Q3 2018 Quarterly Report on Form 10-Q

San Diego, California and Sydney, Australia (Tuesday, 6 November 2018, AEDT) – REVA Medical, Inc. (ASX: RVA) ("REVA" or the "Company") is pleased to present the attached Quarterly Report on Form 10-Q, as filed with the Securities and Exchange Commission today. The Form 10-Q includes the Company's unaudited Financial Statements for the three and nine months ended 30 September 2018 and other required disclosures. The financial statements included in the Form 10-Q were prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and are denominated in United States dollars.

About REVA Medical

REVA Medical is a medical device company focused on the development and commercialization of bioresorbable polymer technologies for vascular applications. The Company's lead products are the Fantom and Fantom Encore bioresorbable vascular scaffolds for the treatment of coronary artery disease. REVA is currently selling Fantom in Germany, Switzerland, Austria, the Netherlands, Belgium, Luxembourg, Italy and Turkey. REVA is based in San Diego, California, and employs 45 people in the U.S. and Europe.

Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions, and expectations and on information currently available to management. All statements that are not statements of historical fact, including those statements that address future operating plans or performance and events or developments that may occur in the future, are forward-looking statements, such as those statements regarding the projections and timing surrounding commercial operations and sales, clinical trials, pipeline product development, and future financings. No undue reliance should be placed on forward-looking statements. Although management believes forward-looking statements are reasonable as and when made, forward-looking statements are subject to a number of risks and uncertainties that may cause actual results to vary materially from those expressed in forward-looking statements, including the risks and uncertainties that are described in the "Risk Factors" section of our Annual Report on Form 10-K filed with the US Securities and Exchange Commission (the "SEC") on March 7, 2018, and as updated in our periodic reports thereafter. Any forward-looking statements in this announcement speak only as of the date when made. REVA does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

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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 September 30, 2018

or

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

For the transition period from to

Commission file number: 000-54192

REVA MEDICAL, INC.

(Exact name of registrant as specified in its charter)

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

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

Indicate by check mark whether the registrant has submitted electronically, every Interactive Data File required to be submitted 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 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 November 1, 2018, 41,479,877 shares of the registrant's common stock, $0.0001 par value per share, were outstanding.

REVA MEDICAL, INC.

FORM 10-Q — QUARTERLY REPORT
For the Quarter Ended September 30, 2018

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REFERENCES

Corporate Information

Our principal executive offices are located at 5751 Copley Drive, Suite B, 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 in the information incorporated herein by reference to "REVA Medical," "REVA," the "Company," "we," "us," and "our" refer to REVA Medical, Inc. and its consolidated subsidiary.

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

Our product name Fantom® is a registered trademark in the United States, Australia and the European Union. We have pending applications to register the mark in Brazil, China and Japan. The names Fantom Encore, Tyrocore™ and MOTIV™ are also our trademarks. We have pending applications to register Tyrocore and MOTIV in the United States. 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 service marks is not intended to and does not imply a relationship with, or endorsement or sponsorship of, us by the owner thereof.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 7,094	$ 18,544
Investment securities	—	1,470
Accounts receivable, net	115	63
Inventory	831	627
Prepaid expenses and other current assets	685	438
Total current assets	8,725	21,142
Property and equipment, net	1,878	1,492
Other non-current assets	23	27
Total assets	$ 10,626	$ 22,661
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 1,010	$ 756
Accrued expenses and other current liabilities	1,544	1,737
Deferred revenue	383	158
Total current liabilities	2,937	2,651
Convertible notes	66,211	99,368
Accrued interest on convertible notes	13,465	8,779
Common stock warrant liability	470	4,176
Other long-term liabilities	813	500
Total liabilities	83,896	115,474
Commitments and contingencies (Note 9)		
Stockholders' deficit:		
Common stock — $0.0001 par value; 100,000,000 shares authorized; 41,479,877 and 41,245,820 shares issued and outstanding, respectively, at September 30, 2018 and December 31, 2017	4	4
Additional paid-in capital	292,651	289,342
Accumulated other comprehensive loss	(2)	(2)
Accumulated deficit	(365,923)	(382,157)
Total stockholders' deficit	(73,270)	(92,813)
Total liabilities and stockholders' deficit	$ 10,626	$ 22,661

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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue, net	$ 93	$ 17	$ 237	$ 17
Cost of revenue	141	7	318	7
Gross margin	(48)	10	(81)	10
Operating expenses:				
Research and development	1,729	3,092	6,669	10,139
Selling, general, and administrative	2,821	1,687	9,250	5,766
Total operating expenses	4,550	4,779	15,919	15,905
Loss from operations	(4,598)	(4,769)	(16,000)	(15,895)
Other income (expense):				
Interest income	19	34	64	36
Interest expense	(1,617)	(1,499)	(4,686)	(5,169)
Loss on issuance of convertible notes payable and warrants to purchase common stock	—	—	—	(520)
(Loss) gain on change in fair value of convertible notes and warrant liability	(2,853)	12,304	36,863	28,620
Other income (expense)	13	(17)	(7)	(98)
Total other income (expense)	(4,438)	10,822	32,234	22,869
Net income (loss)	$ (9,036)	$ 6,053	$ 16,234	$ 6,974
Net income (loss) per share - basic	$ (0.22)	$ 0.15	$ 0.39	$ 0.17
Weighted average shares outstanding - basic	41,456,349	41,197,348	41,326,441	42,001,898
Net loss per share - diluted	$ (0.22)	$ (0.08)	$ (0.31)	$ (0.33)
Weighted average shares outstanding - diluted	41,456,349	58,525,654	52,832,597	56,547,761
Comprehensive Income (Loss):				
Net income (loss)	$ (9,036)	$ 6,053	$ 16,234	$ 6,974
Other comprehensive income (loss)	0	0	0	0
Comprehensive income (loss)	$ (9,036)	$ 6,053	$ 16,234	$ 6,974

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

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

	Nine Months Ended September 30,	
	2018	**2017**
Cash flows from operating activities:		
Net income	$ 16,234	$ 6,974
Non-cash adjustments to reconcile net income to net cash used for operating activities:		
Depreciation and amortization	448	806
Loss on sale of property and equipment	—	45
Stock-based compensation	3,309	1,003
Provision for inventory reserve	60	—
Interest expense on convertible notes	4,686	5,169
Loss on issuance of convertible notes payable and warrants to purchase common stock	—	520
Gain on change in fair value of convertible notes and warrant liability	(36,863)	(28,620)
Deferred rent	14	—
Changes in operating assets and liabilities:		
Accounts receivable	(52)	(65)
Inventory	(264)	(370)
Prepaid expenses and other current assets	(297)	104
Other non-current assets	—	30
Accounts payable	251	(420)
Accrued expenses and other current liabilities	(207)	(338)
Deferred revenue	225	88
Other long-term liabilities	306	234
Net cash used for operating activities	(12,150)	(14,840)
Cash flows from investing activities:		
Purchases of property and equipment	(820)	(335)
Purchases of investment securities	—	(1,470)
Proceeds from sale of property and equipment	50	—
Maturities of investment securities	1,470	—
Net cash provided by/(used for) investing activities	700	(1,805)
Cash flows from financing activities:		
Proceeds from issuances of common stock	—	92
Repurchase of common stock	—	(12,493)
Proceeds from issuances of convertible notes payable and warrants, net	—	44,985
Net cash provided by financing activities	—	32,584
Net increase (decrease) in cash and cash equivalents	(11,450)	15,939
Cash and cash equivalents at beginning of period	18,544	6,674
Cash and cash equivalents at end of period	$ 7,094	$ 22,613
Supplemental non-cash information:		
Property and equipment in accounts payable at end of period	$ 14	$ 23
Adjustment to beginning accumulated deficit upon adoption of ASU 2016-09	$ —	$ 53
Leasehold improvement allowance - lessor paid improvements	$ 787	$ —

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

1. Background and Basis of Presentation

***Background*:** REVA Medical, Inc. 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.

We are a medical device company focused on the development and commercialization of polymer-based bioresorbable products for vascular applications. Coronary artery disease ("CAD") has been our first area of focus. Annually, more than 5.6 million metallic stents are used to treat CAD and worldwide sales are estimated at $4.0 billion[1]. Fantom, our sirolimus-eluting bioresorbable scaffold is marketed in select European and Middle Eastern countries as an alternative to metallic stents in the treatment of CAD. On November 1, 2018, we launched Fantom Encore, our third generation coronary scaffold, in these markets. Fantom Encore has the thinnest struts of any commercially available bioresorbable scaffold in Europe.

We expanded our product portfolio into the treatment of below-the-knee ("BTK") peripheral artery disease ("PAD") with receipt of CE Mark for the MOTIV sirolimus-eluting bioresorbable scaffold in July 2018. PAD in the lower extremities is a large and growing medical issue. According to the Center for Disease Control, more than 8.5 million Americans suffer from PAD. We estimate that the worldwide market for drug-eluting bioresorbable scaffolds in BTK PAD could reach $1.5 billion[2]. We plan to release MOTIV in select centers to assess product performance, inform product development activities and determine commercial strategy.

In December 2010, we completed an initial public offering (the "IPO") of our common stock in Australia and registered with the U.S. Securities and Exchange Commission ("SEC") and, consequently, became an SEC reporting company. Our common stock is traded in the form of CHESS Depositary Interests ("CDIs") on the Australian Securities Exchange ("ASX"); each share of our common stock is equivalent to ten CDIs. Our trading symbol is "RVA.AX." We may pursue a listing of our common stock on a U.S. stock exchange, at which time we would become dual-listed, if we maintain our listing on the ASX.

***Basis of Presentation*:** We have prepared the accompanying consolidated financial statements in accordance with U.S. generally accepted accounting principles ("GAAP") and SEC rules and regulations for reporting of interim financial information and, therefore, certain information and footnote disclosures normally included in annual financial statements are 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 for the year ended December 31, 2017 (the "2017 Form 10-K").

The accompanying consolidated financial statements include the accounts of REVA and its wholly owned subsidiary. All intercompany transactions and balances, if any, have been eliminated in consolidation. The accompanying consolidated financial statements are unaudited; the consolidated balance sheet as of December 31, 2017 was derived from our audited financial statements included in the 2017 Form 10-K. The accompanying consolidated 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 nine month periods ended September 30, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018 or for any other interim period.

***Use of Estimates*:** The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from our estimates.

1 JP Morgan Equity Research Interventional Cardiology Market Model Dec. 2016.
2 BTK: Nehler M, et al. Epidemiology of peripheral arterial disease and critical limb ischemia in an insured national population. JVS 2014; Population data from United Nations online database.

***Liquidity, Capital Resources and Ability to Continue as a Going Concern*:** The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We have incurred significant operating losses since inception and have relied on our ability to fund our operations primarily through equity and debt financings. At September 30, 2018, we had an accumulated deficit of $365.9 million and cash of $7.1 million. Our current planned operating activities call for expenditures over the next 12 months that exceed our current cash. We currently believe that our current cash will be sufficient to fund our operations only through the first quarter of 2019, assuming that we achieve certain minimum levels of sales of our Fantom and Fantom Encore scaffolds between now and the first quarter of 2019 and that we implement cost reductions in November 2018. If we do not achieve the minimum level of sales, or implement such cost reductions, we currently believe that our current cash will be sufficient to fund our operations only through the middle of the first quarter of 2019 unless we further reduce operating and capital expenditures or sell certain assets.

