designs that disappear

Preliminary Final Report on Appendix 4E Year Ended 31 December 2016

Sydney, Australia and San Diego, California (Tuesday, 28 February 2017, AEDT) – REVA Medical, Inc. (ASX: RVA) ("REVA" or the "Company") is pleased to release its preliminary financial report for the year ended 31 December 2016 (the "Results") in the accompanying Appendix 4E. These Results have been audited by the Company's independent registered accounting firm, Grant Thornton LLP, and are being filed with the U.S. Securities and Exchange Commission.

Summary of the Results

For the year ended 31 December 2016 (the "Period"), the Company reports the following results:

- Loss from operations of US$26,780,000, reflecting our progress with the clinical trials of our *Fantom* bioresorbable scaffold, our application for European CE Marking that we completed in August 2016, and our preparations for commercialization. We are currently awaiting notification as to CE Mark regulatory approval. If approved, we intend to commercially sell *Fantom*, which would be our first commercial product, in Europe and other countries that recognize the CE Mark. If approved, we anticipate first sales of *Fantom* during the second quarter of 2017.

- Loss from non-operating items of US$27,318,000, primarily arising from non-cash accounting entries for the convertible notes and warrants issued by the Company in November 2014. In accordance with US generally accepted accounting principles, we elected to account for the notes and warrants at fair value, which requires adjustment to their fair value at each reporting period. Whenever the securities increase in value, a loss on change in fair value is recorded and whenever they decrease in value, a gain on change in fair value is recorded. The Company recorded a non-cash loss of US$25,247,000 on the change in fair value of the notes and warrants during 2016. In addition to the loss, a total of US$2,053,000 in non-cash interest expense on the notes was recorded during 2016.

- Net loss of US$54,098,000.

As of 31 December 2016 (the "Period End"), the Company reports:

- Cash and cash equivalents of US$6,674,000.

- Total stockholders' deficit of US$89,593,000.

Please refer to the attached Appendix 4E, including the audited consolidated financial statements, for additional explanation and details.

Dividends

The Company does not propose to pay dividends to common stockholders at this time. As such, there is no franking or applicable record date.

Important Information Concerning the Financial Results for the Period

REVA's consolidated financial statement and Appendix 4E are prepared in accordance with United States Generally Accepted Accounting Principles. The Results in the attached Appendix 4E are for REVA and its non-operating, wholly owned subsidiary, REVA Germany GmbH. All amounts in the accompanying Appendix 4E are in United States dollars ("US$") unless otherwise indicated.

Briefing Call

Ms. Reggie Groves, the Company's Chief Executive Officer, will host a briefing call to discuss the Company's business outlook and audited financial results through 31 December 2016 on Wednesday, 15 March 2017 at 9:00 a.m. AEDT (which is 3:00 p.m. US PDT on Tuesday, March 14, 2017). Access information will be available approximately one week ahead of the call.

About REVA

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

Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management. All statements that are not statements of historical fact, including those statements that address future operating performance and events or developments that we expect or anticipate will occur in the future, are forward-looking statements, such as those statements regarding our ability to obtain regulatory approvals, timely and successfully complete our clinical trials, protect our intellectual property position, commercialize our products if and when approved, develop and commercialize new products, recruit and retain our key personnel, and estimates regarding our capital requirements and financial performance. You should not place undue reliance on forward-looking statements. Although management believes forward-looking statements are reasonable as and when made, forward-looking statements are subject to a number of risks and uncertainties that may cause our actual results to vary materially from those expressed in forward-looking statements, including the risks and uncertainties that are described in the "Risk Factors" section of our Annual Report on Form 10-K filed with the US Securities and Exchange Commission (the "SEC"). 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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Preliminary Final Report
Appendix 4E
Year Ended 31 December 2016

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ARBN 146 505 777 • REVA Medical, Inc., is a foreign company incorporated in Delaware, USA, whose stockholders have limited liability

Rule 4.3A

Appendix 4E

Preliminary Final Report

1. Company Information

Name of entity

REVA Medical, Inc.

ABN	Year ended ("current year")
ARBN 146 505 777	31 December 2016

The previous corresponding period refers to the comparative amounts for the year ended 31 December 2015.

All values contained in this report are stated in U.S. dollars and have been rounded to the nearest thousand, unless otherwise stated.

