

REVA MEDICAL, INC.

FORM 10-Q (Quarterly Report)

Filed 08/09/17 for the Period Ending 06/30/17

Address	5751 COPLEY DRIVE SAN DIEGO, CA 92111
Telephone	(858) 966-3000
CIK	0001496268
Symbol	RVALL
SIC Code	3842 - Orthopedic, Prosthetic, and Surgical Appliances and Supplies
Industry	Advanced Medical Equipment & Technology
Sector	Healthcare
Fiscal Year	12/31

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2017

or

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

For the transition period from _____ to _____

Commission file number: 000-54192

REVA MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

**5751 Copley Drive
San Diego, CA 92111**

(Address of principal executive offices,
including zip code)

33-0810505

(I.R.S. Employer
Identification No.)

(858) 966-3000

(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 such shorter period that the registrant was required to submit and post such files).

Yes No

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company Emerging growth company

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes No

As of August 1, 2017, a total of 41,167,017 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 June 30, 2017

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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, 2016	June 30, 2017
Assets		
Current Assets:		
Cash and cash equivalents	\$ 6,674	\$ 29,147
Inventory	—	506
Prepaid expenses and other current assets	472	505
Total current assets	7,146	30,158
Non-Current Assets:		
Property and equipment, net	2,277	1,900
Other non-current assets	60	13
Total non-current assets	2,337	1,913
Total Assets	\$ 9,483	\$ 32,071
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable	\$ 778	\$ 949
Accrued expenses and other current liabilities	2,173	1,430
Convertible notes payable	91,655	—
Accrued interest on convertible notes payable	4,204	—
Total current liabilities	98,810	2,379
Long-Term Liabilities:		
Convertible notes payable	—	116,778
Accrued interest on convertible notes payable	—	5,759
Common stock warrant liability	—	6,181
Other long-term liabilities	266	250
Total long-term liabilities	266	128,968
Total Liabilities	99,076	131,347
Commitments and contingencies (Note 7)		
Stockholders' Deficit		
Common stock — \$0.0001 par value; 100,000,000 shares authorized; 42,851,477 and 41,167,017 shares issued and outstanding at December 31, 2016 and June 30, 2017, 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	299,641	289,090
Accumulated deficit	(389,238)	(388,370)
Total Stockholders' Deficit	(89,593)	(99,276)
Total Liabilities and Stockholders' Deficit	\$ 9,483	\$ 32,071

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

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2016	2017	2016	2017
Operating Expense:				
Research and development	\$ 4,665	\$ 3,083	\$ 9,953	\$ 7,047
Selling, general, and administrative	2,366	1,977	4,559	4,079
Loss from operations	<u>(7,031)</u>	<u>(5,060)</u>	<u>(14,512)</u>	<u>(11,126)</u>
Other Income (Expense):				
Interest expense	(505)	(3,079)	(1,010)	(3,670)
Loss on issuance of convertible notes payable and warrants to purchase common stock	—	(520)	—	(520)
Gain (loss) on change in fair value of convertible notes payable and warrant liability	2,966	8,178	(29,798)	16,316
Other income (expense)	<u>15</u>	<u>(22)</u>	<u>(33)</u>	<u>(79)</u>
Other income (expense)	<u>2,476</u>	<u>4,557</u>	<u>(30,841)</u>	<u>12,047</u>
Net Income (Loss) and Comprehensive Income (Loss)	<u>\$ (4,555)</u>	<u>\$ (503)</u>	<u>\$ (45,353)</u>	<u>\$ 921</u>
 Net Income (Loss) Per Common Share :				
Basic	<u>\$ (0.11)</u>	<u>\$ (0.01)</u>	<u>\$ (1.09)</u>	<u>\$ 0.02</u>
Diluted	<u>\$ (0.11)</u>	<u>\$ (0.01)</u>	<u>\$ (1.09)</u>	<u>\$ (0.25)</u>
 Shares Used to Compute Net Income (Loss) per Share:				
Basic	<u>42,569,166</u>	<u>41,988,220</u>	<u>41,520,092</u>	<u>42,410,841</u>
Diluted	<u>42,569,166</u>	<u>41,988,220</u>	<u>41,520,092</u>	<u>53,916,997</u>

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

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

	Six Months Ended June 30,	
	2016	2017
Cash Flows from Operating Activities:		
Net income (loss)	\$ (45,353)	\$ 921
Non-cash adjustments to reconcile net income (loss) to net cash used for operating activities:		
Depreciation and amortization	564	545
Loss on property and equipment disposal	—	43
Stock-based compensation	3,070	1,889
Interest expense on convertible notes payable	1,010	3,670
Loss on issuance of convertible notes payable and warrants to purchase common stock	—	520
Loss (gain) on change in fair value of convertible notes payable and warrant liability	29,798	(16,316)
Changes in operating assets and liabilities:		
Inventory	—	(506)
Prepaid expenses and other current assets	110	(33)
Other non-current assets	—	47
Accounts payable	(277)	122
Accrued expenses and other current liabilities	(238)	(816)
Other long-term liabilities	(88)	(16)
Net cash used for operating activities	(11,404)	(9,930)
Cash Flows from Investing Activities:		
Purchases of property and equipment	(370)	(164)
Net cash used for investing activities	(370)	(164)
Cash Flows from Financing Activities:		
Proceeds from issuances of common stock	11,428	—
Repurchase of common stock	—	(12,493)
Proceeds from issuances of convertible notes payable and warrants, net	—	45,060
Net cash provided by financing activities	11,428	32,567
Net increase (decrease) in cash and cash equivalents	(346)	22,473
Cash and cash equivalents at beginning of period	16,895	6,674
Cash and Cash Equivalents at End of Period	\$ 16,549	\$ 29,147
 Supplemental Non-Cash Information:		
Property and equipment in accounts payable at end of period	\$ 100	\$ 65
Adjustment to beginning accumulated deficit upon adoption of ASU 2016-09	\$ —	\$ 53
Warrant liability transferred to equity upon exercise	\$ 28,579	\$ —

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

REVA Medical, Inc .
Notes to Consolidated Financial Statements
(Unaudited)

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 are a medical device company that is focused on developing and commercializing products for use in humans, utilizing our proprietary polymer technologies. On April 3, 2017, our first product was approved for sale under a CE Mark, which allows us to market and sell in Europe and other jurisdictions that recognize the CE Mark. The product is our *Fantom* scaffold, a drug-eluting bioresorbable stent used to treat coronary artery disease in humans. We received our initial customer order late in our second quarter and anticipate initial revenues to occur during the third quarter of 2017. Prior to its approval, *Fantom* had been implanted in 247 patients in clinical trials conducted in eight countries outside the United States. We used the data from 117 of those patients at a six-month time point in our CE Mark application, which we submitted in 2016.

In December 2010 we completed an initial public offering 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 CHESD Depository 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.” We may pursue a listing of our common stock on a U.S. stock exchange, within the next year, at which time we would become dual-listed.

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, 2016.

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, 2016 was derived from the Company’s audited financial statements included in our Form 10-K for the year ended December 31, 2016. These 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- and six-month periods ended June 30, 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017 or for any other interim period.

Capital Resources : We had cash and cash equivalents totaling \$29,147,000 as of June 30, 2017, which we believe will be sufficient to fund our operating and capital needs through at least the third quarter of 2018. These cash resources include approximately \$32,567,000 in cash proceeds received during the second quarter of 2017 upon the issuance of convertible notes and warrants, net of costs of the transaction and the repurchase of common stock from one investor to the transaction.