Although we initiated commercial sales of Fantom in the third quarter of 2017, we are still very early in the commercialization stage. We are focused on educating physicians regarding the unique features of Tyrocore, Fantom and Fantom Encore, continuing to publish results from our pivotal clinical trial (FANTOM II) and conducting and initiating additional clinical studies, including the commencement of our 1,500 patient post-market trial in May 2018, to build additional clinical evidence to support market adoption. 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. We may never become profitable and even if we attain profitability, we may not sustain profitability or positive cash flows on a recurring basis. Unless we are able to significantly accelerate our sales, we do not anticipate generating positive cash flows in 2018 or 2019, and therefore, will need to raise further capital to support our operations and our ongoing costs, and, if we determine to do so, to conduct additional clinical trials. We plan to address our capital needs by pursuing business development and strategic opportunities and pursuing equity or debt financing options. In addition, the convertible notes we issued in 2014 mature in November 2019 and each holder of the convertible notes we issued in 2017 has a redemption right that it may exercise in November 2019. If the holders of the 2017 convertible notes collectively, or individually, exercise their redemption right, or if the 2014 convertible notes are not converted into shares of our common stock or their maturity date is not extended, we most likely will not have the cash to repay the notes. As of September 30, 2018, the aggregate face value of all such convertible notes plus accrued interest was $85.6 million. See Note 7 *Convertible Notes and Warrants to Purchase Common Stock* for additional information. If we do not successfully execute strategic opportunities that provide us with capital or raise capital through equity or debt financings, we will need to consider significant additional delays, reductions or cessation of our research and development programs and of our commercialization efforts, and we could be forced into bankruptcy or liquidation. There can be no assurance that our efforts will result in the resolution of our liquidity needs. The factors discussed above raise substantial doubt about our ability to continue as a going concern. If we are not able to continue as a going concern, holders of our common stock and our convertible notes could lose their investment. The accompanying consolidated financial statements do not include any adjustments that might result should we be unable to continue as a going concern.

2. Summary of Significant Accounting Policies

***Cash Equivalents*:** We consider all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents. Cash equivalents are carried at cost, which we believe approximates fair value due to the short-term maturities of these investments.

***Inventory*:** We received CE Mark 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. Inventory is 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 cost of revenue. We record the cost of products to be used in research and development or clinical trials as research and development expense when inventory is requisitioned for such use.

***Convertible Notes*:** Convertible notes are analyzed at issue date to determine balance sheet classification, issue discounts or premiums, and embedded or derivative features. Embedded or derivative features are evaluated in accordance with accounting guidance for derivative securities and, if the 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 of the notes and their fair value as a gain or loss in our consolidated statement of operations. We remeasure the fair value at each reporting date and record a gain (upon a decrease in fair value) or loss (upon an increase in fair value), as a component of other income (expense) in our consolidated statement of operations. Inputs to the models 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, and estimated volatility based on the historical prices of our trading securities. For each periodic valuation, we also make assumptions as to our abilities to test and commercialize our product, to obtain future financings when and if needed, and to comply with the terms and conditions of any outstanding convertible notes.

Following an analysis of their embedded and derivative features, we elected to utilize fair value accounting for all issues of convertible notes as management believes the convertible notes will be converted into common stock, rather than repaid, and the fair value method of accounting provides 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 we may not satisfy at the time of exercise, and which, if not so satisfied, will result in a net settlement of warrants. Until the time warrants are exercised or expire, the fair value is assessed at each reporting date. Any change in value is recorded as a gain or loss as a component of other income (expense) in our consolidated statement of operations. Inputs to the valuation models are of the same nature as those used to value our convertible notes.

***Revenue*:** Revenue is generated primarily from the sale of our products, Fantom and Fantom Encore. We recognize revenue following a five-step model: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligations.

We began selling our products in July 2017. We sell our products primarily through direct sales to end-users, though in April 2018, we also began selling them through distributors. Our products are sold only in countries that accept CE Mark. Terms of sale are generally consistent for both end-users and distributors with payment terms generally net 30 to 90 days. No installation, calibration or testing of products is performed subsequent to shipment in order to render products operational. Revenue is categorized based on sales channel: direct sales and distributors.

We recognize revenue in an amount that reflects the amount we expect to be entitled to in exchange for our products when control of promised products is transferred to customers upon delivery to the customer's location. As shipping and handling is performed before control of the product transfers to the customer, it is accounted for as a fulfillment cost included in cost of sales and it is not considered a performance obligation.

Fantom and Fantom Encore have had limited shelf lives. We currently maintain a product exchange program under which we accept product exchanges for units that expire prior to utilization, which we consider a right of return. Due to a lack of historical experience and the risk of significant revenue reversal, we currently defer the recognition of revenue until we believe the right of return has expired based upon estimated usage. Actual amounts may ultimately differ from our estimates. If actual results vary and we adjust these estimates, there could be an effect on earnings in the period of adjustment. We recently received approval for 12-month shelf life for Fantom and Fantom Encore and we will begin phasing out our product exchange program in the fourth quarter of 2018.

Revenue recognized from contracts with customers during the three and nine months ended September 30, 2018 was $93,000 and $237,000, respectively. Total product shipments for these periods was $185,000 and $462,000, respectively. The difference between product shipments and revenue recognized represents our provision for returns

under our product exchange program and was recorded as deferred revenue. There were no open contracts as of September 30, 2018.

An analysis of the change in deferred revenue in our consolidated balance sheet is summarized as follows:

Balance as of December 31, 2017	$	158
Current provisions relating to sales in current year		462
Right of refund expired/sales in current year		(66)
Right of refund expired/sales in prior year		(171)
Balance as of September 30, 2018	$	383

Contract acquisition costs

Contract acquisition costs associated with product sales include sales bonuses and royalties. Because our product sales are performance obligations in contracts that are satisfied at a point in time, sales bonuses associated with and royalties based on our product sales are incurred at the point in time that is generally the same time the contract is executed. Sales bonuses are recorded as selling expense and royalties are recorded as cost of revenue in our consolidated statements of operations and comprehensive income (loss).

Accounts Receivable: Our accounts receivable arise from product sales and represent amounts due from hospitals. We provide reserves against trade receivables for estimated losses that may result from a customer's inability to pay. Amounts determined to be uncollectible are charged or written-off against the reserve. As of September 30, 2018 and December 31, 2017, our reserves against such trade receivables was $0.

Cost of Revenues: Cost of revenues consists of direct product costs, royalties and provisions for excess and/or obsolete products. Our product costs consist primarily of direct labor, overhead, raw materials and components. We incur royalties related to the technology that we license from a third party (Note 9). We assess our reserves for excess and/or obsolete products on a quarterly basis and any changes are recognized in cost of revenues.

***Research and Development Costs*:** Research and development costs are expensed as incurred. These costs include salaries, employee benefits, laboratory supplies, consulting services, manufacturing products and services, preclinical and clinical costs, technology license fees, laboratory equipment depreciation, facility costs, and certain indirect costs.

***Stock-Based Compensation*:** Stock-based compensation expense is recorded in connection with stock options, restricted stock awards, and restricted stock unit awards ("RSUs") to employees, directors, and consultants. We have granted stock options, restricted stock, and RSUs that vest based on the passage of time (time-based vesting awards) as well as stock options and RSUs that vest based on achievement of performance milestones (performance-based vesting awards).

For time-based vesting stock options granted to employees and directors, we determine compensation expense based on estimated grant date fair values utilizing the Black-Scholes option valuation model. The Black-Scholes model requires the input of assumptions, including, among others, volatility, the expected term, and the fair value of the underlying common stock on the date of grant. For time-based vesting restricted stock awards and RSUs, the grant date fair value is equal to the closing market price of our common stock on the date of award. We use the straight-line method to allocate compensation expense to reporting periods over each recipient's requisite service period, which is generally from one to four years. All stock-based compensation expense is recorded as either research and development or selling, general and administrative expense based on a recipient's work classification.

For performance-based vesting stock options and RSUs, we record compensation expense for only the performance milestones that are probable of being achieved, with such expense recorded on a straight-line basis over the expected vesting period. We reassess our performance-based estimates each reporting period and, if the estimated service period changes, we recognize all remaining compensation expense over the remaining service period and, if the probability of achievement changes to or from "probable," we recognize the cumulative effect. Whenever an award recipient terminates service prior to achievement of a performance milestone, the recipient's unvested awards are cancelled and the related compensation expense previously recorded is reversed.

For stock options granted to consultants, all of which are time-based vesting, we estimate fair values at the date of grant and at each subsequent reporting period and record compensation expense during the consultant's service period. We estimate the fair value utilizing the Black-Scholes option valuation model with the same approach to inputs and assumptions as we use to estimate the fair value of employee options, except we use the remaining term as the expected life of the option.

***Recently Adopted Accounting Pronouncements*:** We adopted Accounting Standards Update ("ASU") 2016-09, *Stock Compensation: Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"), 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 increase our accumulated deficit by 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 $1.8 million of forfeitures during the year ended December 31, 2017 related to a reduction in force that occurred in July 2017.

In May 2014, the Financial Accounting Standards Board (the "FASB") issued ASU 2014-09 *Revenue from Contracts with Customers,* which introduced Accounting Standards Codification 606*, Revenue from Contracts with Customers* ("ASC 606"), ASU 2014-09 which introduced ASC 606, an updated standard on revenue recognition. 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 ASC 606 represents 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. The standard permits two methods of adoption: retrospectively to each prior reporting period (full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (modified retrospective method). We adopted ASC 606 effective January 1, 2018 and utilized the modified retrospective method for adoption. The adoption of the new revenue standards did not change our revenue recognition as our revenues continued to be recognized when the customer takes control of our product. No adjustment to retained earnings was required upon adoption because we did not identify any accounting changes that impacted the amount of previously reported revenues.

In January 2016, the FASB issued ASU 2016-01, *"Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities"* ("ASU 2016-01"). The amendments in this update require an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments. In addition, the amendments in this update eliminate the requirement to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet for public entities. For public business entities, the amendments in ASU 2016-01 are effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Except for the early application guidance discussed in ASU 2016-01, early adoption of the amendments in this update is not permitted. We adopted ASU 2016-01 effective January 1, 2018. For the nine months ended September 30, 2018, there were no changes in the value of our convertible notes or common stock warrant liability related to credit risk. Therefore, this guidance had no impact on our consolidated financial statements for the three or nine months ended September 30, 2018. We will continue to evaluate this guidance quarterly.

***Recently Issued Accounting Pronouncements*:** In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, in July 2018 issued ASU 2018-10 *Codification Improvements to Topic 842, Leases* and in August 2018 issued ASU 2018-11 *Leases (Topic 842) – Targeted Improvements*. These updates require a lessee to recognize on the balance sheet a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term for all leases with terms greater than twelve months. For leases less than twelve months, an entity is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. If a lessee makes this election, it should recognize lease expense for such leases generally on a straight-line basis over the lease term. These updates are effective for fiscal years beginning with fiscal year 2019, including interim periods within those years, with early adoption permitted. Although we are currently evaluating the impact of this guidance on our consolidated financial statements, we expect that most of our operating lease commitments will be recognized as right-of-use assets and liabilities upon adoption of the new guidance and will significantly increase both the assets and liabilities recognized and reported on our balance sheet. The Company currently expects to complete its assessment of the full financial impact of the new lease accounting guidance during the next three to six months.