2. Results for Announcement to the Market

		Current Year 12 Months Ended 31 December 2016 $'000 USD	Prior Year 12 Months Ended 31 December 2015 $'000 USD	Increase or (Decrease) $'000 USD	Percentage Increase or (Decrease)
2.1	Revenue from ordinary activities	$0	$0	N/A	N/A
	Loss from ordinary operating activities operations	$(26,780)	$(23,970)	$2,810	12%
	Non-operating expenses and losses	$(27,318) *	$(58,624)	$(31,306)	(53)%
2.2	Loss from ordinary activities, after tax, attributable to members	$ (54,098)	$ (82,594)	$(28,496)	(35)%
2.3	Loss attributable to members	$(54,098)	$(82,594)	$(28,496)	(35)%

* See page 3 for details of the non-cash items

2.4 The Company does not propose to pay dividends to common stockholders at this time. As such, there is no franking or applicable record date.

2.5 Not applicable; we are not proposing to pay dividends at this time.

2.6 We are a pre-revenue stage medical device company working toward commercialization of our proprietary technologies. We are in the later stages of developing and clinically testing bioresorbable drug-eluting coronary stents, which are called "scaffolds" because they are not permanent devices like metal stents. We completed an application for European CE Marking of our *Fantom* scaffold in August 2016 and are currently awaiting notification as to approval. If approved, we intend to commercially sell *Fantom*, which would be our first commercial product, in Europe and other countries that recognize the CE Mark. If approved, we anticipate first sales of *Fantom* during the second quarter of 2017.

We enrolled 240 patients in a clinical trial of *Fantom* between March 2015 and March 2016 and obtained data on approximately 100 of the patients at a six-month time point to use in our CE Mark application. We will continue to follow the patients for a total trial period of five years. During 2016, we also performed follow-up assessment of the patients and collected and analyzed related clinical data. We have been preparing for commercialization, including planning and implementing our sales and marketing approach,

finalizing our manufacturing processes, arranging warehousing and distribution capabilities, and preparing our back office resources. We believe our current manufacturing facilities will accommodate our commercial needs through at least 2017.

In November 2014, we issued senior unsecured convertible notes payable and warrants to purchase 8,750,000 shares of our common stock. We received cash proceeds of $25.0 million from the convertible notes in November 2014 and cash proceeds totaling $20.9 million from the exercise of the warrants in October 2015 and February 2016.

We perform all of our manufacturing, research, and development activities from one location in San Diego, California. We have three clean rooms, a polymer manufacturing lab, and multiple engineering and chemistry labs at our facility, which is also our corporate and administrative office. We are ISO certified to the medical device standard 13485:2012 and intend to maintain that certification. We had 59 employees as of December 31, 2016, a significant number of who are degreed professionals and five of whom are PhDs. We leverage our internal expertise with contract research and preclinical laboratories, catheter manufacturing, outside lasing, and other outside services as needed. We maintain an extensive patent portfolio of approximately 290 U.S. and foreign patents that we own directly or license from a third party; all costs associated with the portfolio are expensed as incurred.

The net loss attributable to members as reported comprises two primary components: loss from ordinary operating activities and other non-operating expenses and losses. Our loss from ordinary operating activities of $26,780,000 in 2016 was $2,810,000 higher than our loss in 2015. Comprising the increase, our research and development ("R&D") costs increased $1,411,000 and our general and administrative ("G&A") costs increased $1,399,000. Our loss from other non-operating items of $27,318,000 for 2016 was $31,306,000 lower than such loss in 2015.

Compared to 2015, R&D personnel costs increased $552,000 in 2016 primarily due to an approximate 11 percent increase in average headcount between years, offset by a $202,000 decrease in stock compensation. Direct materials that include polymer costs, polymer lasing, and purchased catheters increased $965,000 between years, and testing and non-recurring verification costs increased $447,000, as we made process improvements and performed verification activities in advance of commercialization. We incurred an additional $90,000 in 2016 in connection with our technology license from Rutgers, The State University of New Jersey, in accordance with license terms. Clinical costs decreased $209,000 in 2016 compared to 2015; the clinical trial initiated in March 2015 completed enrollment in March 2016 and the patient follow-up assessment activity that primarily occurred in 2016 resulted in comparatively lower costs. Preclinical costs decreased $579,000 between years due to the timing of studies and related analyses; a majority of preclinical tests for *Fantom* began in 2014 and 2015 and concluded by the first quarter of 2016. The remainder of the change in R&D expenses between years resulted from individually immaterial changes in lab supplies, engineering services, depreciation, and facilities expenses.