Although we have received CE Marking of our *Fantom* scaffold and have initiated commercial sales, until we generate revenue at a level to support our cost structure, we expect to continue to incur substantial operating losses and net cash outflows. 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 profitability or positive cash flows on a recurring basis. Until we generate positive cash flows from operations, we plan to continue to fund our operating and capital needs by utilizing current cash resources. We may need to raise further capital in the future if we determine to conduct a U.S. clinical trial, if our operations cannot support our ongoing costs, or if unanticipated cash needs arise. While we may consider raising additional funds concurrent with a U.S. listing of our common stock, there can be no assurance that we will be successful in raising additional capital if needed, or that it will be on terms that are acceptable to us.

REVA Medical, Inc .
Notes to Consolidated Financial Statements
(Unaudited)

1. Background and Basis of Presentation (continued)

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

Inventory : We received CE Mark regulatory approval of our *Fantom* scaffold on April 3, 2017, at which time we began capitalizing raw material purchases and commercial scaffold production costs to inventory. Through June 30, 2017, we had not sold any product and our inventory consisted of \$178,000 in raw materials, \$16,000 of work-in-process, and \$312,000 of finished goods, stated at the lower of cost or net realizable value based on the first-in, first-out cost method (“FIFO”). Our policy is to record an estimated allowance against inventory for unsalable, obsolete, or impaired inventory, with a corresponding increase to costs of revenue; through June 30, 2017, no inventory was considered to be unsalable, obsolete, or impaired and, therefore, no allowance was recorded. We record the cost of product used in research and development or clinical trials as research and development expense; we do not use commercial inventory for such purposes.

Convertible Notes Payable : We analyze convertible notes payable at issue date to determine balance sheet classification, issue discounts or premiums, and embedded or derivative features. If embedded or derivative features give rise to separate accounting, we make an election to account for the notes at cost or at fair value. If fair value accounting is elected, on the issue date we record the difference between the issue price and the fair value of the combined securities issued in a transaction as a gain or loss in the consolidated statement of operations. We remeasure the fair value of the notes at each reporting date and record the change in fair value as a gain (upon a decrease in fair value) or a loss (upon an increase in fair value) as a component of other income (expense) in our consolidated statement of operations. Following our analysis of their embedded and derivative features, we elected fair value accounting for all issues of our convertible notes payable as management believes the notes will be converted into common stock, rather than repaid, and the fair value method presents an estimate of the value of the underlying common stock, and, therefore a more appropriate value of these liabilities than would be provided under the cost method.

Common Stock Warrants : The fair value of warrants issued for the purchase of common stock is recorded as a liability whenever warrants call for issuance of registered shares upon exercise, a condition that we may not be able to accommodate and which would then result in a net settlement of the warrants. Until the time warrants are exercised or expire, we remeasure their fair value at each reporting date and record the change in fair value as a gain or loss component of other income (expense) in our consolidated statement of operations.

Revenue : Through June 30, 2017, we had not recorded any revenue. Once we begin commercial sales, we will recognize revenue when title and risk of loss transfers to a customer, which is expected to be following shipment and when the customer’s right of return or replacement expires.

Research and Development Costs : We expense our research and development costs as incurred. These costs include salaries, employee benefits, laboratory supplies, consulting services, production materials and services, preclinical and clinical costs, technology license fees, laboratory equipment depreciation, facility costs, certain indirect costs, and the costs to commercially manufacture our *Fantom* scaffold prior to receiving the CE Mark regulatory approval. Following regulatory approval on April 3, 2017, the costs of commercial manufacturing are capitalized to inventory.

Recently Adopted Accounting Pronouncements : We adopted ASU 2016-09, *Stock Compensation: Improvements to Employee Share-Based Payment Accounting* , effective January 1, 2017. ASU 2016-09 simplifies certain aspects of accounting for stock-based compensation, including the accounting for income taxes, the option to recognize forfeiture credits as they occur rather than as an estimate of future activity, and classifications in the statement of cash flows. Upon the adoption, we recorded a cumulative effect adjustment to our accumulated deficit of approximately \$53,000, with a corresponding increase to additional paid-in capital, to reverse our forfeiture estimate for unvested awards. All forfeitures occurring after adoption are being recognized in the consolidated statement of operations in the reporting period in which they occur. We had no forfeitures during the six months ended June 30, 2017.

REVA Medical, Inc .
Notes to Consolidated Financial Statements
(Unaudited)

1. Background and Basis of Presentation (continued)

Recent Accounting Pronouncements : In May 2014, ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* , was issued; several subsequent pronouncements were issued to clarify and refine the guidance in ASU 2014-09. The standard outlines a single comprehensive model to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance. Revenue recognized under ASU 2014-09 will represent the consideration an entity expects to be entitled to in exchange for the transfer of goods or services to a customer; it also requires additional disclosures about the nature, amount, timing, and uncertainty of revenue and cash flows arising from customer contracts. We will be required to adopt this pronouncement in the first quarter of 2018, using either a full retrospective or modified retrospective approach. Since we are currently launching commercial operations, had no commercial sales through June 30, 2017, and do not yet have a standard approach to customer contracting, we are evaluating ASU 2014-09 and plan to determine an implementation approach once we have established at least a small base of commercial customers and contracts.

In February 2016, ASU 2016-02, *Leases* , was issued. ASU 2016-02 requires lessees to recognize assets and liabilities for all leases with terms exceeding 12 months, including those currently identified and accounted for as operating leases. ASU 2016-02 is effective the first quarter of 2019. We currently have only one lease to which the ASU would apply, which expires in January 2018; we will continue to evaluate the impact of implementation as we renew the lease and possibly acquire additional leases.

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.

We carry our convertible notes payable (the “Notes”) and common stock warrant liability at fair value; these recurring financial instruments are considered to be Level 3 financial liabilities. Through June 30, 2017, we carry our other assets and liabilities at amortized cost, which we consider to be reasonable estimates of their fair values due to their short-term nature and, therefore, do not provide their fair value information in the following table. Utilizing the lowest level inputs available under the measurement hierarchy, the fair values of our measured financial instruments, consisting only of liabilities, are as follows:

	Level 3
	(in thousands)
Fair Value of Liabilities at December 31, 2016:	
Convertible notes payable	\$ 91,655
Fair Value of Liabilities at June 30, 2017:	
Convertible notes payable	\$ 116,778
Common stock warrant liability	6,181
	\$ 122,959

We had no Level 1 or Level 2 financial instruments through June 30, 2017.

REVA Medical, Inc .
Notes to Consolidated Financial Statements
(Unaudited)

2. Fair Value Measurements (continued)

The fair values of our Notes were determined utilizing a Least Squares Monte Carlo simulation model; the fair value of our warrants to purchase common stock was determined using either a Least Squares Monte Carlo simulation model or a Black-Scholes valuation model, depending on their exercise price and other features. These 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 use 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 make assumptions as to our abilities to test and commercialize our product(s), to obtain future financings when and if needed, to comply with the terms and conditions of our Notes, and the probability of a change in control event.