In August 2018, the FASB issued ASU 2018-15, *Intangibles - Goodwill and Other - Internal Use Software - Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, which amends the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract to align with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The update is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted. We are in the process of evaluating the impact on our consolidated financial statements and the timing of adoption of this update.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*. This new guidance removes certain disclosure requirements related to the fair value hierarchy, modifies existing disclosure requirements related to measurement uncertainty and adds new disclosure requirements. The new disclosure requirements include disclosing the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. This new guidance is effective for the Company beginning on January 1, 2020, with early adoption permitted. Certain disclosures in the new guidance will need to be applied on a retrospective basis and others on a prospective basis. While the Company is currently assessing the impact of the new guidance, it is not expected to have a material impact on our consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, *Compensation - Stock Compensation (Topic 718)*, which simplifies the accounting for non-employee share-based payment transactions. The new standard expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018 (including interim periods within that fiscal year), with early adoption permitted. We do not believe that the application of the new standard will have a material impact on our consolidated financial statements.

In July 2017, ASU 2017-11, *Earnings Per Share, Distinguishing Liabilities from Equity, Derivatives and Hedging*, was issued. ASU 2017-11 changes the accounting treatment and the earnings per share calculation for certain instruments with down round features. The amendments in this update should be applied using a cumulative-effect adjustment as of the beginning of the fiscal year of adoption or retrospective adjustment to each period presented. This update is effective for annual periods beginning after December 15, 2018, and interim periods within those periods. We are determining the impact the adoption will have on our consolidated financial statements and whether to early adopt the new guidance.

3. Investment Securities

Investment securities are marketable equity or debt securities. As of September 30, 2018, we had no investment securities. Prior to this quarter, all of our investment securities were “available-for-sale” securities and carried at fair value. Fair value for securities with short maturities and infrequent secondary market trades typically is determined by using a curve-based evaluation model that utilizes quoted prices for similar securities. The evaluation model takes into consideration the days to maturity, coupon rate and settlement date convention. Net unrealized gains or losses on these securities are included in accumulated other comprehensive loss, which is a separate component of stockholders’

deficit. Realized gains and realized losses are included in other income (expense) while amortization of premiums and accretion of discounts are included in interest income. Interest and dividends on available-for-sale securities are included in interest income. We periodically evaluate our investment securities for impairment. If we determine that a decline in fair value of any investment security is other than temporary, then the cost basis would be written down to fair value and the decline in value would be charged to other expense at that time.

Historically, when we had investment securities, they were under the custodianship of a major financial institution, consisted of certificates of deposit insured by the Federal Deposit Insurance Corporation, and were classified as current assets on our consolidated balance sheets because we considered them to be highly liquid and available for use, if needed, in current operations.

4. Inventory

The Company began capitalizing inventory upon obtaining CE Mark approval during the second quarter of 2017. Inventory at September 30, 2018 and December 31, 2017 was as follows (in thousands):

	September 30, 2018	December 31, 2017
Raw materials	$ 653	$ 255
Work in process	159	61
Finished goods	97	329
Excess and obsolete reserve	(78)	(18)
	$ 831	$ 627

5. Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets, which is generally three to five years. Leasehold improvements are amortized over the economic life of the asset or the lease term, whichever is shorter. Upon disposition or retirement of an asset, its cost and related accumulated depreciation are written off and any gain or loss is recognized in the consolidated statement of operations.

Property and equipment at September 30, 2018 and December 31, 2017 were as follows (in thousands):

	September 30, 2018	December 31, 2017
Furniture, office equipment, and software	$ 580	$ 601
Laboratory equipment	5,728	5,705
Leasehold improvements	3,208	2,422
Construction in progress	12	—
	9,528	8,728
Accumulated depreciation and amortization	(7,650)	(7,236)
	$ 1,878	$ 1,492

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities at September 30, 2018 and December 31, 2017 were as follows (in thousands):

	September 30, 2018	December 31, 2017
Accrued salaries and other employee costs	$ 985	$ 1,296
Accrued clinical and preclinical expenses	234	220
Accrued operating expenses	303	184
Accrued use taxes and other	22	37
	$ 1,544	$ 1,737

7. 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 $47.1 million. We used a portion of these proceeds to repurchase 1,732,260 shares of our common stock from one of the purchasers in the 2017 Notes at $7.212 per share, for a total repurchase price of $12.5 million, and incurred transaction costs of $2.1 million, resulting in net proceeds of $32.6 million. The 2017 Notes are convertible at any time at the holders' election; the conversion rate as of September 30, 2018 was $8.655 per share, which, if converted at that conversion rate, would result in issuing 5,441,941 shares of common stock upon conversion. The conversion rate may decrease depending on the price at which we issue securities in a future financings, 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. Upon at least 30 days' written notice, each holder of the 2017 Notes has a right to request that we redeem the notes (face value plus accrued interest) on November 4, 2019, if they have not been previously converted or redeemed.

On their issue dates, we evaluated the 2017 Notes and, following an analysis of the embedded and derivative features, irrevocably elected to account for the notes at fair value. Their fair value as of September 30, 2018 and December 31, 2017 was estimated to be $39.7 million and $38.4 million, respectively. Their fair value as of September 30, 2018 was $7.4 million below their $47.1 million face value.

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 $25.0 million. The 2014 Notes are convertible at any time at the holders' election into a total of 11,506,156 shares of common stock, which represents 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, the terms of the 2014 Notes that provided the holders with a one-time option to require us to redeem the notes on June 30, 2017 and that provided for an automatic conversion of the 2014 Notes were eliminated, and the 2014 Notes were modified to be subordinate to the 2017 Notes. Our stockholders approved the foregoing modifications to the terms of the 2014 Notes.

On their issue date, we evaluated the 2014 Notes and, following an analysis of the embedded and derivative features, we irrevocably elected to account for the notes at fair value. Following the modifications to the notes that were effective on June 1, 2017, we continued to account for the 2014 Notes under the fair value method. Their fair value as of September 30, 2018 and December 31, 2017 was estimated to be $26.5 million and $61.0 million, respectively. Their fair value as of September 30, 2018 was $1.5 million higher than the $25.0 million face value.

Changes in the fair value of the 2014 Notes and 2017 Notes (collectively, the "convertible notes") are recorded as gains or losses in the other income (expense) portion of our consolidated statement of operations. During the three months and nine months ended September 30, 2018, we accrued $1.6 million and $4.7 million in interest expense on the convertible notes, respectively. During the three and nine months ended September 30, 2017, we accrued $1.5 million and $3.1 million in interest expense on the convertible notes, respectively, as well as $2.1 million in transaction costs related to issuance of the 2017 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 to the purchasers of the 2017 Notes. The warrants are immediately exercisable and expire five years from issue date. The exercise price of each warrant is $5.00 per share, which may increase depending on the price at which we issue securities in future financings, if any, to a maximum of $7.212 per share. The fair value of the warrants on September 30, 2018 and December 31, 2017 was estimated to be $0.5 million and $4.2 million, respectively. Changes in the fair value of the warrants are recorded as gains or losses in the other income (expense) portion of our consolidated statement of operations.

The aggregate fair value of the 2017 Notes and warrants on their issue dates was estimated to be $47.6 million, which was $0.5 million higher than the $47.1 million issue price; we recorded this difference as a loss on issuance in the consolidated statement of operations.

As previously discussed, the 2014 Notes mature in November 2019 and each holder of the 2017 Notes has a redemption right that it may exercise in November 2019. As of September 30, 2018, the aggregate face value of all the convertible notes plus accrued interest was $85.6 million. If the holders of the 2017 Notes collectively, or

individually, exercise their redemption right, or if the 2014 Notes are not converted into shares of our common stock or their maturity date is not extended, we most likely will not have the cash to repay the notes (see Note 1 – *Liquidity, Capital Resources and Ability to Continue as a Going Concern*).

8. Fair Value Measurements

Our convertible notes and common stock warrant liability are carried at fair value. Our cash equivalents and investment securities, when we had them, were also carried at fair value. The fair value of financial assets and liabilities is measured under a framework that establishes "levels" which are defined as follows: (i) Level 1 fair value is determined from observable, quoted prices for identical assets or liabilities; (ii) Level 2 fair value is determined from quoted prices for similar items in active markets or quoted prices for identical or similar items in markets that are not active, and (iii) Level 3 fair value is determined using the entity's own assumptions about the inputs that market participants would use in pricing an asset or liability.

The fair values of our cash equivalents, investment securities, convertible notes and common stock warrant liability are summarized in the following tables (in thousands):

	September 30, 2018			
	Total Fair Value	Fair Value Determined Under: Level 1	Level 2	Level 3
Liabilities:				
Convertible notes	$ 66,211	$ —	$ —	$ 66,211
Common stock warrant liability	$ 470	$ —	$ —	$ 470

	December 31, 2017			
	Total Fair Value	Fair Value Determined Under: Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 4,388	$ 4,388	$ —	$ —
Investment securities	$ 1,470	$ —	$ 1,470	$ —
Liabilities:				
Convertible notes	$ 99,368	$ —	$ —	$ 99,368
Common stock warrant liability	$ 4,176	$ —	$ —	$ 4,176

2017 Notes and Warrants: The fair value of the 2017 Notes as of September 30, 2018 was determined using a Least Squares Monte Carlo simulation model; the fair value of our warrants to purchase common stock was determined using the same model with an embedded Black-Scholes valuation model to evaluate the early exercise 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, an estimate of the credit spread based on the implied spread as of the commencement date of the 2017 Notes, 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 convertible notes, and the probability of a change in control event.

The following is a summary of the assumptions used to value the 2017 Notes:

	September 30, 2018	December 31, 2017
Price per share of common stock	$ 2.13	$ 5.31
Risk-free interest rate	2.9%	2.1%
Expected volatility of common stock	45.0%	45.0%
Expected life (in years)	3.63	4.37
Bond yield of equivalent securities	26.5%	26.5%

A significant change in the market price per share, expected volatility, or bond yield of equivalent securities, in isolation, would result in significantly higher or lower fair value measurements. In combination, changes in these inputs

could result in a significantly higher or lower fair value measurement if the input changes were to be aligned, or could result in a minimally higher or lower fair value measurement if the input changes were of a compensating nature.

2014 Notes: The fair value of the 2014 Notes as of September 30, 2018 was determined using a Least Squares Monte Carlo simulation model. This model requires 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, estimates of the forward AUD/USD exchange rate, an estimate of the credit spread calculated by adding a subordination spread based on an analysis of comparable bonds to our implied spread from the valuation of the 2017 Notes and warrants, and an estimate of volatility based on the historical prices of our trading securities.

The primary assumptions used to value the 2014 Notes as of September 30, 2018 were: expected life of 1.1 years, AUD stock price of $2.94 (US equivalent of $2.13), expected volatility of common stock of 45%, forward exchange rate volatility of 10%, credit spread of 26.5% and risk-free interest rate of 2.0% to 2.5%.