Compared to 2015, G&A stock compensation costs increased $1,491,000 in 2016 primarily due to equity grants to our Chief Executive Officer in September 2015 and February 2016 and equity awards to members of our Board of Directors in May 2016 and July 2016. Offsetting the increase, non-recurring severance costs of $210,000 and recruiting costs of $132,000 recorded in 2015 were not repeated in 2016. Also, travel costs decreased approximately $181,000 in 2016, primarily as a result of less clinical support travel following completion of study enrollment. The remainder of the change in G&A expenses between years was due to individually immaterial changes in investor relations costs, office supplies, marketing and tradeshow costs, audit and tax fees, legal fees, facilities costs, depreciation, insurance, and other overhead expenses.

Our other non-operating expenses for 2016 primarily arose from the convertible notes and warrants issued in November 2014. In accordance with U.S. generally accepted accounting principles ("GAAP"), we elected to account for our convertible notes and warrants at fair value; consequently, we record a non-cash loss on the change in fair value when the value of those securities increase and we record a non-cash gain when their values decrease. Accordingly, we recorded a loss of $16,290,000 from the change in fair values of the Notes during 2016 and a loss of $8,957,000 from the change in fair value of the warrants during the period January 1, 2016 to the exercise date of February 12, 2016. During 2015, we had recorded a loss on change in fair

value of $56,788,000 for the notes and warrants. Interest expense of $2,053,000 accrued on the notes in 2016, compared to $1,904,000 during 2015. We also recorded interest income of $3,000 and exchange rate losses of $23,000 during 2016.

Please see our consolidated financial statements, with accompanying notes, which are attached hereto, for additional detail.

3. Statement of Operations and Comprehensive Loss

Please see our consolidated financial statements, with accompanying notes, which are attached hereto.

4. Statement of Financial Position

Please see our consolidated financial statements, with accompanying notes, which are attached hereto.

5. Statement of Cash Flows

Please see our consolidated financial statements, with accompanying notes, which are attached hereto.

6. Statement of Retained Earnings

Please see our consolidated financial statements, with accompanying notes, which are attached hereto.

7. Dividends per Security

We did not declare or pay any dividends on common stock (or CDIs) and we do not propose to pay any such dividends at this time.

8. Dividend or Distribution Reinvestment Plans

Not applicable; the Company has no dividend or distribution reinvestment plans.

9. Net Tangible Assets per Security

	Current Year 31 December 2016	Prior Year 31 December 2015
Net tangible assets (in $'000 USD)	$(89,593)	$(80,564)
Issued equity (common stock and APIC) (in $'000 USD)	$299,645	$254,576
Number of shares of common stock on issue at reporting date (as if all CDIs were converted to common stock)	42,851,477	38,155,986
Net tangible assets per common share	($2.09) or ($0.209) per CDI	($2.11) or ($0.211) per CDI

10. Acquisitions and Divestments

Not applicable; no entities were acquired or disposed during 2016.

11. Joint Ventures

Not applicable; we are not and have not been party to any joint ventures.

12. Other Information

Please see our consolidated financial statements, with accompanying notes, attached hereto.

13. Foreign Entity Accounting Standards

Our financial statements are presented in accordance with accounting principles generally accepted in the United States and are denominated in U.S. dollars.

14. Commentary on Results for 2016

Please see our Annual Report on Form 10-K, including our consolidated financial statements and "Management's Discussion and Analysis of Financial Condition and Results of Operations," which is attached hereto.

We operated in one segment only during 2016.

15. Status of Audit or Review

Our consolidated financial statements for the year ended 31 December 2016, including accompanying notes, have been audited by Grant Thornton LLP. The audit opinion for 2016 accompanies our consolidated financial statements in the Annual Report on Form 10-K attached hereto.

16. Audit Report (Unaudited Financials)

Not applicable; our consolidated financial statements for 2016 have been audited.

17. Audit Report (Audited Financials)

There were no disputes with our auditors and the audit opinion on our consolidated financial statements is unqualified. The opinion contains an "emphasis of matter paragraph" related to the uncertainty surrounding our ability to continue as a going concern.