A summary of the assumptions used to value these Level 3 securities is as follows:

	<u>December 31,</u> <u>2016</u>	<u>June 30,</u> <u>2017</u>
Market price per share of common stock	\$7.88	\$6.60
Risk-free interest rate	2.0%	1.9%
Expected volatility of common stock	80.0%	45.0%
Expected life (in years)	2.87	2.37 – 4.96
Bond yield of equivalent securities	27.0%	25.4% – 27.1%

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.

We recorded a total of \$2,966,000 and \$8,178,000 in unrealized gains during the three-month periods, and a total of \$29,798,000 in unrealized losses and \$16,316,000 in unrealized gains during the six-month periods, ended June 30, 2016 and 2017, respectively, that arose from the change in fair value on our Level 3 financial liabilities. Our Level 3 fair value activity through June 30, 2017 is as follows:

	<u>Level 3</u> <u>(in thousands)</u>
Balance at December 31, 2016	\$ 91,655
Gain from Change in Fair Value:	
Convertible notes payable	(8,138)
Balance at March 31, 2017	83,517
Fair Value on Issuance Dates:	
Convertible notes payable	40,954
Warrants to purchase common stock	6,666
Gain from Change in Fair Value:	
Convertible notes payable	(7,693)
Warrants to purchase common stock	(485)
Balance at June 30, 2017	<u>\$ 122,959</u>

REVA Medical, Inc .
Notes to Consolidated Financial Statements
(Unaudited)

3. Convertible Notes Payable and Warrants to Purchase Common Stock

In May 2017, we issued 338 convertible notes and in June 2017 we issued 133 convertible notes (collectively, the “2017 Notes”), each with a face value of \$100,000, for total gross cash proceeds of \$47,100,000. From these cash proceeds, we repurchased 1,732,260 shares of our common stock from one of the 2017 Note investors at \$7.212 per share, for a total repurchase of \$12,493,000, and incurred transaction costs of \$2,115,000, leaving us with net proceeds of \$32,492,000. The 2017 Notes are convertible at any time at the holders’ election; the conversion rate as of June 30, 2017 was \$8.655 per share, which would result in issuing 5,441,941 shares of common stock upon conversion. The conversion rate is downward adjustable based on the issue price of securities in a future Company financing, if any, to a minimum of \$7.212 per share. The 2017 Notes mature five years from issue date, if not converted or redeemed earlier. Interest accrues at the rate of 8.0 percent per annum, compounded annually, and is payable upon redemption or maturity; accrued interest is not payable or convertible upon conversion of the notes. Holders of the 2017 Notes have a right to request redemption of the notes (face value plus accrued interest) on November 4, 2019, if they have not been previously converted or redeemed, if the holders have provided at least 30 days’ written notice to elect such a redemption.

On their issue dates, we evaluated the 2017 Notes and, following an analysis of the embedded and derivative features, made an irrevocable election to account for the notes at fair value. The fair value on June 30, 2017 was estimated to be \$6,259,000 below the \$47,100,000 face value of the 2017 Notes. A decrease of \$113,000 in the fair value of the notes between their issue dates in May and June 2017 and the June 30, 2017 reporting date was recorded as a gain in our consolidated statement of operations. In addition to the \$2,115,000 transaction costs, which we recorded as interest expense in our consolidated statement of operations upon the fair value accounting election, we accrued a total of \$474,000 in interest expense on the 2017 Notes for the period from issue date to June 30, 2017.

In November 2014, we issued 250 convertible notes (the “2014 Notes”), each with a face value of \$100,000, for total gross cash proceeds of \$25,000,000. The 2014 Notes are convertible at any time at the holders’ election into a total of 11,506,155 shares of common stock, which is a conversion rate of \$2.17275 per share. The 2014 Notes mature on November 14, 2019, if not converted or redeemed earlier. Interest accrues 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 2014 Notes. Effective June 1, 2017, upon stockholder approval, the one-time option for holders to redeem the notes on June 30, 2017 and the provision for an automatic conversion of the notes were eliminated and the 2014 Notes were modified to be subordinated to the 2017 Notes.

On their issue date, we evaluated the 2014 Notes and, following an analysis of the embedded and derivative features, we made an irrevocable election to account for the notes at fair value. Following the June 1, 2017 modifications, we continued to account for the 2014 Notes under the fair value method. The fair values of the 2014 Notes as of December 31, 2016 and June 30, 2017 were calculated to be \$66,655,000 and \$50,937,000, respectively, higher than the unpaid principal balance of the Notes of \$25,000,000. The increase of \$29,798,000 and the decrease of \$15,718,000 in the fair value of the Notes during the six months ended June 30, 2016 and 2017, respectively, were recorded as a loss and a gain, respectively, in our consolidated statement of operations. We accrued \$505,000 and \$544,000 for the three-month periods, and \$1,011,000 and \$1,081,000 for the six-month periods, ended June 30, 2016 and 2017, respectively, in interest expense on the 2014 Notes.

In connection with issuing the 2017 Notes, in May 2017 and June 2017 we issued warrants to purchase up to 2,119,500 shares of common stock. The warrants are immediately exercisable and expire five years from issue date. Through June 30, 2017, the exercisable price of the warrants was \$5.00 per share; the exercise price could be adjusted upward to a maximum of \$7.212 per share, based on the issue price of securities in a future Company financing, if any. The fair value of the warrants on June 30, 2017 was estimated to be \$485,000 less than the fair value on issue date, which we recorded as a gain on change in fair value in our consolidated statement of operations.

The aggregate fair value of the 2017 Notes and warrants on their issue dates was estimated to be \$47,620,000, which was \$520,000 higher than the \$47,100,000 issue price; we recorded this difference as a loss on issuance in the consolidated statement of operations.

The warrants we issued in November 2014 in connection with issuing the 2014 Notes were exercised in full on or before February 12, 2016. Prior to their exercise, we recorded their change in fair value in our consolidated statement of operations. The loss on change in fair value from January 1, 2016 to February 12, 2016 was \$8,957,000.

REVA Medical, Inc .
Notes to Consolidated Financial Statements
(Unaudited)

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,	June 30,
	2016	2017
	(in thousands)	
<i>Property and Equipment:</i>		
Furniture, office equipment, and software	\$ 655	\$ 655
Laboratory equipment	6,604	6,112
Leasehold improvements	<u>2,412</u>	<u>2,412</u>
	9,671	9,179
Accumulated depreciation and amortization	<u>(7,394)</u>	<u>(7,279)</u>
	<u><u>\$ 2,277</u></u>	<u><u>\$ 1,900</u></u>
<i>Accrued Expenses and Other Current Liabilities:</i>		
Accrued salaries and other employee costs	\$ 1,456	\$ 836
Accrued operating expenses	519	481
Accrued use taxes and other	<u>198</u>	<u>113</u>
	<u><u>\$ 2,173</u></u>	<u><u>\$ 1,430</u></u>

5. Income Taxes

We have reported tax net operating losses since our inception through June 30, 2017; 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 (“RSUs”) 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, 2017, an additional 1,285,544 shares were reserved for issuance under the Plan. An aggregate of 9,266,190 shares are reserved for issuance under the Plan as of June 30, 2017. One share of common stock is issued for each stock option that is exercised or each RSU that vests. 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.