The fair value of the 2014 Notes as of December 31, 2017 was determined using an "as-converted" method. This involved multiplying the number of shares into which the 2014 Notes convert (11,506,156 shares) by the Company's stock price as of December 31, 2017 (the last trading day of the quarter). We performed an evaluation as to whether the "as-converted" method would yield a materially different result from the Least Squares Monte Carlo simulation model used in previous quarters and determined that it would not. We use the "as-converted" method for calculating fair value when the 2014 Notes are significantly in the money as they no longer have complex features which would require a more complicated valuation model.

Reconciliation: A reconciliation of the convertible notes and common stock warrant liability that are measured and recorded at fair value on a recurring basis using significant unobservable inputs (Level 3) is as follows (in thousands):

	Convertible Notes	Common Stock Warrant Liability
Balance at December 31, 2016	$ 91,655	$ —
Net issuances	40,954	6,666
Total unrealized gains on change in fair value	(33,241)	(2,490)
Balance at December 31, 2017	$ 99,368	$ 4,176
Total unrealized gains on change in fair value	(33,157)	(3,706)
Balance at September 30, 2018	$ 66,211	$ 470

9. Commitments and Contingencies

We license certain patents and other intellectual property rights related to the composition and coating of our bioresorbable scaffolds and our other biomaterial products from Rutgers University. We entered into an amendment to this license in July 2018. Previously, the license required minimum annual royalties upon sales of products utilizing the licensed technology. The amendment eliminated all minimum annual royalties, which prior to the amendment could have eventually exceeded $2 million per year. Under the amendment, the current royalty rate is less than five percent. Upon a change in control of the Company, the royalty rate will reduce if and when certain revenue goals are attained. Additionally, under the terms of the amended license, future milestone payments, payments due upon a sublicense of our technology and extension fees applicable to other indications have all been eliminated. The accrual of $500,000 for extension fees as of June 30, 2018 was eliminated in the third quarter of 2018. The amended license increased the amount of payment we owe upon a change in control of the Company to $7.85 million plus 1% of the amount by which the purchase price to be paid at closing, net of debt repayment to creditors, exceeds $500 million, subject to a $10.0 million cap on the amount of the change in control payment.

We lease approximately 37,000 square feet of office and lab space for our corporate headquarters in San Diego, California. In October 2017, we amended this lease to extend the expiration date by 88 months from January 2018 to May 2025. Effective February 1, 2018, our monthly rent became $66,000 and it will increase every February by three percent. The amended lease also contains a leasehold improvement allowance of $787,000 and rent abatements of $274,000. We utilized the leasehold improvement allowance to upgrade our facilities and all construction was completed in the third quarter of 2018.

We record rent expense on a straight-line basis over the life of the lease; the difference between average rent expense and cash payments for rent is recorded as a deferred rent liability. As o f September 30, 2018, our deferred rent liability was $809,000, all of which, except for $14,000, was classified as a long-term liability.

10. Capital Stock

Our certificate of incorporation, as amended, authorizes us to issue 100,000,000 shares of common stock, par value $0.0001 per share, 25,000,000 shares of Class B common stock, par value $0.0001 per share and 5,000,000 shares of undesignated preferred stock, par value $0.0001 per share. As of September 30, 2018 and December 31, 2017, 41,479,877 and 41,245,820 shares of common stock were outstanding, respectively, and no shares of Class B common stock or preferred stock were outstanding.

Certain stockholders, as well as the holders of our convertible notes, if such convertible notes are converted into common stock, have the right to cause us to file a registration statement that would register the resale of such shares on their behalf and to include their shares in registration statements that we may file on behalf of other stockholders.

11. Stock-Based Compensation

***The Plan*:** Our 2010 Equity Incentive Plan, as amended (the "Plan"), provides for grants of incentive and non-qualified stock options to purchase our common stock at a price per share equal to the closing market price on the date of grant and of RSU and restricted stock awards, for which there is no consideration payable by the recipient. An RSU entitles the recipient to one share of our common stock upon vesting. All stock issuances under the Plan are made with new shares from our authorized but unissued common stock. The number of shares reserved for issuance under the Plan may be increased annually by up to three percent of our outstanding stock. On January 1, 2018, an additional 1,237,374 shares were added to the Plan. As of September 30, 2018, there were 3,574,479 shares reserved for issuance under the Plan.

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.

The term of awards granted under the Plan may not exceed ten years. Vesting periods of awards are determined by our board of directors.

Stock option activity under the Plan was as follows:

	Options Outstanding	Weighted Average Exercise Price
Balance at December 31, 2016	6,128,192	$ 6.65
Granted	897,100	6.80
Cancelled	(783,123)	7.42
Exercised	(121,678)	2.81
Balance at December 31, 2017	6,120,491	$ 6.65
Granted	901,469	2.87
Cancelled	(1,053,323)	6.87
Exercised	(83,425)	1.40
Balance at September 30, 2018	5,885,212	$ 6.10

A majority of the vesting periods of outstanding stock options is 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 prior to vesting, are subject to a lapsing right of repurchase by us at the exercise price until fully vested. As of September 30, 2018, no unvested options had been exercised and, therefore, no shares were subject to repurchase.

During March 2015, we granted 316,000 options that vest based on achievement of certain performance milestones. We estimated the vesting term for each performance milestone 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 weighted average remaining vesting term to be 12 months and 15 months as of December 31, 2017 and September 30, 2018, respectively. A total of 65 percent of these options had vested as of September 30, 2018. During the year ended December 31, 2017, 63,000 unvested options were cancelled. None of these options were cancelled during the nine months ended September 30, 2018.

During 2013, we awarded 87,500 shares of restricted stock; 25 percent of each award vested on each annual anniversary date of the award. As of September 30, 2018, all of these awards had vested and none had been cancelled.

RSU activity under the Plan was as follows:

	RSUs Outstanding	Performance Based	Time Based
Balance at December 31, 2016	754,000	706,200	47,800
Granted	397,300	162,500	234,800
Cancelled	(526,000)	(479,200)	(46,800)
Vested	(47,800)	—	(47,800)
Balance at December 31, 2017	577,500	389,500	188,000
Granted	228,000	—	228,000
Cancelled	—	—	—
Vested	(209,083)	(162,500)	(46,583)
Balance at September 30, 2018	596,417	227,000	369,417

We estimated the vesting term for each performance-based RSU on the award date, and on each reporting date thereafter, based on our internal timelines and operating projections. As of September 30, 2018, we estimated the remaining weighted average vesting term for performance-based RSUs to be 13.1 months for those granted during 2015. The performance-based RSUs granted in 2017 vested on June 30, 2018.

Time-based RSUs generally vest over one year for non-employee directors and ratably over three years for employees.

No tax benefits arising from stock-based compensation have been recognized in the consolidated statements of operations and comprehensive loss through September 30, 2018.

***Grants and Awards to Employees*:** We account for option grants, restricted stock awards, and RSUs 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. The fair value of restricted stock and RSUs is equal to the closing market price of our common stock on the date of award. The fair value of option grants was estimated on the date of grant using the following weighted-average assumptions:

	Nine Months Ended September 30,	
	2018	2017
Risk-free interest rate	2.8%	2.2%
Expected volatility of common stock	66.6%	65.4%
Expected life in years	6.25	6.21
Dividend yield	0%	0%

The assumed risk-free interest rate was based on the implied yield on a U.S. Treasury zero-coupon issue with a remaining term equal to the expected life of the option. The assumed volatility was calculated based on the historical market prices of a selected group of publicly traded companies considered our peers; we used peer group data because we had limited historical trading data for our common stock, but adjusted the 2016 volatility upward by approximately ten percent to allow us to move toward using the historical trading data for our common stock, which is more volatile than our peer group. In 2017, we began using the historical trading data for our common stock; our stock began trading on December 23, 2010, the date of our IPO, which provides approximately 7.75 years' history as of September 30, 2018. For options that have time-based vesting, the expected option life was calculated using the simplified method under the accounting standard for stock compensation and a ten-year option expiration; we use the simplified method because we do not yet have adequate history as a public company traded on a U.S. stock exchange to establish a

reasonable expected life. For options that have performance-based vesting, the expected life was calculated based on our internal timelines and operating projections. The expected dividend yield of zero reflects that we have not paid cash dividends since inception and do not intend to pay cash dividends in the foreseeable future.

The options granted to employees during the nine months ended September 30, 2018 had a weighted average grant date fair value of $1.80.

The aggregate intrinsic value of options exercised during the nine months ended September 30, 2018 and 2017, was $54,000 and $362,000, respectively.

Stock-based compensation arising from employee options and awards under the Plan was as follows for the periods indicated (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development expense	156	(548)	501	(202)
Selling, general, and administrative expense	732	(338)	2,808	1,205
	$ 888	$ (886)	$ 3,309	$ 1,003

As of September 30, 2018, we had approximately $6.3 million of unrecognized compensation costs related to unvested employee equity awards that are expected to be recognized over a weighted-average period of 1.7 years.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Diluted Net Loss:				
Net income (loss) used for basic net income (loss) per share	$ (9,036)	$ 6,053	$ 16,234	$ 6,974
Interest expense on convertible notes	—	1,499	1,754	3,054
Gain on change in fair value of convertible notes and warrants	—	(12,304)	(34,509)	(28,620)
	$ (9,036)	$ (4,752)	$ (16,521)	$ (18,592)
Weighted Average Shares Used to Compute Diluted Net Loss per Share:				
Shares used for basic net income (loss) per share	41,456,349	41,197,348	41,326,441	42,001,898
Common share equivalents	—	17,328,306	11,506,156	14,545,863
	41,456,349	58,525,654	52,832,597	56,547,761
Diluted Net Loss Per Share	$ (0.22)	$ (0.08)	$ (0.31)	$ (0.33)

Diluted net loss per share for prior year periods have been corrected to reflect dilutive convertible notes and warrants that were previously considered not dilutive. For the three months ended September 30, 2017, previously reported diluted net loss per share was $(0.04), which is $0.04 less than the corrected amount of $(0.08). For the nine months ended September 30, 2017, previously reported diluted net loss per share was $(0.30), which is $0.03 less than the corrected amount of $(0.33).

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Options to purchase common stock	6,920,126	6,478,522	6,708,709	6,410,542
Unvested restricted stock	—	—	—	6,914
Restricted stock units	602,433	667,432	664,143	789,189
Warrants to purchase common stock	2,119,500	—	2,119,500	—
Common share equivalents of convertible notes	16,948,097	—	5,441,941	—
	26,590,156	7,145,954	14,934,293	7,206,645

13. Income Taxes

We have reported tax net operating losses since our inception through September 30, 2018; 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.

On December 22, 2017, new tax reform legislation in the U.S., known as the Tax Cuts and Jobs Act of 2017 (the "Act") was signed into law. As a result of the Act, we recorded a provisional adjustment at December 31, 2017 as a result of the remeasurement of the deferred tax assets to the lower corporate tax rate, offset with an adjustment to the valuation allowance.