Annual Report on Form 10-K
Including Consolidated Financial Statements
Year Ended 31 December 2016

HEAD OFFICE: 5751 Copley Drive, San Diego, CA 92111 • +1 (858) 966-3000 • +1 (858) 966-3099 (FAX) • www.revamedical.com
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ARBN 146 505 777 • REVA Medical, Inc., is a foreign company incorporated in Delaware, USA, whose stockholders have limited liability

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

FORM 10-K

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

For the fiscal year ended December 31, 2016

or

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

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, San Diego, CA 92111	**(858) 966-3000**
(Address of principal executive offices including zip code)	*(Registrant's telephone number, including area code)*

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: Common Stock, $0.0001 par value per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

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

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

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

The aggregate market value of the common equity held by non-affiliates of the registrant as of June 30, 2016 totaled approximately $228,838,000 based on the closing price for the registrant's Common Stock trading in the form of CHESS Depositary Interests, or CDIs, as reported by the Australian Securities Exchange and based on the closing currency exchange rate in effect that day. Such value excludes Common Stock and CDIs held by directors, executive officers, and 10% or greater stockholders as of June 30, 2016. The identification of 10% or greater stockholders as of June 30, 2016 is based on Schedule 13G and amended Schedule 13G reports publicly filed before June 30, 2016. This calculation does not reflect a determination that such parties are affiliates for any other purposes.

As of February 15, 2017, there were 42,851,477 shares of the registrant's Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document Description
Portions of registrant's definitive proxy statement for its 2017 annual meeting of stockholders, to be filed pursuant to Regulation 14A within 120 days after its December 31, 2016 fiscal year end, are incorporated by reference into Part III (items 10, 11, 12, 13, and 14) of this report.

REVA MEDICAL, INC.

FORM 10-K — ANNUAL REPORT
For the Fiscal Year Ended December 31, 2016

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PART I

Forward-Looking Statements

This Annual Report on Form 10-K for the year ended December 31, 2016, or "Form 10-K," contains forward-looking statements concerning our business, operations, and financial performance and condition, as well as our plans, objectives, and expectations for business operations and financial performance and condition. Any statements contained herein other than statements of historical facts may be deemed to be forward-looking statements. You can identify these statements by words such as "aim," "anticipate," "assume," "believe," "could," "due," "estimate," "expect," "forecast," "goal," "intend," "may," "objective," "plan," "predict," "project," "potential," "positioned," "should," "target," "will," "would," and other similar expressions that are predictions of or indicate future events and future trends. These forward-looking statements are based on current expectations, estimates, forecasts, and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or developments and involve known and unknown risks, uncertainties, and other factors that are in some cases beyond our control. We caution readers that forward-looking statements are not guarantees of future performance and our actual results may differ materially from those anticipated, projected, or assumed in the forward-looking statements in this Form 10-K. Factors that can cause our actual results to differ materially from those anticipated in the forward-looking statements include, but are not limited to, the risks described under "Risk Factors," including:

- failure of our *Fantom* scaffold, or any future product, to meet our required clinical specifications;
- our inability to obtain regulatory clearance or approval for any of our products;
- failure of our products to gain market acceptance domestically or internationally;
- less than anticipated growth in the market for bioresorbable scaffolds generally;
- changes in the regulatory environment which may adversely impact the commercialization of our products and result in significant additional capital expenditures;
- refusal of third-party payors to reimburse our customers for use of our products;
- our history of net losses and our expectation of operating losses for the foreseeable future;
- increases in our projected expenditures on research and development and administrative activities;
- our inability to attract or retain skilled personnel for our product development and commercialization efforts;
- our inability to protect our intellectual property and operate our business without infringing upon the intellectual rights of others, which could result in litigation and significant expenditures;
- our inability to repay our convertible notes when, and if, required or otherwise comply with their requirements;
- changes in the fair value of our convertible notes and the gains or losses that may arise upon such changes;
- failure to complete financings to fund our operations when needed or on terms favorable to us; and,
- our ability to continue as a going concern;

Stockholders, potential investors, and other readers are urged to consider these factors carefully in evaluating the forward-looking statements and are cautioned not to place undue reliance on the forward-looking statements. These forward-looking statements speak only as of the date of this Form 10-K. Unless required by law, we do not intend to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the Securities and Exchange Commission, or SEC, after the date of this Form 10-K.

General Information

Unless the context implies otherwise, references in this report and the information incorporated herein by reference to "REVA Medical," "REVA," the "Company," "we," "us," and "our" refer to REVA Medical, Inc.

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

Unless indicated otherwise in this Form 10-K, 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.