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Notes to Consolidated Financial Statements
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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
<i>Balance at December 31, 2015</i>	5,912,425	\$6.46
Granted	570,100	\$8.22
Cancelled	(106,834)	\$10.81
Exercised	(247,499)	\$4.04
<i>Balance at December 31, 2016</i>	6,128,192	\$6.65
Granted	474,600	\$7.60
Cancelled	(6,980)	\$5.95
<i>Balance at June 30, 2017</i>	6,595,812	\$6.72

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 12 months as of December 31, 2016 and to be nine months as of June 30, 2017. A total of 65 percent of these options had vested as of June 30, 2017; a total of 12,250 were cancelled during the year ended December 31, 2016 and none were cancelled during the six months ended June 30, 2017.

During January 2013 and May 2013 we awarded 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. As of June 30, 2017 all of these awards had vested and none had been cancelled.

During March 2015, we awarded 824,200 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 8.1 months as of December 31, 2016 and to be 10.1 months as of June 30, 2017. None of these RSUs had vested as of June 30, 2017; a total of 118,000 were cancelled during the year ended December 31, 2016 and none were cancelled during the six months ended June 30, 2017.

During May 2016, we awarded 35,200 RSUs and during July 2016 we awarded 12,600 RSUs to non-employee directors; all of these RSUs vested on May 25, 2017 and none were cancelled. During March 2017, we awarded 175,550 RSUs and during May 2017 we awarded 29,250 RSUs to employees; one-third of each award vests on each annual anniversary date of the award. Through June 30, 2017, 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 June 30, 2017.

REVA Medical, Inc .
Notes to Consolidated Financial Statements
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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 for the third performance target during the second quarter of 2016. We continued to believe all three performance targets were probable of being achieved through June 30, 2017 and recorded straight-line expense of \$128,000 and \$208,000 for the awards during the respective three- and six-month periods ended June 30, 2017. Stock-based compensation arising from employee options and awards under the Plan is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2017	2016	2017
	(in thousands)		(in thousands)	
Employee Stock-Based Compensation:				
Research and development expense	\$ 800	\$ 184	\$ 1,164	\$ 346
Selling, general, and administrative expense	1,075	793	1,866	1,543
	\$ 1,875	\$ 977	\$ 3,030	\$ 1,889

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:

	Six Months Ended June 30,	
	2016	2017
Risk-free interest rate	1.6%	2.3%
Expected volatility of common stock	57.5%	66.1%
Expected life in years	6.17	6.25
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 through June 30, 2016 was calculated based on the historical market prices of a selected group of publicly traded companies considered to be our peers; we used peer group data due to our 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. Beginning in 2017, we use our historical market prices; our securities began trading on our IPO date of December 23, 2010, which provides approximately 6.5 years' history as of June 30, 2017. 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 option activity history 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 six months ended June 30, 2017 had a weighted average grant date fair value of \$4.70.

The aggregate intrinsic value of options exercised during the six months ended June 30, 2016 was \$92,000; no options were exercised during the six months ended June 30, 2017.

REVA Medical, Inc .
Notes to Consolidated Financial Statements
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7. Commitments and Contingencies

We have licensed certain patents and other intellectual property rights related to the composition and coating of our scaffolds and other biomaterial technologies. Terms of these licenses include provisions for royalty payments upon sales of products utilizing the technology. The amount of royalty 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 \$15 per unit to a maximum of approximately \$50 per unit sold, with license provisions for escalating minimum royalties that could be as high as \$2,200,000 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. Since commercial sales of our *Fantom* scaffold are anticipated to begin in July 2017, we do not expect this annual license fee to continue. 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 \$250,000 per year during 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 Income (Loss) Per Common Share

Basic net income (loss) per common share is calculated by dividing the net income (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 this calculation, common stock options and restricted stock subject to forfeiture are considered to be common stock equivalents; common stock equivalents are used in the calculation of diluted net loss per share only when their effect is dilutive.

Basic net income (loss) per share reconciles to fully diluted net loss per share as follows (dollars in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2017	2016	2017
<i>Diluted Net Loss:</i>				
Net income (loss) used for basic net income (loss) per share	\$ (4,555)	\$ (503)	\$ (45,353)	\$ ()
Interest expense on convertible notes payable	—	—	—	—
Gain on change in fair value of convertible notes payable	—	—	—	()
	<u>\$ (4,555)</u>	<u>\$ (503)</u>	<u>\$ (45,353)</u>	<u>\$ ()</u>
<i>Weighted Average Shares Used to Compute Diluted Net Loss per Share:</i>				
Shares used for basic net income (loss) per share	42,569,166	41,988,220	41,520,092	42,4
Common share equivalents	—	—	—	11,5
	<u>42,569,166</u>	<u>41,988,220</u>	<u>41,520,092</u>	<u>53,9</u>

REVA Medical, Inc .
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8. Net Income (Loss) Per Common Share (continued)

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		Six Months Ended	
	June 30,		June 30,	
	2016	2017	2016	2017
<i>Weighted Average Shares Excluded from EPS:</i>				
Options to purchase common stock	6,414,854	6,565,952	6,300,137	6,375,868
Unvested restricted stock	37,693	7,569	40,562	10,428
Restricted stock units	931,699	923,411	957,949	850,813
Warrants to purchase common stock	—	1,068,083	1,009,615	536,991
Common share equivalents of convertible notes	11,506,156	14,248,521	11,506,156	12,884,914
	<u>18,890,402</u>	<u>22,813,536</u>	<u>19,814,419</u>	<u>20,659,014</u>

9. Subsequent Events

On July 13, 2017, we announced that two executives would retire and that ten additional employees had been terminated as the Company transitions from research and development activities to commercial operations. As a result, during the third quarter of 2017, the Company anticipates incurring \$570,000 in severance expense, of which approximately \$300,000 is expected to be paid by September 30, 2017 and the remainder is expected to be paid between October 1, 2017 and March 31, 2018. Additionally, upon retirement or termination date, all unvested equity grants or awards will be forfeited by these employees. The Company expects to reverse approximately \$1,817,000 in stock compensation expense during the three months ended September 30, 2017 related to these unvested forfeits.

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, 2016. 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 commercial operations and sales, clinical trials, pipeline product development, future financings, listing our securities for sales on a U.S. stock exchange, and 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, 2016 and as may be updated in our periodic reports thereafter. 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 medical device company that is focused on developing and commercializing products for use in humans, utilizing our proprietary polymer technologies. On April 3, 2017, our first product was approved for sale under a CE Mark, which allows us to commercialize in Europe and other jurisdictions that recognize the CE Mark. The product is our *Fantom* scaffold, a drug-eluting advanced generation bioresorbable scaffold designed specifically for coronary stenting. We believe *Fantom* is uniquely positioned to meet a market opportunity because of its distinctive features. Earlier generations of bioresorbable scaffolds created excitement as a solution to metal stents because they potentially reduce the long-term complications inherent with permanent metal implants. *Fantom* is the only scaffold made from a proprietary polymer and its unique features include full radiopacity, delivery similar to metal stents, a low profile, a wide expansion range, relevant sizing, and robust strength during the healing period followed by complete resorption.

We have commenced commercial operations and expect to record initial sales during the third quarter of 2017. Prior to its approval, *Fantom* had been implanted in 247 patients in clinical trials conducted in eight countries outside the United States. We used the data from 117 of those patients at a six-month time point in our CE Mark application.

Bioresorbable stents are called "scaffolds" because they are not permanent devices like metal stents. 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."