Staff Accounting Bulletin No. 118 ("SAB 118") was issued to address the application of US GAAP when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Act. In accordance with SAB 118, we provisionally determined that there is no deferred tax benefit or expense with respect to the remeasurement of certain deferred tax assets and liabilities due to the full valuation allowance against net deferred tax assets at December 31, 2017. We expect to finalize our provisional adjustment in the fourth quarter of 2018 and do not expect a significant adjustment from the provisional amounts recorded at December 31, 2017.

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 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, 2017 (the "2017 Form 10-K"). 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 the 2017 Form 10-K and as may be updated in our periodic reports thereafter. Investors are cautioned that many 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 focused on the development and commercialization of our proprietary polymer-based bioresorbable products for vascular applications. On April 3, 2017, our first product, Fantom, was approved for sale under CE Mark, which allows us to commercialize in Europe and other jurisdictions that recognize the CE Mark. Fantom is a sirolimus-eluting bioresorbable scaffold designed specifically for coronary vascular applications and made from our proprietary polymer, Tyrocore.

In February 2018, we received CE Mark for a third generation product, Fantom Encore, in the 2.5 millimeter diameter size, and in June 2018, we received approval for our 3.0 and 3.5 millimeter sizes. Fantom Encore, also made from Tyrocore, has thinner struts than Fantom (95, 105 and 115 microns for the 2.5, 3.0 and 3.5 diameter sizes, respectively, versus 125 microns for all diameters of Fantom) and comparable strength and x-ray visibility. Fantom Encore has the thinnest struts of any commercially available bioresorbable scaffold. Thin struts are associated with better healing and clinical outcomes. Physicians consider a reduction in strut thickness one of the most important improvements for bioresorbable scaffolds.

We began our commercial launch of Fantom late in the second quarter of 2017 and shipped our first product in the third quarter of 2017. We launched Fantom in a phased approach beginning first with a Vice President, Europe and a 5-person direct sales force targeting Germany, Switzerland and Austria. In July 2018, we hired a part-time consultant to support direct sales in Belgium, Luxembourg and the Netherlands. In August 2018, we hired a clinical specialist to augment our sales force. In addition to our direct sales initiatives, we are also expanding sales efforts into other countries with distributors. In certain countries, it is often favorable to use distributors due to longer customer payment terms and tender requirements. In April 2018, we announced our first commercial distribution partnership in Turkey, and in July 2018, we announced our second in Italy. We will continue to expand our sales efforts geographically as we move into additional phases of our launch.

Our initial commercial launch plan for Fantom assumed we were bringing to market a second generation product with better performance than the then worldwide leading first generation product from Abbott Laboratories, Absorb. After our launch, however, Abbott withdrew Absorb from the market and the negative publicity related to Absorb's adverse events has severely impacted the market for bioresorbable scaffolds. In August 2018, the European Society of Cardiology ("ESC") announced the publication of new ESC/European Association for Cardio-Thoracic Surgery guidelines on myocardial revascularization (the "2018 ESC Guidelines"). According to the 2018 ESC Guidelines, clinical practice guidelines summarize and evaluate all available evidence at the time of the writing process on a particular issue with the aim of assisting physicians in selecting the best management strategies for an individual patient with a given condition, taking into account the impact on outcome as well as the risk–benefit ratio of particular diagnostic or therapeutic means. The publication also states that the 2018 ESC Guidelines "do not override…the individual responsibility of health professionals to make appropriate and accurate decisions in consideration of each patient's health condition…Nor…exempt health professions from…consideration of updated recommendations or guidelines issued by the competent public health authorities…" The 2018 ESC Guidelines state that the safety and efficacy profile of Absorb (based on randomized trial data) has been compared with contemporary drug-eluting stents

in several trials, that the findings of these trials as well as meta-analyses "consistently indicate the inferior efficacy and safety of Absorb compared with contemporary drug-eluting stents during long-term follow-up", and that "bioresorbable scaffolds should not be used outside well-controlled clinical studies." The 2018 ESC Guidelines encourage consideration of prolonged dual antiplatelet therapy ("DAPT"). In the 2018 ESC Guidelines, the ESC recommends that bioresorbable scaffolds have a Class III designation, which means that there is "evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful."

As a result of the Absorb withdrawal in 2017 and the negative view on bioresorbable scaffolds contained in the 2018 ESC Guidelines, we believe bioresorbable scaffold competition within the percutaneous coronary intervention ("PCI") stent market continues to diminish. Companies with bioresorbable scaffolds made from the same polylactic acid polymer as Absorb have reduced their commercial efforts for such scaffolds. Although we have become a leader in the market, re-building the market for bioresorbable scaffolds is more challenging than selling into an existing, healthy market. We believe that the timeframe to achieve significant commercial progress in the PCI stent market has been extended, and we intend to shift some of our investment away from that market and into peripheral arterial disease ("PAD") and embolization therapies. The markets for both PAD and embolization therapies are growing quickly and with reasonable cash outlays, we believe we can make significant clinical progress in these markets over the next two years. We will focus our investment in the PCI stent market on building the clinical evidence needed to influence the ESC guidelines and maintaining our commercial presence.

We recently expanded our product portfolio into PAD. In July 2018, we received CE Mark for our sirolimus-eluting bioresorbable scaffold for below-the-knee ("BTK") PAD which we call MOTIV. Treatment options for BTK PAD patients are limited, and many patients progress to amputation. MOTIV has the potential to expand treatment options for millions of patients suffering from BTK PAD. We plan to release MOTIV in select centers to assess product performance, inform product development activities and determine commercial strategy.

We also continue to make progress on new vascular embolization therapies. Embolic beads are used to occlude arteries that feed tumors, such as liver cancer or uterine fibroids. We believe our technology is uniquely suited to embolic beads because to our knowledge, there are no x-ray visible, bioresorbable embolic products available in the world. We are currently evaluating a 510k pathway in the United States to take our technology forward for development and commercialization in the embolic bead market. Embolic beads are interesting because of established reimbursement, attractive margins, and a relatively straight-forward regulatory path relative to bioresorbable scaffolds.

As of September 30, 2018, we had a cash balance of $7.1 million, which, based on our current operating plans and projections, we believe will be sufficient to fund our operating and capital needs only through the first quarter of 2019. We have incurred substantial losses since our inception; as of September 30, 2018, we had accumulated a deficit of approximately $365.9 million. See "—Liquidity, Capital Resources and Ability to Continue as a Going Concern," below.

Key Components of our Results of Operations

The significant components contributing to our results of operations through September 30, 2018:

***Research and Development Expenses*:** Our research and development, or R&D expenses were 42 percent and 60 percent of total operating expenses for the nine months ended September 30, 2018 and the year ended December 31, 2017, respectively. These percentages have decreased from our historical averages of 70 to 75 percent of total operating expenses as we transitioned to commercialization of Fantom. As we focus our resources on the commercialization of Fantom and Fantom Encore and supporting post-market trial activities, we expect our R&D expenses to continue to decrease in 2018 as compared to 2017, however, we believe R&D expenses will still be a significant portion of our operating expenses as we continue to research, prove feasibility, and develop additional products.

See "—Critical Accounting Policies and Estimates," below for additional information regarding our R&D expenses.

***Selling, General, and Administrative Expenses*:** Our selling, general, and administrative, or SG&A, expenses consist primarily of salaries and benefits for our executive officers, administrative and marketing staff and sales force, corporate office and other overhead expenses, legal expenses including patent costs, audit and tax fees, sales and marketing expenses, investor relations and other public company costs, and travel expenses.

Our SG&A expenses were 58 percent and 40 percent of total operating expenses for the nine months ended September 30, 2018 and the year ended December 31, 2017, respectively. These percentages have increased from our historical averages of 25 to 30 percent of total operating expenses as we expanded our corporate infrastructure to support the commercialization of Fantom and Fantom Encore and the ongoing needs of being a public company.

***Other Income (Expense)*:** Following our issuance of convertible notes and warrants in 2014 and 2017, the components of other income and expense primarily comprise interest expense on the convertible notes and gains or losses related to the changes in fair values of the convertible notes and warrants. We account for the convertible notes and warrants (until they are exercised) at fair value, which means we remeasure their fair values at each reporting date and, if those fair values change, record a corresponding gain (upon a decrease in fair value) or loss (upon an increase in fair value) in our statement of operations.

Until the convertible notes are either repaid or converted into common stock, we expect our other income and expense to fluctuate, and possibly by a significant amount, by future gains or losses on the changes in their fair value. Also, we will continue to accrue and record interest expense on the convertible notes at the rate of 7.54 percent per annum and 8.0 percent per annum for the convertible notes we issued in 2014 and 2017, respectively, until they are either converted or repaid.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles. Their preparation requires us to make and 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 to be 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 our other accounting policies and, therefore, are the most critical to understanding and evaluating our consolidated financial condition and results of operations through September 30, 2018.

***Revenue*:** Revenue is generated primarily from the sale of our products, Fantom and Fantom Encore. We recognize revenue following a five-step model: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligations.

We began selling our products in July 2017. Our products are sold primarily through a direct sales force, though in April 2018, we also began selling them through distributors. Our products are sold only in countries that accept CE Mark. Terms of sale are generally consistent for both end-users and distributors with payment terms generally net 30 to 90 days. No installation, calibration or testing of products is performed subsequent to shipment in order to render products operational. Revenue from the sale of products is categorized based on sales channel: direct sales and distributors.

We recognize revenue in an amount that reflects the amount we expect to be entitled to in exchange for our products when control of promised products is transferred to customers upon delivery to the customer's location. As shipping and handling is performed before control of the product transfers to the customer, it is accounted for as a fulfillment cost included in cost of sales and it is not considered a performance obligation.

Fantom and Fantom Encore have had limited shelf lives. We currently maintain a product exchange program under which we accept product exchanges for units that expire prior to utilization, which we consider a right of return. Due to a lack of historical experience and the risk of significant revenue reversal, we currently defer the recognition of revenue until we believe the right of return has expired based upon estimated usage. Actual amounts may ultimately differ from our estimates. If actual results vary and we adjust these estimates, there could be an effect on earnings in the period of adjustment. We recently received approval for 12-month shelf life for Fantom and Fantom Encore and we will begin phasing out our product exchange program in the fourth quarter of 2018.

Revenue recognized from contracts with customers during the nine months ended September 30, 2018 was $237,000. Total product shipments for this period was $462,000. The difference between product shipments and revenue recognized represents our provision for product returns under our product exchange program and was recorded as deferred revenue. There were no open contracts as of September 30, 2018.

An analysis of the change in deferred revenue in our consolidated balance sheet is summarized as follows:

Balance as of December 31, 2017	$	158
Current provisions relating to sales in current year		462
Right of refund expired/sales in current year		(66)
Right of refund expired/sales in prior year		(171)
Balance as of September 30, 2018	$	383

Contract Acquisition Costs: Contract acquisition costs associated with product sales include sales bonuses and royalties. Because our product sales are performance obligations in contracts that are satisfied at the point in time, sales bonuses associated with and royalties based on product sales are incurred at that point in time that is generally the same time the contract is executed. Sales bonuses are recorded as selling expense and royalties are recorded as cost of revenue in our consolidated statements of operations and comprehensive income.