Corporate Information

Our company was founded in California in June 1998 as MD3, Inc. We changed our name to REVA Medical, Inc. in March 2002. In October 2010, we reincorporated from the State of California to the State of Delaware. Our principal executive offices are located at 5751 Copley Drive, San Diego, California 92111, 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.

We make available on our website, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Australian Securities Exchange (the "ASX") and the U.S. Securities and Exchange Commission (the "SEC"). Our SEC reports can be accessed in the Investor Relations section of our website. The information found on our website is not part of this or any other report we file with or furnish to the SEC.

Item 1. Business

Overview

We are a pre-revenue stage medical device company working toward commercialization of our proprietary technologies to provide minimally invasive medical devices for treating conditions in humans. Since our inception in 1998, our efforts have been concentrated on the development of a stent for use in coronary applications. We completed an application for CE Marking of our *Fantom* bioresorbable drug-eluting coronary stent in August 2016 and are currently awaiting notification as to approval. If approved, we intend to commercially sell *Fantom*, which would be our first commercial product, in Europe and other countries that recognize the CE Mark. If approved, we anticipate first sales of *Fantom* during the second quarter of 2017.

Bioresorbable stents are referred to as "scaffolds" because they are not permanent devices like metal stents. In clinical use, a scaffold is implanted by an interventional cardiologist utilizing x-ray imaging during a minimally invasive surgery. The scaffold is delivered to the site of a lesion, or blockage, in a coronary artery with a delivery catheter system, whereupon the scaffold is deployed to restore blood flow through the artery. Drug-eluting stents and scaffolds additionally medicate the artery to prevent excessive tissue growth, which is called "restenosis," that could occur from the stenting procedure.

Bioresorbable scaffolds were first sold commercially, outside the United States, approximately four years ago. The market for scaffolds has grown since that time, with initial U.S. sales occurring in 2016. Our scaffolds combine our proprietary bioresorbable polymer with various designs, including conventional designs and internally developed designs. Compared to other bioresorbable scaffolds, our scaffolds have unique features that include full x-ray visibility, standard clinical delivery, low profile, and a wide expansion range. Our scaffolds also contain standard features of relevant sizing, robust strength during the healing period, and controlled and safe resorption. Due to their unique features, ease of clinical use, and positive clinical results, we believe our products will enable us to compete effectively in the broader stent market, which had approximately $3.9 billion in worldwide revenues in 2016. Of the total stent market, bioresorbable scaffolds had estimated annual revenues of approximately $127.0 million in 2016.

Our clinical study data to-date shows *Fantom* to be safe and effective. We enrolled 240 patients in a clinical trial of *Fantom* between March 2015 and March 2016, obtained follow-up data on approximately 100 of the patients at a six-month time point to use in our CE Mark application, and are continuing to follow the patients for a total trial period of five years. In addition to this clinical trial, we have invested significant time and funds in development, having performed scientific research, engineering development, and testing in laboratory and preclinical studies. We have developed, tested, and selected polymer formulations, tested and selected anti-restenotic drugs and the coating process, created and iterated the device designs, and identified and implemented methods and processes to produce and test our scaffolds. We designed and performed extensive preclinical tests that ranged from bench and engineering studies to in vitro and in vivo laboratory studies. We also enrolled approximately 165 patients in prior clinical studies between 2007 and 2014 that showed the viability of the technology.

While we expect our *Fantom* scaffold to be approved and that we will initiate sales this year, our efforts to generate substantial revenue and achieve positive cash flows from our operations may take several years, even if our clinical results continue to be favorable.

We have been preparing for commercialization, including planning and implementing our sales and marketing approach, finalizing our manufacturing processes, arranging warehousing and distribution capabilities, and preparing our back office resources. We believe our current manufacturing facilities will accommodate our commercial needs through at least 2017.

During the course of our product development and testing, we have invented, co-invented, and licensed a portfolio of proprietary technologies. Our design-related technologies have been invented by our employees and consultants and our materials-related technologies have been either invented by our employees or licensed from or co-invented with Rutgers, The State University of New Jersey. We consider our patent portfolio to be significant and have invested considerable time and funds to develop and maintain it. Our goal is to continue to perform feasibility tests on additional technologies covered by our patent portfolio as our resources allow and, if feasibility is proven, develop and commercialize additional products. We anticipate devoting resources to new product testing in 2017, with the goal to identify at least one technology for development by year end.