Prior to receiving CE Marking for *Fantom*, we invested significant time and funds in development, having performed scientific research, engineering development, and testing in laboratory and preclinical studies. We 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 areas for further development. We have been developing and advancing our scaffolds in both design and polymer composition since that study and have undertaken significant testing, including enrollment of 165 patients in two clinical trials between 2011 and 2014 with a prior generation product design. We follow all clinical trial patients for a period of five years, including the 247 patients implanted with our *Fantom* scaffold between December 2014 and March 2016.

We have prepared our manufacturing capabilities for commercialization and have developed our sales, marketing, and distribution strategies. We began our commercial launch late in the second quarter of 2017 and shipped our first product in the third quarter. Once we have successfully completed our launch, we will expand our commercial capabilities to allow for such things as increased volumes and jurisdictions. We have been preparing our systems and back-office needs for commercialization and will continue to expand these during the remainder of 2017.

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, development, and manufacturing activities from one location in San Diego, California. As of June 30, 2017, we had 60 employees, a majority of whom are degreed professionals and four of whom are PhDs. On July 13, 2017, we terminated 11 of these employees as we continue to transition from research and development activities to commercial operations. We have begun to establish a small sales force in Europe to perform our commercial sales activities; we have hired the sales leader, effective August 1, 2017, and will continue to build the sales team during the remainder of 2017. We leverage our internal expertise with contract research and preclinical laboratories, outside catheter manufacturing, a third party distribution and logistics service, and other outside services as needed. We have three clean rooms, a polymer manufacturing lab, and multiple engineering and chemistry labs at our facility in San Diego, in addition to our corporate and administrative office. We are ISO certified to the medical device standard 13485:2012 and intend to maintain this certification.

As of June 30, 2017, our cash balance was approximately \$29.1 million, which we believe will be sufficient to fund our operating and capital needs through the third quarter of 2018 and beyond. These cash resources include approximately \$32.6 million in cash proceeds received during the second quarter of 2017 upon the issuance of convertible notes and warrants, net of transaction costs and the repurchase of 1,732,260 shares of our common stock for \$12.5 million from one of the investors to the transaction.

We have incurred substantial losses since our inception; as of June 30, 2017, we had accumulated a deficit of approximately \$388.4 million. We expect our losses to continue as we start commercial operations, continue to conduct clinical trials, and develop and test additional products. While *Fantom* has been approved for sale and we expect first sales in July 2017, our efforts to generate substantial revenue and achieve positive cash flows from our operations may take several years, even if we are successful with our initial commercial efforts. 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 current cash resources. Also, management expects to pursue listing of our common stock on NASDAQ, or another exchange approved by our noteholders, in early 2018 and may consider raising additional funds concurrent with that listing in order to conduct a U.S. clinical trial.

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

Through June 30, 2017, we have not sold any commercial product and have not recorded revenue. We received CE Mark regulatory approval of our *Fantom* scaffold on April 3, 2017; prior to that date, our activities focused on research and development, including clinical studies and commercial preparations, and our operating costs consisted of research and development and general and administrative expenses. Upon CE Marking, we began capitalizing raw material purchases and commercial scaffold production costs to inventory, recording a total of \$506,000 in inventory as of June 30, 2017. We began to incur selling expenses during the second quarter of 2017. We will record revenue and costs of revenue once we begin commercial sales, which are expected in the third quarter of 2017. In addition to our operating expenses, we record other income or expense that primarily arises from the convertible notes we issued in 2014 and the second quarter of 2017 and the warrants we issued in the second quarter of 2017. Following are the more significant components contributing to our results of operations through June 30, 2017.

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.

We recorded the costs to commercially manufacture our *Fantom* scaffold prior to receiving the CE Mark as research and development expense. Following receipt of CE Mark, costs of commercial manufacturing have been capitalized to inventory.

Historically, our research and development expenses have represented between 70 and 75 percent of our total operating expenses; they represented 68 percent of total operating expenses for the year ended December 31, 2016 and 63 percent for the six months ended June 30, 2017, reflecting our decreasing development and clinical trial activities as we move toward commercial operations. We expect our research and development expenses to continue to decrease during the remainder of 2017 and to decrease as a percentage of our total expenses as we continue this transition; however, we expect our research and development expenses to continue to be a significant portion of our operating expenses as we continue to research, prove feasibility, and develop additional products.

Selling, General, and Administrative Expenses : Our selling, 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. Through June 30, 2017, we incurred an immaterial amount of selling 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 32 percent of total operating expenses for the year ended December 31, 2016 and 37 percent for the six months ended June 30, 2017. 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 during the remainder of 2017 to support the commercialization of *Fantom* and the ongoing needs of being a public company. We also expect to incur sales and marketing expenses, including salaries and overhead for our sales team, to support our commercial sales efforts beginning in the third quarter of 2017.

Revenue and Costs of Revenue : Following the April 3, 2017 receipt of CE Mark and our initiation of commercial sales during the third quarter of 2017, we anticipate recording initial revenue and costs of revenue by September 30, 2017. Our success, or lack thereof, will determine the amounts of revenues and costs in future periods.

Other Income and Expense : The components of other income and expense include interest expense on our convertible notes and the gains or losses arising from the changes in fair values of our outstanding convertible notes and warrants. We elected to account for our convertible notes using the fair value method; consequently, we recorded the offering costs arising from our financing transactions as interest expense when incurred and we recognize a gain or loss on issuance of convertible notes and warrants, measured as the difference between the issue price and fair value on the date of issuance. We remeasure fair value at each reporting date and 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.

The fair values of our convertible notes and warrants have fluctuated significantly during the periods they have been outstanding due to a variety of factors. These factors include the successful completion of operating milestones such as enrollment of patients in clinical trials, positive clinical results, receipt of CE Mark, and completion of financings, as well as uncertainties, delays in milestones and progress, and changes in the market price of our trading securities. We recorded a \$29.8 million loss on increases in fair value during the six months ended June 30, 2016 and a \$16.3 million gain from decreases in fair value during the six months ended June 30, 2017. Until the Notes are either converted into common stock or repaid and the warrants are either exercised or expire, we expect our other income and expense to fluctuate, possibly by significant amounts, by future gains or losses on changes in their fair values. Also, we will continue to accrue and record interest expense on the notes at their stated rates until they are either converted or repaid.

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 through June 30, 2017. 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 several years. 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 continue to decrease since we have passed the primary measurement points for 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 equity grants and awards to employees, directors, and consultants. Most of these grants and awards vest based on the passage of time; in 2015 we awarded restricted stock units ("RSU") and stock options that vest based on achievement of performance milestones.

For awards to employees and directors, we determine the amount of compensation expense by estimating fair value on the date of award and recording the resulting stock-based compensation over the vesting period, which ranges from one to four years, on a straight-line basis. For awards that vest upon achievement of performance milestones, we record compensation expense for only the performance milestones that are probable of being achieved, on a straight-line basis over the vesting period. Through March 31, 2016, we determined that two of the three milestones for the 2015 performance-based awards were probable of being achieved and, therefore, recorded expense for those two milestones only. During the second quarter of 2016, we determined that all three performance milestones were probable of being achieved and, therefore, recorded cumulative expense for the third milestone at that time and have been recording straight line expense for all three performance milestones since that time. We reverse cumulative expense recorded whenever unvested performance based awards are cancelled.

Stock-based compensation expense has been recorded as either research and development or general and administrative expense based on a recipient's work classification. For stock options, we estimate the grant date 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. We used peer group data through December 31, 2016 due to the fact that we had limited historical trading data. Beginning in 2017, we use our historical market prices; our securities began trading on our IPO date of December 23, 2010, which provides approximately 6.5 years' history as of June 30, 2017. The fair values of RSUs and restricted stock awards are equal to the closing market price of our common stock on the date of award.