Accounts Receivable: Our accounts receivable arise from product sales and represent amounts due from hospitals. We provide reserves against trade receivables for estimated losses that may result from a customer's inability to pay. Amounts determined to be uncollectible are charged or written-off against the reserve. As of September 30, 2018 and December 31, 2017, our allowance for reserves against such trade receivables was $0.

Cost of Revenues: Cost of revenues consists of direct product costs, royalties and provisions for excess and/or obsolete products. Our product costs consist primarily of direct labor, overhead, raw materials and components. We incur royalties related to technology that we license from a third party. We assess our reserves for excess and/or obsolete products on a quarterly basis and any changes are recognized in cost of revenues.

***Research and Development Expenses*:** Our research and development, or R&D, 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 other development activities. Our external costs primarily consist of contract research, engineering consulting, polymer consulting and certain production costs, polymer lasing costs, catheter system and anti-restenotic drug purchases, preclinical and clinical trial expenses, regulatory consulting, and license fees paid for the technology underlying our polymer materials. All R&D costs are expensed when incurred.

Stock-Based Compensation: Stock-based compensation expense is recorded in connection with stock options, restricted stock awards, and restricted stock unit awards, or RSUs, to employees, directors, and consultants. We have granted stock options, restricted stock, and RSUs that vest based on the passage of time (time-based vesting awards) as well as stock options and RSUs that vest based on achievement of performance milestones (performance-based vesting awards).

For time-based vesting stock options granted to employees and directors, we determine compensation expense based on estimated grant date fair values utilizing the Black-Scholes option valuation model. The Black-Scholes model requires the input of assumptions, including volatility, the expected term, and the fair value of the underlying common stock on the date of grant, among other inputs. For time-based vesting restricted stock awards and RSUs, the grant date fair value is equal to the closing market price of our common stock on the date of award. We use the straight-line method to allocate compensation expense to reporting periods over each recipient's requisite service period, which is generally from one to four years. All stock-based compensation expense is recorded as either research and development or selling, general and administrative expense based on a recipient's work classification.

For performance-based vesting stock options and RSUs, we record compensation expense for only the performance milestones that are probable of being achieved, with such expense recorded on a straight-line basis over the expected vesting period. We reassess our performance-based estimates each reporting period and, if the estimated service period changes, we recognize all remaining compensation expense over the remaining service period and, if the probability of achievement changes to or from "probable," we recognize the cumulative effect. Whenever an award recipient terminates service prior to achievement of a performance milestone, the recipient's unvested awards are cancelled and the related compensation expense previously recorded is reversed.

For stock options granted to consultants, all of which are time-based vesting, we estimate fair values at the date of grant and at each subsequent reporting period and record compensation expense during the consultant's service period. We estimate the fair value utilizing the Black-Scholes option valuation model with the same approach to inputs and assumptions as we use to estimate the fair value of employee options, except we use the remaining term as the expected life of the option.

***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. Inventory is stated at the lower of cost or net realizable value based on the first-in, first-out cost method. Our policy is to record an estimated allowance against inventory for unsalable, obsolete, or impaired inventory, with a corresponding increase to cost of revenue. We record the cost of products to be used in research and development or clinical trials as research and development expense when they are identified as such.

***Convertible Notes*:** Convertible notes are analyzed at issue date to determine balance sheet classification, issue discounts or premiums, and embedded or derivative features. Embedded or derivative features are evaluated in accordance with accounting guidance for derivative securities and, if the 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 of the notes and their fair value as a gain or loss in our consolidated statement of operations. We remeasure the fair value at each reporting date and record a gain (upon a decrease in fair value) or loss (upon an increase in fair value), as a component of other income (expense) in our consolidated statement of operations. Inputs to the models 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, and estimated volatility based on the historical prices of our trading securities. For each periodic valuation, we also make assumptions as to our abilities to test and commercialize our product, to obtain future financings when and if needed, and to comply with the terms and conditions of any outstanding convertible notes.

Following an analysis of their embedded and derivative features, we elected to utilize fair value accounting for all issues of convertible notes as management believes the convertible notes will be converted into common stock, rather than repaid, and the fair value method of accounting provides 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 we may not satisfy at the time of exercise, and which, if not so satisfied, will result in a net settlement of warrants. Until the time warrants are exercised or expire, the fair value is assessed at each reporting date. Any change in value is recorded as a gain or loss component of other income (expense) in our consolidated statement of operations. Inputs to the valuation models are of the same nature as those used to value our convertible notes.

Results of Operations

During the first nine months of 2018, our operating activities focused on expanding commercial operations of Fantom and preparing for our post-market registry trial which commenced in the second quarter of 2018. Additionally, we completed our CE Mark submission for our bioresorbable scaffold for BTK PAD, MOTIV, and we received approval for it in July 2018.

During the first nine months 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 September 30, 2018 and 2017

Our operating results were as follows for the periods indicated (dollars in thousands):

	Three Months Ended September 30,		Change	
	2018	2017	$	%
Revenue, net	$ 93	$ 17	$ 76	447%
Gross margin	$ (48)	$ 10	$ (58)	-580%
Research and development expense	$ 1,729	$ 3,092	$ (1,363)	-44%
Selling, general, and administrative expense	$ 2,821	$ 1,687	$ 1,134	67%
Interest expense	$ 1,617	$ 1,499	$ 118	8%
(Loss) gain on change in fair values of convertible notes and warrant liability	$ (2,853)	$ 12,304	$ (15,157)	-123%

We recognized $93,000 of net revenue during the three months ended September 30, 2018 compared to $17,000 of net revenue for the same period in 2017. We began selling our products in the third quarter of 2017. Net revenue during the three months ended September 30, 2018 was consistent with net revenue during the three months ended June 30, 2018. Total product shipments for the three months ended September 30, 2018 was $185,000, a 24 percent increase as compared to total product shipments for the three months ended June 30, 2018. Additionally, we saw an 18 percent increase in the total number of customers as of September 30, 2018 versus June 30, 2018.

Gross margin for the three months ended September 30, 2018 was negative $48,000. Cost of goods sold for the three months ended September 30, 2018 included an additional charge of $45,000 for potential excess and obsolete inventory, a write off of $8,000 in raw materials and $36,000 of standard cost variances, all primarily related to our transition from Fantom to Fantom Encore. Because we launched our Fantom Encore product on November 1, 2018, we do not anticipate selling many or producing more of our Fantom product. Excluding these charges, gross margin would have been $41,000 or 44 percent of net revenue. We anticipate that our gross margin will continue to be lower than industry standards until we reach higher sales and manufacturing volumes.

R&D expense decreased by $1.4 million, or 44 percent, to $1.7 million for the three months ended September 30, 2018 compared to $3.1 million for the same period in 2017. The decrease was due primarily to a $0.8 million decrease in licensing fees and $0.3 million decrease in materials. The $0.8 million decrease in licensing fees was due to the elimination of a $0.5 million accrual for extension fees as a result of the amendment to the Rutgers license that was signed in July 2018 and the absence of fees that were paid in 2017 when Fantom received CE Mark approval. The $0.3 million decrease in materials was related to decreased R&D activity as we have focused on commercialization in 2018.

SG&A expense increased by $1.1 million, or 67 percent, to $2.8 million for the three months ended September 30, 2018 compared to $1.7 million for the same period in 2017. The increase was due primarily to increases in personnel costs of $1.1 million. These increases were related to the expansion of our sales force and corporate infrastructure to support the commercialization of Fantom and the ongoing needs of being a public company.

Interest expense increased by $0.1 million, or 8 percent to $1.6 million for the three months ended September 30, 2018 compared to $1.5 million for the same period in 2017. The increase in interest expense was related to the compounding of interest for the 2014 and 2017 convertible notes.

We recorded a loss of $2.9 million on the change in fair value of convertible notes and warrant liability for the three months ended September 30, 2018, as compared to a gain of $12.3 million for the same period in 2017. The fair value of convertible notes is impacted by the principal amount of convertible notes outstanding for each period, as well as other factors that drive fair value, including management assumptions related to the timing and amounts of potential financing transactions, the remaining term of the convertible notes and the market trading price of our stock.

Comparison of the Nine Months Ended September 30, 2018 and 2017

Our operating results were as follows for the periods indicated (dollars in thousands):

	Nine Months Ended September 30,		Change	
	2018	2017	$	%
Revenue, net	$ 237	$ 17	$ 220	1294%
Gross margin	$ (81)	$ 10	$ (91)	-910%
Research and development expense	$ 6,669	$ 10,139	$ (3,470)	-34%
Selling, general, and administrative expense	$ 9,250	$ 5,766	$ 3,484	60%
Interest expense	$ 4,686	$ 5,169	$ (483)	-9%
Loss on issuance of convertible notes payable and warrants	$ —	$ 520	$ (520)	-100%
Gain on change in fair values of convertible notes and warrant liability	$ 36,863	$ 28,620	$ 8,243	29%

We recognized $237,000 of net revenue during the nine months ended September 30, 2018 compared to $17,000 of net revenue for the same period in 2017. The increase is related primarily to nine months of selling activities in 2018 versus three months of selling activities in 2017, as well as growth in our customer base. Total product shipments for the nine months ended September 30, 2018 was $462,000 compared to $105,000 for the nine months ended September 30, 2017.

Gross margin for the nine months ended September 30, 2018 was negative $81,000. Cost of goods sold for the nine months ended September 30, 2018 included an additional charge of $111,000 for potential excess and obsolete inventory, a write off of $15,000 in raw materials and $58,000 in standard cost variances, all primarily related to our transition from Fantom to Fantom Encore. Because we launched our Fantom Encore product on November 1, 2018, we do not anticipate selling many or producing more of our Fantom product. Excluding these charges, gross margin would have been $103,000 or 43 percent of net revenue. We anticipate that our gross margin will continue to be lower than industry standards until we reach higher sales and manufacturing volumes.

R&D expense decreased by $3.4 million, or 34 percent, to $6.7 million for the nine months ended September 30, 2018 compared to $10.1 million for the same period in 2017. The decrease was due primarily to a $1.3 million decrease in licensing fees, a $0.8 million decrease in personnel costs, a $0.5 million decrease in R&D materials, a $0.5 million decrease related to overhead allocations and a $0.4 million decrease in depreciation. The decrease in licensing fees was due to the elimination of a $0.5 million accrual for extension fees as a result of the amendment to the Rutgers license that was signed in July 2018 and the absence of fees that were paid in 2017 when Fantom received CE Mark approval. The decrease in personnel costs was primarily related to the reduction in force that occurred in the third quarter of 2017. The decrease in R&D materials, overhead allocations and depreciation were each related to reduced activities in those areas as we transitioned from R&D to commercialization.

SG&A expense increased by $3.5 million, or 60 percent, to $9.3 million for the nine months ended September 30, 2018 compared to $5.8 million for the same period in 2017. The increase was due primarily to increases in personnel costs of $2.7 million, legal and consulting fees of $0.4 million, travel costs of $0.2 million and facility costs of $0.2 million. These increases were related to the expansion of our sales force and corporate infrastructure to support the commercialization of Fantom and the ongoing needs of being a public company.