We perform all of our manufacturing and research and development activities from one location in San Diego, California. We have three clean rooms, a polymer manufacturing lab, and multiple engineering and chemistry labs at our facility, which is also our corporate and administrative office. We are ISO certified to the medical device standard 13485:2012 and intend to maintain the certification to support our commercialization plans. We had 59 employees as of December 31, 2016, a significant number of who are degreed professionals and five of whom are PhDs. We leverage our internal expertise with clinical contract research organization, contracted preclinical consultants and laboratories, outside catheter manufacturing, outside lasing, and other outside services as needed.

We have not yet produced a product to a saleable stage and we have not, therefore, generated any product or other revenues. We have funded our research, development, and clinical study activities with a variety of private, strategic, and public investments, including our $84.3 million Initial Public Offering ("IPO") on the Australian Securities Exchange ("ASX") in December 2010 and, prior to the IPO, investments from health care venture capital funds and global medical device manufacturers including Medtronic, Inc. ("Medtronic") and Boston Scientific Corporation ("BSC"). Most recently, in November 2014, we issued convertible notes (the "Notes") and warrants to purchase our common stock. We received cash proceeds of $25.0 million from the Notes in November 2014 and cash proceeds of $20.9 million from exercise of the warrants between October 2015 and February 2016. As approved by our stockholders in March 2016, terms of the Notes were modified to extend an early redemption right held by the noteholders to June 30, 2017 and to add a third condition, being that the Company list its common stock on the NASDAQ stock exchange (or another exchange approved by the noteholders), before the Notes will automatically convert into common stock. The prior conditions to an automatic conversion of the Notes were the receipt of a CE mark on *Fantom* combined with a market trading price of our securities of at least A$0.60 for 20 or more consecutive trading days.

As of December 31, 2016, we had approximately $6.7 million in cash available for operations, which we believe will be sufficient to fund our operating and capital needs through the first fiscal quarter of 2017. We have incurred substantial losses and cash outflows since our inception; as of December 31, 2016, we had accumulated a deficit of approximately $389.2 million and we had approximately $98.8 million in current liabilities (of which, approximately $32.2 million could become due and payable in 2017). While we are currently pursuing a financing, these conditions, combined with the uncertainty of the timing of receipt of a financing, if any, raise substantial doubt about our ability to continue as a going concern.

We expect our losses to continue as we complete our clinical studies, prepare for commercialization, and, if we receive regulatory approval of *Fantom*, initiate commercial sales. In order to transition to profitable operations, we will need to achieve a level of revenues and product margins to support our cost structure. Until such time as we generate positive cash flow, we plan to continue to fund our operations by utilizing our existing cash and by raising additional capital through equity or debt financings or strategic or other transactions.

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

Market Opportunity

Coronary Artery Disease

Cardiovascular disease ("CVD") is a term used to describe all diseases and conditions that relate to the heart and blood vessels in the body. Coronary arteries, which supply blood to the heart, are susceptible to the buildup of plaque and the formation of lesions, which can inhibit or block blood flow, a condition known as coronary artery disease. If arteries become too narrow as a result of plaque buildup, the heart ("cardiac") muscle may become starved of nutrients and oxygen, resulting in chest pain known as angina. As artery narrowing becomes more severe, death of cardiac muscle downstream from the blockage can occur due to a lack of oxygen. The sudden death of cardiac muscle can result in a heart attack, or "myocardial infarction."

Cardiovascular disease is a leading cause of death. A January 2015 report published by the World Health Organization cited CVD as the number one cause of death globally, with an estimated 17.5 million deaths in 2012, representing 31 percent of all global deaths. Of these, an estimated 7.4 million deaths were due to coronary heart disease. The American Heart Association ("AHA") reported that coronary heart disease accounted for more than 360,000 deaths in the United States during 2014, or approximately one in every seven deaths, and that coronary artery disease would cost an estimated $129.6 billion in direct and indirect costs in 2015. According to the AHA, each year nearly one million people in the United States will have a coronary heart attack.

The European Heart Network reported in early 2017 that ischemic (coronary) heart disease is the single leading cause of death in Europe, accounting for approximately 1.7 million deaths per year, or 14 percent of all male and 12 percent of all female deaths. In addition, the Australia Institute of Health and Welfare reported that coronary artery disease kills more Australians than any other disease, accounting for 21,500 deaths in 2011, or 15 percent of all deaths in Australia. In 2011, an estimated 69,900 people in Australia over the age of 25 had a heart attack.