Through December 31, 2016, we reduced the amount of recorded compensation expense to allow for potential forfeitures of awards; the forfeiture rate was based on actual historical forfeitures and ranged from approximately 1.7 percent to 3.4 percent. Upon adoption of ASU 2016-09 on January 1, 2017, we recorded a cumulative effect adjustment to our accumulated deficit of approximately \$53,000, with a corresponding increase to additional paid-in capital, to reverse the forfeiture estimate for unvested awards. All forfeitures occurring after January 1, 2017 will be recognized in the consolidated statement of operations in the reporting period in which they occur. We had no forfeitures during the six months ended June 30, 2017.

We occasionally grant options to consultants; no consultant options remained subject to vesting at either June 30, 2016 or June 30, 2017. When we grant or have unvested consultant options, we estimate the fair value at date of grant and at each subsequent reporting date until vesting is complete and record compensation expense based on the fair value during the service period of the consultant.

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 grant additional employee options or awards during the remainder of 2017 as we expand our workforce, including the addition of a direct sales force, and begin commercial sales, which could result in an increase of our stock-based compensation in the future. In July 2017, we announced a reduction in workforce; this reduction will result in a one-time reversal during the third quarter of 2017 of approximately \$1,817,000 in stock compensation expense that had been recorded from March 2015 to June 2017.

Inventory : We received CE Mark regulatory approval of our *Fantom* scaffold on April 3, 2017, at which time we began capitalizing raw material purchases and commercial scaffold production costs to inventory. Through June 30, 2017, we had not sold any product and our inventory consisted of raw materials, work-in-process, and finished goods totaling \$506,000, stated at the lower of cost or net realizable value based on the first-in, first-out cost method (“FIFO”). Our policy is to record an estimated allowance against inventory for unsalable, obsolete, or impaired inventory, with a corresponding increase to costs of revenue; through June 30, 2017, no inventory was considered to be unsalable, obsolete, or impaired and, therefore, no allowance was recorded. We expect the value of our inventory to increase as we initiate and expand commercial sales and we expect to establish an allowance for unsalable, obsolete, or impaired inventory as early as the third quarter of 2017. Since we have no history of commercial inventory or estimating an inventory allowance, if our initial or future estimates are inaccurate, possible material changes to our inventory or the related allowance could be required, which could materially affect our results of operations. We record the cost of product used in research and development or clinical trials as research and development expense; we do not use commercial inventory for such purposes.

Notes Payable : We analyze notes payable as of their issue date to determine their balance sheet 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, 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. On the issue date of convertible notes, we record the difference, if any, between the issue price of the combined securities issued in a transaction and their fair value as a gain or loss in the consolidated statement of operations. 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.

Following our analyses of their embedded and derivative features, we elected to utilize fair value accounting for the convertible notes issued in November 2014 and those issued during the second quarter of 2017. The fair values are determined using a Least Squares Monte Carlo simulation model, which requires 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.

Until such time as they are converted into common stock or repaid, we accrue interest on the notes at the stated interest rate.

Common Stock Warrants : The fair value of warrants issued for the purchase of common stock is recorded as a liability whenever warrants call for issuance of registered shares upon exercise, a condition that we may not be able to accommodate and which would then result in a net settlement of the warrants. Whenever we have a warrant liability, we remeasure the fair value of the underlying warrants at each reporting date and record the change in fair value as a gain or loss component of other income (expense) in our consolidated statement of operations. We value warrants utilizing either a Least Squares Monte Carlo simulation model or a Black-Scholes valuation model, depending on the exercise price and other features. Inputs to the valuation models would be of the same nature as those used to value our notes payable and involve the use of subjective assumptions.

Results of Operations

During the first half of 2016, our operating activities consisted of clinical trial enrollments, 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 was completed in August 2016, and refining our manufacturing processes in preparation for the commercialization of *Fantom*.

During the first half of 2017, our operating activities focused on finalizing processes for commercial operations in anticipation of initial sales during the third quarter of 2017. Additionally, we completed our financing transaction with issuances of convertible notes and warrants in May 2017 and June 2017, receiving net cash proceeds of approximately \$32.6 million.

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

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

	Three Months Ended June 30,		Change	
	2016	2017	\$	%
Research and development expense	\$ 4,665	\$ 3,083	\$ (1,582)	(34%)
Selling, general, and administrative expense	\$ 2,366	\$ 1,977	\$ (389)	(16%)
Interest expense	\$ 505	\$ 3,079	\$ 2,574	510%
Loss on issuance of convertible notes payable and warrants	\$ —	\$ 520	\$ 520	100%
Gain on change in fair values of convertible notes and warrant liability	\$ 2,966	\$ 8,178	\$ 5,212	176%
Other income (expense)	\$ 15	\$ (22)	\$ (37)	(247%)

Research and development expense decreased \$1,582,000, or 34 percent, for the three months ended June 30, 2017 compared to the three months ended June 30, 2016. The change primarily comprises reductions in personnel, material, and clinical costs, which were offset by increases in license fees and contract research costs. Personnel costs decreased a total of \$891,000 between the comparative quarters primarily due to decreases of \$616,000 in stock compensation and \$289,000 in salaries. Stock compensation decreased primarily as a result of non-recurring expenses recorded in the second quarter of 2016 for performance-based equity grants that were not repeated in 2017. Salary expense decreased as a result of capitalizing \$204,000 in labor costs to inventory combined with a \$95,000 reduction in incentive bonuses during the second quarter of 2017 compared to the second quarter of 2016. Direct material and testing costs decreased \$576,000 between comparative quarters due to decreases in clinical device manufacturing and process validation activities as we moved toward commercialization. Clinical costs decreased \$255,000 between the comparative quarters; the clinical trial initiated in March 2015 completed enrollment in March 2016 and patient follow-up assessment activity was substantially complete by March 31, 2017. Offsetting the decreases, we incurred a non-recurring license fee of \$150,000 upon receipt of CE Mark in the second quarter of 2017 and we incurred approximately \$84,000 in increased contract research fees as we undertook feasibility work on new technologies. The remainder of the change in research and development expenses between quarters resulted from individually immaterial changes in preclinical costs, lab supplies, depreciation, and facilities expenses.

Selling, general, and administrative expense decreased \$389,000, or 16 percent, for the three months ended June 30, 2017 compared to the three months ended June 30, 2016. This decrease primarily resulted from a \$393,000 decrease in personnel costs, combined with 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. Driving the decrease in personnel costs, stock compensation decreased \$282,000 primarily as a result of non-recurring expenses recorded in the second quarter of 2016 for performance-based equity grants that were not repeated in 2017 and incentive bonuses decreased \$95,000 during the second quarter of 2017 compared to the second quarter of 2016.

The increase of \$2,574,000 in interest expense between comparative quarters reflects the completion of our financing transaction during the second quarter of 2017. We incurred \$2,115,000 in transaction costs, which were recorded as interest expense due to our election of fair value accounting for the notes payable issued in the transaction. Additionally, we accrued \$474,000 in interest expense on the notes payable for the period from their issue dates to June 30, 2017.

The loss on issuance of convertible notes payable and warrants is a non-recurring charge that represents the difference between the issue price and the market value of our notes payable and warrants on the date of issue. This difference was recorded in the statement of operations since we elected to account for the notes payable at fair value.