Interest expense decreased by $0.5 million, or 9 percent to $4.7 million for the nine months ended September 30, 2018 compared to $5.2 million for the same period in 2017. The decrease was due primarily to the absence of $2.1 million in transaction costs related to the 2017 convertible notes issued in the second quarter of 2017, offset by an increase in interest expense of $1.6 million related to the convertible notes we issued in May and June 2017. During the 2018 period, we had a full nine months of interest related to such notes, as compared to a partial nine-month period of interest during the 2017 period.

We recorded a gain of $36.9 million on the change in fair value of convertible notes and warrant liability for the nine months ended September 30, 2018, as compared to a gain of $28.6 million for the same period in 2017. The fair value of convertible notes is impacted by the principal amount of convertible notes outstanding for each period, as well as other factors that drive fair value, including management assumptions related to the timing and amounts of potential financing transactions, the remaining term of the convertible notes and the market trading price of our stock.

Liquidity, Capital Resources and Ability to Continue as a Going Concern

Sources of Liquidity

As of September 30, 2018, we had a cash balance of $7.1 million, which we believe is sufficient to fund our operating and capital needs only through the first quarter of 2019. See "—Operating Capital and Capital Expenditure Requirements," below.

Cash Flows

Our cash flows for the periods indicated were as follows (in thousands):

	Nine Months Ended September 30,	
	2018	2017
Net cash used for operating activities	$ (12,150)	$ (14,840)
Net cash provided by/(used for) investing activities	700	(1,805)
Net cash provided by financing activities	—	32,584
Net increase (decrease) in cash and cash equivalents	$ (11,450)	$ 15,939

Net cash flow used for operating activities

Net cash used for operating activities of $12.2 million for the nine months ended September 30, 2018 primarily reflects the loss from operations of $16.0 million, offset by non-cash expenses of $3.3 million for stock-based compensation and $0.4 million of depreciation and amortization. The interest on convertible notes, loss on issuance of convertible notes and warrants to purchase common stock, and the gain on change in fair value of convertible notes and warrant liability are non-cash items that had no effect on cash flows.

Net cash used for operating activities of $14.8 million for the nine months ended September 30, 2017 primarily reflects the loss from operations of $15.9 million and changes in assets and liabilities of $0.7 million, offset by non-cash expenses of $1.0 million for stock-based compensation and $0.8 million of depreciation and amortization. The interest on convertible notes and the loss on change in fair value of convertible notes and warrant liability are non-cash items that had no effect on cash flows.

Net cash flow provided by (used for) investing activities

Cash provided by investing activities of $0.7 million for the nine months ended September 30, 2018 was associated primarily with purchases of property and equipment of $0.8 million, offset by maturities of investment securities of $1.5 million and proceeds from the sale of equipment of $50,000. Cash used for investing activities of $1.8 million for the nine months ended September 30, 2017 was for purchases of $1.5 million of investment securities and $0.3 million of lab and other equipment.

Net cash flow provided by financing activities

There was no cash provided by (used in) financing activities for the nine months ended September 30, 2018.

Cash provided by financing activities during the nine months ended September 30, 2017 consisted of $47.1 million in proceeds from the issuance of convertible notes, offset by payments of $2.0 million for transaction costs and $12.5 million to repurchase 1,732,260 shares of our common stock.

Operating Capital and Capital Expenditure Requirements

On April 3, 2017, our first product, Fantom, was approved for sale under a CE Mark, which allows us to commercialize in Europe and other jurisdictions that recognize the CE Mark. We initiated commercial sales in July 2017. Fantom is our first commercial product; prior to 2017, we had not commercialized any products or generated any revenue since our inception in June 1998. Although we initiated commercial sales of Fantom in the third quarter of 2017, we are still very early in the commercialization stage. Our initial commercial launch plan for Fantom assumed we were bringing to market a second generation product with better performance than the then worldwide leading first generation product from Abbott Laboratories, Absorb. After our launch, however, Abbott withdrew Absorb from the market and the negative publicity related to Absorb's adverse events have severely impacted the market for

bioresorbable scaffolds. In August 2018, the European Society of Cardiology ("ESC") announced the publication of new ESC/European Association for Cardio-Thoracic Surgery guidelines on myocardial revascularization (the "2018 ESC Guidelines"). According to the 2018 ESC Guidelines, clinical practice guidelines summarize and evaluate all available evidence at the time of the writing process on a particular issue with the aim of assisting physicians in selecting the best management strategies for an individual patient with a given condition, taking into account the impact on outcome as well as the risk–benefit ratio of particular diagnostic or therapeutic means. The publication also states that the 2018 ESC Guidelines "do not override…the individual responsibility of health professionals to make appropriate and accurate decisions in consideration of each patient's health condition…Nor…exempt health professions from…consideration of updated recommendations or guidelines issued by the competent public health authorities…" The 2018 ESC Guidelines state that the safety and efficacy profile of Absorb (based on randomized trial data) has been compared with contemporary drug-eluting stents in several trials, that the findings of these trials as well as meta-analyses "consistently indicate the inferior efficacy and safety of Absorb compared with contemporary drug-eluting stents during long-term follow-up", and that "bioresorbable scaffolds should not be used outside well-controlled clinical studies." The 2018 ESC Guidelines encourage consideration of prolonged DAPT therapy. In the 2018 ESC Guidelines, the ESC recommends that bioresorbable scaffolds have a Class III designation, which means that there is "evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful."

As a result of the Absorb withdrawal in 2017 and the negative view on bioresorbable scaffolds contained in the 2018 ESC Guidelines, we believe bioresorbable scaffold competition within the percutaneous coronary intervention ("PCI") stent market continues to diminish. Companies with bioresorbable scaffolds made from the same polylactic acid polymer as Absorb have reduced their commercial efforts for such scaffolds. Although we have become a leader in the market, re-building the market for bioresorbable scaffolds is more challenging than selling into an existing, healthy market. We believe that the timeframe to achieve significant commercial progress in the PCI stent market has been extended, and we intend to shift some of our investment away from that market and into peripheral arterial disease ("PAD") and embolization therapies. The markets for both PAD and embolization therapies are growing quickly and with reasonable cash outlays, we believe we can make significant clinical progress in these markets over the next two years. We will focus our investment in the PCI stent market on building the clinical evidence needed to influence the ESC guidelines and maintaining our commercial presence.

We have incurred substantial losses since our inception and anticipate that our losses will continue in the near term. As of September 30, 2018, we had accumulated a deficit of $365.9 million. 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. We may never become profitable and even if we attain profitability, we may not sustain profitability or positive cash flows on a recurring basis. Until we generate positive cash flows from operations on a sustainable basis, we plan to continue to fund our operating and capital needs from our current cash resources and proceeds from future capital raising efforts. As of September 30, 2018, we had a cash balance of $7.1 million. Our current planned operating activities call for expenditures over the next 12 months that exceed our current cash balance, which we currently believe will be sufficient to fund our operations only through the first quarter of 2019, assuming that we achieve certain minimum levels of sales of our Fantom and Fantom Encore scaffolds between now and the first quarter of 2019 and that we implement cost reductions in November 2018. If we do not achieve the minimum level of sales, we currently believe that our current cash will be sufficient to fund our operations only through the middle of the first quarter of 2019 unless we further reduce operating and capital expenditures or sell certain assets.

Until we are able to significantly accelerate our revenues, we do not anticipate generating positive cash flows in 2018 or 2019, and therefore, will need to raise significant additional capital to support our operations and our ongoing costs, and, if we determine to do so, to conduct additional clinical trials. We plan to address our capital needs by pursuing business development and strategic opportunities and by pursuing equity or debt financing options.

In addition, the convertible notes we issued in 2014 mature in November 2019 and the convertible notes we issued in May and June 2017 mature in May and June 2022, respectively. No payments of interest or principal are required on any of the notes until maturity. However, each holder of the notes we issued in 2017 has a right to request that we redeem the notes (face value plus accrued interest) on November 4, 2019. Accordingly, we may be required to repay an aggregate of $72.1 million plus accrued interest in November 2019. As of September 30, 2018, the aggregate principal amount of all convertible notes plus accrued interest was $85.6 million. If the holders of the 2017 convertible notes collectively, or individually, exercise their redemption right, or if the 2014 convertible notes are not converted into shares of our common stock or their maturity date is not extended, we most likely will not have the cash to repay the notes, and the noteholders could commence legal action against us and/or we may need to reduce operating

activities and personnel, sell assets, such as our intellectual property, and/or declare bankruptcy, and we may not be able to remain in business. If the value of our common stock increases, management believes that it is more likely that all the convertible notes will be converted into shares of our common stock, rather than redeemed.

The warrants we issued in connection with the convertible notes we issued in May and June 2017 are exercisable, have a five-year life, and their exercise price may be paid only in cash. Management does not view the warrants as a source of funding because exercise is at the holders' option.

There can be no assurance that we will be successful in accelerating our revenue or raising additional capital. Additionally, we may be limited by the terms of our convertible notes as to the type, quantity, timing, or other aspects of any financing, unless the noteholders agree to modify or waive certain terms of the convertible notes. If we do not significantly increase revenue or raise additional capital when needed or on acceptable terms, we would need to consider a delay, reduction or cessation of our research and development programs and our commercialization efforts. There can be no assurance that our efforts will resolve our liquidity needs. The factors discussed above raise substantial doubt about our ability to continue as a going concern. If we are not able to continue as a going concern, holders of our common stock could lose most or all of their investment. The accompanying consolidated financial statements do not include any adjustments that might result should we be unable to continue as a going concern.

Because of the numerous risks and uncertainties associated with developing, testing, and commercializing medical devices such as our bioresorbable scaffolds, our estimates as to the amounts and timing of capital outlays and operating expenditures are subject to change. Our ongoing funding requirements will depend on many factors, including, but not limited to:

- the success of our sales and marketing initiatives;
- whether the holders of the 2017 convertible notes exercise their redemption right;
- the success, or failure, of our competitors who marketed bioresorbable scaffolds before us, including their ability to identify and remedy the causes of very late stent thrombosis reported from their products;
- our ability to provide additional clinical data regarding Fantom's potential long-term benefits;
- the time and effort it will take to successfully complete our clinical trials and analyze patient data;
- the requirements, cost, and timing of regulatory approvals;
- the time and effort required to refine and scale-up manufacturing processes and the cost of establishing commercial supplies of our products;
- the scope of research and development for any of our other product opportunities and the terms and timing of any collaborative, licensing, or other arrangements that we may establish;
- the cost of filing and prosecuting patentable technologies and defending and enforcing our patent and other intellectual property rights and the effect of competing technological and market developments; and
- our ability to influence the ESC guidelines and the timing of any updates to such guidelines.

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 San Diego facility has the capacity to produce the quantities of Fantom Encore that will be needed for our expected commercial sales for the foreseeable future and therefore, we do not have any plans for facility expansion at this time.

Contractual Obligations, Commitments, and Contingencies

As of September 30, 2018, there were no material changes outside of the ordinary course of business in our outstanding contractual obligations from those disclosed within "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the 2017 Form 10-K.