Current Interventional Treatments for Coronary Artery Disease

There are various methods to prevent, slow progression, reduce symptoms, and reverse ("treat") coronary artery disease. Lifestyle factors contribute to the development of coronary artery disease and lifestyle interventions such as eating healthy and being physically active are used for prevention and treatment. Evidence shows that healthy lifestyle alternatives are not being universally adopted. As an added therapy, medications such as beta blockers, diuretics, aspirin, nitroglycerin, and calcium channel blockers are used to reduce blood pressure and cholesterol levels and/or aid in the treatment of coronary artery disease. Although lifestyle changes and drug therapy can improve quality of life and prolong survival, a large number of patients will require an invasive surgery or a minimally invasive treatment such as stenting, to improve cardiac health.

Surgical or minimally invasive procedures, developed and used over the past four decades, quickly and safely restore blood flow by either surgically rerouting the flow around a plaque buildup or by reopening the artery with an interventional procedure. As technology has advanced, procedure-related complications have decreased, costs have been reduced, and procedure and recovery times have been shortened. Physicians have rapidly adopted each new advancement. The main treatment options used by physicians and available to patients are:

- ***Coronary Artery Bypass Surgery*:** An extremely invasive procedure requiring open heart surgery. The bypass is achieved by removing a vein or artery from somewhere else in a patient's body and connecting it to the blocked artery, bypassing the blockage. This allows oxygen-rich blood to reach the heart muscle.
- ***Balloon Angioplasty*:** A minimally invasive procedure developed in the 1970s in which a balloon-tipped catheter is inserted into an artery in the groin or wrist and advanced to a blockage in the heart. At the blockage site, the balloon is inflated to compress plaque and widen the narrowed artery, restoring blood flow. Although rapidly adopted because it is minimally invasive and results in shorter hospital and recovery times compared to bypass surgery, the long-term effectiveness of balloon angioplasty is limited by restenosis, a re-narrowing of the artery caused by the elastic recoil of the artery wall or formation of arterial scar tissue. Restenosis typically requires another angioplasty procedure or bypass surgery. Also, some patients experience abrupt vessel closure after angioplasty, leading to complications such as heart attack, emergency bypass surgery, or death.
- ***Bare Metal Stents*:** A minimally invasive therapy introduced in the 1990s to address the issues of abrupt vessel closure and restenosis following balloon angioplasty. Stents are small permanently implanted tube-like devices that are inserted into an artery to prop it open and facilitate blood flow. While bare metal stents minimized the issues and complications of abrupt vessel closure, restenosis continued to be a significant problem.

- ***Drug-Eluting Metal Stents*:** A metal stent that additionally delivers a therapeutic drug to help minimize buildup of scar tissue during healing. After bare metal stents were introduced, physicians determined that restenosis resulted from the trauma of the procedure and stent, rather than from the underlying coronary artery disease. To overcome restenosis, delivery of pharmacological agents from stents was developed; the drugs used range from cytotoxic types (for example, paclitaxel) to immunosuppressants (sirolimus, zotarolimus, and everolimus). Patients usually also undergo treatment with aspirin and anti-clotting or anti-platelet drugs, such as clopidogrel (sold as *Plavix*) or ticlopidine (*Ticlid*) after stenting, to reduce the incidence of blood clots, or "thrombosis."

  In coronary stenting, we believe the key measures of success or failure of the therapy are:

  - ***Target Lesion Revascularization***, or "TLR," which measures the incidence of required re-stenting or bypass surgery due to a failure of the initial coronary angioplasty and stenting; and
  - ***Major Adverse Cardiac Events***, or "MACE," which are events of cardiac death, ischemia ("heart attack"), or TLR.

- ***Bioresorbable Scaffolds*:** A stent therapy that achieves the benefits of metal stents with the added advantage that the stent dissolves after the artery has healed. After drug-eluting metal stents were introduced and studies showed they successfully lowered the rates of restenosis, safety concerns arose when other studies suggested they caused risks from late stent thrombosis and the failure to restore the natural movement of the artery. To achieve the proven benefits of drug-eluting metal stents, but also to eliminate the long-term risks of a permanent implant and allow an artery to return to its natural function, bioresorbable stents were devised. While numerous coronary bioresorbable stents have been under development, due to the many technical challenges of the technology only three are available for sale.