The increase in gain recorded on the change in fair value on the convertible notes and warrants during the second quarter of 2017 compared to the second quarter of 2016 reflects the increase in securities outstanding for which fair value is measured, combined with the change in factors driving fair value, including a decrease in the market trading price of our securities of approximately nine percent during the second quarter of 2017 compared to a decrease of approximately three percent during the second quarter of 2016 (a decrease in market price generally results in a non-cash accounting gain).

The change in other income (expense) primarily reflects currency exchange rate gains or losses based on the relative strength of the U.S. dollar compared to the Australian and European currencies in which we make our clinical trial payments.

Comparison of the Six Months Ended June 30, 2016 and 2017

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

	Six Months Ended June 30,		Change	
	2016	2017	\$	%
Research and development expense	\$ 9,953	\$ 7,047	\$ (2,906)	(29%)
Selling, general, and administrative expense	\$ 4,559	\$ 4,079	\$ (480)	(11%)
Interest expense	\$ 1,010	\$ 3,670	\$ 2,660	263%
Loss on issuance of convertible notes payable and warrants	\$ —	\$ 520	\$ 520	100%
Gain (loss) on change in fair values of convertible notes and warrant liability	\$ (29,798)	\$ 16,316	\$ 46,114	(155%)
Other expense	\$ (33)	\$ (79)	\$ (46)	139%

Research and development expense decreased \$2,906,000, or 29 percent, for the six months ended June 30, 2017 compared to the six months ended June 30, 2016. The change primarily comprises reductions in personnel, clinical, material, and preclinical costs, which were offset by increases in license fees and contract research costs. Personnel costs decreased a total of \$1,008,000 between the comparative periods primarily due to a decrease of \$858,000 in stock compensation, a decrease of \$267,000 in salaries, and an increase of \$97,000 in recruiting costs. Stock compensation decreased primarily as a result of non-recurring expenses recorded in 2016 for performance-based equity grants that were not repeated in 2017, combined with final vesting of option grants made in prior years for which comparable grants were not made in 2016 or 2017. Salary expense decreased as a result of capitalizing \$204,000 in labor costs to inventory combined with a \$95,000 reduction in incentive bonuses during the first half of 2017 compared to 2016. Clinical costs decreased \$980,000 between the comparative periods; the clinical trial initiated in March 2015 completed enrollment in March 2016 and patient follow-up assessments were substantially complete by March 31, 2017. Direct material and testing costs decreased \$839,000 between years due to decreases in clinical device manufacturing and process validation activities as we moved toward commercialization. Preclinical study costs decreased \$280,000 between years due to the timing of tests and analyses; a majority of the preclinical tests for *Fantom* concluded during the first quarter of 2016. Offsetting the decreases, we incurred a non-recurring license fee of \$150,000 upon receipt of CE Mark in 2017 and we incurred approximately \$118,000 in increased contract research fees as we undertook feasibility work on new technologies in 2017. The remainder of the change in research and development expenses between years resulted from individually immaterial changes in lab supplies, depreciation, and facilities expenses.

Selling, general, and administrative expense decreased \$480,000, or 11 percent, for the six months ended June 30, 2017 compared to the six months ended June 30, 2016. This decrease primarily resulted from a \$427,000 decrease in personnel costs, combined with 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. Driving the decrease in personnel costs, stock compensation decreased \$323,000 primarily as a result of non-recurring expenses recorded in 2016 for performance-based equity grants that were not repeated in 2017, incentive bonuses decreased \$95,000 during 2017 compared to 2016, and recruiting costs increased \$86,000 in 2017 compared to 2016.

The increase of \$2,660,000 in interest expense between comparative periods reflects the completion of our financing transaction during the second quarter of 2017. We incurred \$2,115,000 in transaction costs, which were recorded as interest expense due to our election of fair value accounting for the notes payable issued in the transaction. Additionally, we accrued \$474,000 in interest expense on the notes through June 30, 2017.

The loss on issuance of convertible notes payable and warrants is a non-recurring charge that represents the difference between the issue price and the market value of our notes payable and warrants on the date of issue. This difference was recorded in the statement of operations since we elected to account for the notes payable at fair value.

We recorded a gain on the change in fair value of convertible notes and warrants during 2017 compared to a loss on the change in fair value during 2016. This difference reflects the increase in securities outstanding for which fair value is measured, combined with the change in factors driving fair value, including a decrease in the market price of our trading securities of approximately 16 percent during the first half of 2017 compared to an increase of approximately 30 percent during the first half of 2016.

The increase in other expense primarily arose from currency exchange rate losses based on the relative strength of the U.S. dollar compared to the Australian and European currencies in which we make our clinical trial payments.

Liquidity and Capital Resources

Sources of Liquidity

We received CE Mark regulatory approval of our *Fantom* scaffold on April 3, 2017 and initiated commercial sales in July 2017. *Fantom* is our first commercial product; we have not commercialized any products or generated any revenue since our inception in June 1998.

During the second quarter of 2017, we completed a two-stage financing. On May 4, 2017 we issued \$33.8 million in convertible notes and on June 16, 2017 we issued \$13.3 million in convertible notes, for total cash proceeds of \$47.1 million. From these proceeds we repurchased 1,732,260 shares of our common stock from one of the investors at a total repurchase price of \$12.5 million and incurred transaction costs of \$2.1 million, leaving us with net proceeds from the financing of \$32.5 million. As of June 30, 2017, we had a cash balance of \$29.1 million, which we believe is sufficient to fund our operating and capital needs through the third quarter of 2018 and beyond. As part of the financing, we issued warrants to purchase 2,119,500 shares of our common stock at an initial exercise price of \$5.00 per share.

The convertible notes we issued in November 2014 mature in November 2019 and the convertible notes we issued in 2017 mature the second quarter of 2022. While no payments of interest or principal are required on any of the notes until maturity, if the notes are not converted prior to that time, holders of the 2017 notes have a one-time right to request redemption on November 4, 2019 for face value plus accrued interest, provided they have given at least 30 days' written notice of the redemption request and the notes have not been otherwise converted or repaid. Management believes that it is more likely the notes will be converted, rather than redeemed, if the value of the underlying equity continues to increase and, therefore, has no plans for redemption.

While the warrants we issued in May and June 2017 are immediately exercisable, have a five-year life, and only provide for cash exercise, management does not look to the warrants as a source of funding for operating or capital needs as exercise is at the holders' option.

We have incurred substantial losses since our inception; as of June 30, 2017, we had accumulated a deficit of approximately \$388.4 million. We expect our losses to continue as we initiate commercial operations, continue to conduct clinical trials, and develop and test additional products. While *Fantom* has been approved for sale, our efforts to generate substantial revenue and achieve positive cash flows from our operations may take several years, even if we are successful with our initial commercial efforts. In order to successfully transition to profitable operations, we will need to achieve a level of revenues and product margins to support our cost structure. Until such time as we generate positive cash flow, we plan to continue to fund our operating and capital needs by utilizing current cash resources. We may need to raise further capital in the future if we determine to conduct a U.S. clinical trial, if our operations cannot support our ongoing costs, or if unanticipated cash needs arise. While we may consider raising additional funds concurrent with a U.S. listing of our common stock, there can be no assurance that we will be successful in raising additional capital if needed, or that it will be on terms that are acceptable to us.