In July 2018, we entered into an amendment to our exclusive license agreement with Rutgers related to the composition and coating of our bioresorbable scaffolds and our other biomaterial products. The amendment eliminated all minimum annual royalties, which prior to the amendment could have eventually exceeded $2 million per year. Under the amendment, the current royalty rate is less than five percent. Upon a change in control of the Company, the royalty rate will reduce if and when certain revenue goals are attained. Additionally, under the terms

of the amended license, future milestone payments, payments due upon a sublicense of our technology and extension fees applicable to other indications have all been eliminated. The accrual of $500,000 for extension fees as of June 30, 2018 was eliminated in the third quarter of 2018. The amended license increased the amount of the payment we owe upon a change in control of the Company to $7.85 million plus 1% of the amount by which the purchase price to be paid at closing, net of debt repayment to creditors, exceeds $500 million, subject to a $10.0 million cap on the amount of the change in control payment.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

There have been no material changes to our market risk during the nine months ended September 30, 2018. For a discussion of our exposure to market risk, refer to our market risk disclosures set forth in Part II, Item 7A, "Quantitative and Qualitative Disclosure about Market Risk" of the 2017 Form 10-K.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Based on an evaluation under the supervision and with the participation of our management, our Chief Executive Officer and Chief Financial Officer, have concluded that our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act were effective as of September 30, 2018 to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms and (ii) accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarterly period covered by this report, which were identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We may from time to time become subject to various claims and legal actions during the ordinary course of our business. As of the date of filing this report, there is no material pending legal proceedings to which we are a party or to which any of our property is subject.

Item 1A. Risk Factors

Our business, financial condition, results of operations and future growth prospects are subject to various risks, including those described in Item 1A "Risk Factors" of the 2017 Form 10-K, which we strongly encourage you to review. In addition to the risks described therein, we revised the following risk factors:

Our available cash is limited and we will need additional funding to pursue our long-term business strategy and there can be no assurance that we will be able to obtain such funding on a timely basis or on commercially reasonable terms, if at all. If we are unable to raise additional funds, there will be substantial doubt in our ability to continue as a going concern.

As of September 30, 2018, we had cash of approximately $7.1 million, which we believe will be sufficient to fund our operating and capital needs only through the first quarter of 2019, assuming that we achieve certain minimum levels of sales of our Fantom and Fantom Encore scaffolds between now and the first quarter of 2019 and that we

implement cost reductions in November 2018. We have incurred recurring losses from operations and cash outflows from operating activities that raise substantial doubt about our ability to continue as a going concern. Although we initiated commercial sales of Fantom in the third quarter of 2017, we are still very early in the commercialization stage. 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. We may never become profitable and even if we attain profitability, we may not sustain profitability or positive cash flows on a recurring basis. Unless we are able to significantly accelerate our sales, we do not anticipate generating positive cash flows in 2018 or 2019, and therefore, will need to raise further capital to support our operations and our ongoing costs, and, if we determine to do so, to conduct additional clinical trials. If we do not achieve the minimum level of sales, we currently believe that our current cash will be sufficient to fund our operations only through the middle of the first quarter of 2019.

In addition, as of September 30, 2018, we had current liabilities and long-term liabilities of approximately $2.9 million and $81.0 million, respectively, including convertible notes with an aggregate face value plus accrued interest of $85.6 million that mature or that we may be required to redeem in November 2019. See "*We have a significant amount of indebtedness that we may not be able to repay in accordance with its terms* ," below.

To pursue our long-term business strategy, we will need additional capital. We plan to address our capital needs by pursuing business development and strategic opportunities and by pursuing equity or debt financing options. However, we may not be able to successfully execute our plan or obtain sufficient additional funding through any of those alternatives on a timely basis or on satisfactory terms, if at all. If we do not successfully execute strategic opportunities that provide us with capital or raise capital through equity or debt financings, we will need to consider significant additional delays, reductions or cessation of our research and development programs and of our commercialization efforts, and we could be forced into bankruptcy or liquidation. There can be no assurance that our efforts will result in the resolution of our liquidity needs. The factors discussed above raise substantial doubt about our ability to continue as a going concern. If we are not able to continue as a going concern, holders of our common stock and our convertible notes could lose their investment.

We have a significant amount of indebtedness that we may not be able to repay in accordance with its terms.

Our convertible notes issued in 2014, which have a face value of $25.0 million and accrue interest at the rate of 7.54 percent per annum, compounded annually, mature in November 2019. Our convertible notes issued in 2017, which have a face value of $47.1 million and accrue interest at the rate of 8.00 percent per annum, compounded annually, mature in May and June 2022. Each holder of the 2017 convertible notes has a one-time right to require us to redeem such holder's note (face value plus accrued interest) in November 2019. Accordingly, we may be required to repay an aggregate of $72.1 million plus accrued interest in November 2019. As of September 30, 2018, the aggregate principal amount of all convertible notes plus accrued interest was $85.6 million. If the holders of the 2017 convertible notes collectively, or individually, exercise their redemption right, or if the 2014 convertible notes are not converted into shares of our common stock or their maturity date is not extended, we most likely will not have the cash to repay the notes, and the noteholders could commence legal action against us and/or we may need to reduce operating activities and personnel, sell assets, such as our intellectual property, and/or declare bankruptcy, and we may not be able to remain in business.

In addition, the convertible notes include certain events of default, including without limitation failure to make a payment obligation and failure to observe other covenants. While we are in compliance with the covenants and other terms at September 30, 2018, there can be no assurance that we will be able to continue to comply with all of the covenants. In the event of default, the noteholders have the right to call for the immediate redemption of their notes.

W***e have a history of net losses and negative cash flows and we may never achieve or maintain profitability.***

We are in the very early stages of commercialization. We have incurred net operating losses since our inception, including net operating losses of approximately $16.0 million for the nine months ended September 30, 2018 and $21.3 million and $26.8 million for the fiscal years ended December 31, 2017 and 2016, respectively. As of September 30, 2018, our accumulated deficit was approximately $365.9 million. Although we initiated commercialization activities in 2017, based on our current expectations, it will take a significant amount of time to generate sufficient revenues to cover anticipated costs, and we may never achieve or maintain profitability.

Unless we are able to significantly accelerate our sales, we expect to continue to incur significant operating losses and cash outflows through 2018 and 2019 as we incur costs associated with, among other matters:

- collecting clinical data and conducting clinical studies to differentiate our Fantom and Fantom Encore scaffolds from products offered by our competitors and to demonstrate the value of our Fantom and Fantom Encore scaffolds to current and prospective customers and payors;
- seeking regulatory approvals in the EU, Australia, Japan, China and United States for Fantom, Fantom Encore and MOTIV;
- additional product research and development efforts and follow-on clinical trials;
- growing, maintaining, and protecting our intellectual property;
- expanding our manufacturing capabilities, broadening our infrastructure, and initiating and growing sales and marketing capabilities to commercialize our products; and
- complying with the requirements of being a public company in the United States listed on the ASX.

We cannot predict the extent of our future operating losses and accumulated deficit, we may never generate sufficient revenues or positive cash flow to achieve or sustain profitability, and we may be unable to repay our convertible notes when required to do so, either at maturity or earlier. To become and remain profitable, we must succeed in commercializing products with significant market potential. This will require us to succeed in a range of challenging activities, including those listed above. We may not succeed in these activities and we may be unsuccessful in developing alternatives; therefore, we may not ever achieve profitability. If we do achieve profitability, we may not be able to sustain it. Our failure to achieve or sustain profitability could negatively affect the value of our securities and our ability to attract and retain personnel, raise capital, execute our long-term business strategy or continue operations.

In addition to our current capital needs, we may need additional funding in the future to continue to meet our operating, capital, and debt service needs, and we may be unable to raise capital when needed or on acceptable terms.

Our future operating and capital requirements will depend on many factors, including the timing and achievement of regulatory approval of our products, the growth of revenue, the amount of intellectual property and technology expenditures, the number and size of our clinical trials, the extent of new product development, and the timing of repayment of our convertible notes, should they become due and payable. Until we generate a level of revenue to support our cost structure, we expect to continue to incur substantial net cash outflows and we may need to raise additional capital in the future to continue to meet our operating, capital, and debt service needs. We may not be able to obtain sufficient additional funding on satisfactory 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. See also, "*Raising additional capital may cause dilution to our existing stockholders, require us to relinquish proprietary rights or restrict our operations*," below.

Because our need for capital arises as a result of significant past cash outflows and losses, the continuing occurrence of losses and cash outflows may make it difficult for us to raise necessary capital when needed, which would force us to delay, reduce, or eliminate our product development programs or commercialization efforts. In addition, we may incur substantial costs in connection with evaluating and negotiating future capital-raising transactions, the effect of which may be to shorten the period through which our current operating funds will sustain us. Even if we incur costs in pursuing, evaluating and negotiating particular capital-raising transactions, our efforts may not prove successful.

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

We may raise additional capital at any time and may do so through one or more financing alternatives, including public or private sales of our equity securities, debt financings, collaborations, licensing arrangements or other strategic transactions. Each of these financing alternatives carries certain risks. Raising capital through the issuance of common stock, or securities convertible, exercisable or exchangeable for shares of our common stock, may depress the market price of our stock and may substantially dilute our existing stockholders. In addition, our currently outstanding convertible notes are convertible into shares of our common stock at any time at the option of the holder. If we instead seek to raise capital through strategic transactions, such as licensing arrangements, we may be required to relinquish valuable rights. Debt financings could involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens or make investments and may, among other things, preclude us from

making distributions to stockholders (either by paying dividends or redeeming stock) and taking other actions beneficial to our stockholders. In addition, investors could impose more one-sided investment terms and conditions on companies that have or are perceived to have limited remaining funds or limited ability to raise additional funds. The lower our cash balance, the more difficult it is likely to be for us to raise additional capital on commercially reasonable terms, or at all.

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

None.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. 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	Composite Bylaws		10-K	000-54192	3/07/2018
4.1	Form of Stock Certificate		S-1/A	333-168852	11/12/2010
4.2 (a)	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
4.2 (b)	First Amendment to Amended and Restated Investors' Rights Agreement dated September 24, 2014		DEF14A	000-54192	5/15/2017
10.1#	Amendment #4 to Exclusive License Agreement Number 2, by and between Rutgers, the State University of New Jersey and the Company, dated July 30, 2018		8-K	000-54192	08/03/2018
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	X			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase	X			
101.DEF	XBRL Taxonomy Extension Definition Linkbase	X			
101.LAB	XBRL Taxonomy Extension Label Linkbase	X			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase	X			

Confidential treatment has been granted with respect to certain portions of this exhibit.

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

REVA Medical, Inc.

Date: November 5, 2018

/s/ Regina E. Groves

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

Date: November 5, 2018

/s/ Brandi L. Roberts

Brandi L. Roberts
Chief Financial Officer and Secretary
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

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

I, Regina E. Groves, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 5, 2018

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

Exhibit 31.2

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

I, Brandi L. Roberts, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 5, 2018

/s/ Brandi L. Roberts
Brandi L. Roberts
Chief Financial Officer
(principal financial officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of REVA Medical, Inc. (the "Company") for the quarterly period ended September 30, 2018, as filed with the Securities and Exchange Commission (the "Report"), Regina E. Groves, Chief Executive Officer of the Company, and Brandi L. Roberts, Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: November 5, 2018

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

/s/ Brandi L. Roberts
Brandi L. Roberts
Chief Financial Officer
(principal financial officer)