee will pay Rutgers an amount of $[***] on July 1 of the year for which the extension is granted, and an additional amount of $[***] immediately upon the earliest to occur of the following events:**

1. **Termination of License #2 for any reason**
2. **Change of Control as defined in License #2**
3. **January 1, 2019"**

IN WITNESS HEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

| **RUTGERS, THE STATE UNIVERSITY OF NEW JERSEY** | **REVA MEDICAL, INC.** |
|---|---|
| */s/ S. David Kimball* | */s/ Robert K. Schultz* |
| Signature | Signature |
| S. David Kimball, Ph.D.<br>Associate Vice President<br>Office of Research Commercialization | Robert K. Schultz, Ph.D.<br>President & COO |
| Date: *9/12/2016* | Date: *9-8-16* |

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission.

**Exhibit 31.1**

**CERTIFICATION PURSUANT TO**
**SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Regina E. Groves, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of REVA Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2016

/s/ Regina E. Groves
Regina E. Groves
Chief Executive Officer
(principal executive officer)

**Exhibit 31.2**

**CERTIFICATION PURSUANT TO**
**SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Katrina L. Thompson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of REVA Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2016

/s/ Katrina L. Thompson
Katrina L. Thompson
Chief Financial Officer
(principal financial officer)

**Exhibit 32.1**

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

In connection with the Quarterly Report on Form 10-Q of REVA Medical, Inc. (the "Company") for the quarterly period ended September 30, 2016, as filed with the Securities and Exchange Commission (the "Report"), Regina E. Groves, Chief Executive Officer of the Company, and Katrina L. Thompson, Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- The information in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2016

/s/ Regina E. Groves
Regina E. Groves
Chief Executive Officer
(principal executive officer)

/s/ Katrina L. Thompson
Katrina L. Thompson
Chief Financial Officer
(principal financial officer)