Cash Flows

Our cash flows for the periods indicated are as follows:

	Six Months Ended	
	June 30,	
	2016	2017
	(in thousands)	
Net cash used for operating activities	\$ (11,404)	\$ (9,930)
Net cash used for investing activities	\$ (370)	\$ (164)
Net cash provided by financing activities	\$ 11,428	\$ 32,567
Net increase (decrease) in cash and cash equivalents	\$ (346)	\$ 22,473

Net Cash Flow from Operating Activities

Net cash used for operating activities during the first six months of 2016 primarily reflects the loss from operations of \$14,512,000 and the changes in operating assets and liabilities of \$493,000. These items were offset by non-cash expenses of \$3,070,000 for stock-based compensation and \$564,000 of depreciation and amortization. The interest on convertible notes payable and the loss on change in fair value of convertible notes payable and warrant liability are non-cash items that had no effect on cash flows.

Net cash used for operating activities during the first six months of 2017 primarily reflects the loss from operations of \$11,126,000 and the changes in operating assets and liabilities of \$1,202,000. These items were offset by non-cash expenses of \$1,889,000 for stock-based compensation, \$545,000 of depreciation and amortization, and a \$43,000 loss on property and equipment disposals. The interest on convertible notes payable, loss on issuance of convertible notes payable and warrants to purchase common stock, and the gain on change in fair value of convertible notes payable and warrant liability are non-cash items that had no effect on cash flows.

Net Cash Flow from Investing Activities

Cash used for investing activities during the first six months of each of 2016 and 2017 consisted of the purchase of lab and other equipment.

Net Cash Flow from Financing Activities

Cash provided by financing activities during the first six 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.

Cash provided by financing activities during the first six months of 2017 consisted of \$47,100,000 in proceeds from the issuance of convertible notes payable, offset by payments of \$2,040,000 for transaction costs and \$12,493,000 to repurchase 1,732,260 shares of our common stock.

Operating Capital and Capital Expenditure Requirements

We received CE Mark regulatory approval of our *Fantom* scaffold on April 3, 2017 and initiated commercial sales in July 2017. *Fantom* is our first commercial product; we have not commercialized any products or generated any revenue since our inception in June 1998. 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 2017 and into 2018 as we establish commercial operations, continue current and initiate new clinical trials, develop and test new technologies and product opportunities, and expand our corporate infrastructure.

Until we reach a sales volume to generate positive cash flow, we plan to fund our operating and capital needs with our current cash resources, which totaled \$29.1 million as of June 30, 2017 and which management believes will be sufficient to fund our operating and capital needs through the third quarter of 2018 and beyond. Also, in either late 2017 or early 2018, we may pursue listing of our common stock on NASDAQ, or another exchange approved by our noteholders, and may consider raising additional funds concurrent with that listing in order to conduct a U.S. clinical trial.

Even though we completed a financing during the second quarter of 2017 and may begin to generate cash inflows from operations as we commercialize *Fantom*, 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 our convertible 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.

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 June 30, 2017. We have not included our convertible notes in the table as we believe they will be converted into common stock rather than repaid. Our operating lease obligations represent the contractual rental payments due under our facility lease, which matures in January 2018.

	Payments Due by Period		
	< 1 Year	1 to 3 Years	Total
	(in thousands)		
Contractual Obligations:			
Operating lease obligations	\$ 419	\$ —	\$ 419
Deferred technology license fees	—	\$ 250	250
Purchase obligations	272	30	302
	<u>\$ 691</u>	<u>\$ 280</u>	<u>\$ 971</u>

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 June 30, 2017.

Interest Rate Sensitivity

As of June 30, 2017, 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 and we have not recorded any revenues. 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 resulted in relatively immaterial foreign currency exchange impacts through June 30, 2017, we plan to initiate commercial sales during the third quarter of 2017 in Europe. We anticipate we will denominate those sales in European currencies and we expect to be subject to foreign currency exchange risks on our revenues until payment is received. We do not enter into foreign currency hedging transactions. We believe we currently have minimal exposure to foreign currency rate fluctuations.

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 June 30, 2017.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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 June 30, 2017, the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2017.

Changes in Internal Control Over Financial Reporting

During the quarter ended June 30, 2017, following receipt of regulatory approval to market our commercial first product, we began capitalizing the costs of commercial manufacturing to inventory, which required us to develop and implement policies and procedures for inventory, including controls over the accounting and reporting for inventory. As a part of this process, we engaged a consultant who had experience in standard cost models, accounting for inventory, and designing controls over the accounting and reporting of inventory. Other than as relates to inventory, 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) during the quarter ended June 30, 2017 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, 2016, which we strongly encourage you to review. In addition to the risks described therein, we revised the following risk factor:

If we default on any material provision of our convertible notes, or if they are called for redemption prior to maturity, there could be a significant adverse effect on the Company, including our ability to remain in business.

We issued \$25.0 million of convertible notes in November 2014 and another \$47.1 million during the second quarter of 2017. We have a total of \$72.1 million in convertible notes outstanding as of June 30, 2017. The notes mature five years after issue date and bear interest at 7.54 percent and 8.00 percent per annum, respectively, with no interest required to be paid until redemption. The notes are convertible into common stock at any time and contain customary covenants and events of default and, with respect to the notes issued in 2017, a one-time option for redemption for face value plus accrued interest in November 2019.

In a decision to either convert the notes or elect redemption in November 2019, the factors influencing noteholders may be out of our control, or if within our control we may fail to perform, which may cause the noteholders to consider redemption over conversion. For example, a noteholder may consider global economic trends in making their decision, or they may evaluate the progress we have made, or not made, in developing and commercializing products. Additionally, if we are in default of any provisions of the notes, the noteholders have the right to call for their immediate redemption.

If the noteholders collectively, or individually, call for redemption prior to maturity or prior to converting the notes into common stock, we most likely would not have the cash resources to repay the notes. If we were unable to redeem the notes by raising additional capital, which might not be available on favorable terms, if at all, the noteholders could cause the Company to take extreme measures, including reduction of operations and personnel, sale of assets such as our intellectual property assets, and/or declaring bankruptcy. Any of these actions would have a material adverse effect on the Company.

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: August 9, 2017

/s/ Regina E. Groves

Regina E. Groves
Chief Executive Officer
(Principal Executive Officer)

Date: August 9, 2017

/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	First Amendment to Amended and Restated Investors' Rights Agreement dated September 24, 2014		DEF14A	000-654192	5/15/17
4.4	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
4.5	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
4.6	Second Amendment to Convertible Note Deed and Subordination, dated April 22, 2017, by and among REVA Medical, Inc., Goldman Sachs International, and Senrigan Master Fund		8-K	000-54192	4/26/2017
4.7	Convertible Note Deed dated April 22, 2017, by and among REVA Medical, Inc. and Each Person set out in Schedule 1 and Schedule 2		8-K	000-54192	4/26/2017
10.1	Stock Repurchase Agreement, dated April 22, 2017, by and between REVA Medical, Inc. and Medtronic, Inc.		8-K	000-54192	4/26/2017
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			

* 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.

**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: August 9, 2017

/s/ Regina E. Groves

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

**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: August 9, 2017

/s/ Katrina L. Thompson

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

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

In connection with the Quarterly Report on Form 10-Q of REVA Medical, Inc. (the "Company") for the quarterly period ended June 30, 2017, 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: August 9, 2017

/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)