Coronary Stent Market

In 2016, annual worldwide revenues from coronary stent sales approximated $3.9 billion, of which drug-eluting stents accounted for approximately $3.6 billion in revenues and 91 percent of units sold. There are three companies with significant market share that have received approval for five drug-eluting metal stents. According to analyst reports, approximate 2016 annual coronary stent revenues were:

- $1.4 billion in the United States from approximately 1.2 million stent implants;
- $2.0 billion in Europe and Asia (excluding Japan) from approximately 3.9 million stent implants; and,
- $0.4 billion in Japan from approximately 233,000 stent implants.

Sales of bioresorbable scaffolds began in 2012 in locations outside the United States. Of the worldwide stent sales, bioresorbable scaffold revenues were estimated to be $86.0 million in 2013, with an increase to an estimated $127.0 million in 2016. Scaffold revenues may continue to grow, especially if a more effective device becomes commercially available and as scaffolds are approved for sale in additional countries.

Sales of bioresorbable scaffolds in Europe represent a large portion of all scaffold revenues. When and if we receive CE Marking, the European regulatory approval required for commercial sales, our plan is to initially sell in Europe and other countries that recognize the CE Mark. We would then expand into additional locations as we apply for, and receive, appropriate regulatory approvals. Due to the extensive clinical data and regulatory approvals needed to commercialize in the United States, we do not anticipate selling in the United States until several years after we have achieved initial sales in Europe.

Our Products

The *Fantom* scaffold we developed and intend to commercially sell is a drug-eluting fully bioresorbable polymer stent. Bioresorbable stents are called "scaffolds" because they are temporary in nature and their purpose is to hold an artery open during healing after an implant procedure. Our scaffolds were designed to help ensure that, after being implanted, they become fully captured inside the artery wall and maintain their strength for at least three months, a period of time that allows for sufficient healing of the artery. After healing, our scaffolds gradually degrade and benignly clear from the body, a process called "resorption." As a scaffold resorbs, arterial tissue integrates into the space previously occupied by the scaffold and the artery returns to its natural state.

We believe the features of bioresorbable scaffolds, combined with their temporary nature, provide advantages over permanent metal stents that include elimination of risks and ongoing complications from a permanent implant and better retreatment options if future cardiovascular disease occurs. We designed our scaffolds to overcome many of the limitations associated with bare metal and drug-eluting metal stents. Our extensive preclinical testing, including bench and animal tests, provides data and results that indicate our scaffolds have the potential to provide the following benefits over metal stents:

- ***Restoration of Vessel Movement*:** We believe there is significant benefit to allowing an artery's natural movement, which is not possible with a permanently implanted metal stent. Our bioresorbable scaffolds dissolve after an artery has healed, allowing restoration of "vasomotion," or the artery's ability to contract and expand with blood flow and exertion. We also believe that by restoring the artery's natural state and blood flow, disease progression downstream in the artery may be reduced.
- ***Minimization of Thrombosis Risk and Reduction of Long-Term Drug Therapy*:** We believe the potential for very late stent thrombosis and TLR is reduced because our bioresorbable scaffolds become fully encapsulated into the artery wall and safely dissolve over time. Once fully resorbed, there is no foreign body present, thus the risks associated with a foreign body are eliminated. We believe these characteristics also will help in reducing the incidence of blood clots, potentially decreasing the need for prolonged anti-platelet drug therapy.
- ***Enhanced Applications for Future Medical Treatment*:** We believe that bioresorption makes future medical treatments (diagnostic imaging and invasive procedures) easier because there is no metal to interfere. Coronary artery disease is typically progressive and many patients will require additional treatments. A patient may undergo re-stenting, be treated for lesions located downstream from the original stent, or undergo surgical procedures to an artery. These treatments may be inhibited by the existence of a metal stent, whereas the disappearance of a scaffold helps to ensure all treatment options remain available. In addition, we believe our scaffolds have potential to be used in the treatment and reduction of vulnerable plaque and as a delivery platform for drugs. We believe that if our products are used for these purposes, they will treat a broader range of lesions more safely than today's stent alternatives.

We have been developing and advancing our bioresorbable technology in both its design and polymer composition since approximately 2003. We have developed the following key specifications we believe our scaffold products should possess to be commercially viable and competitive:

- ***Intended Use*:** Treats coronary artery disease using minimally invasive techniques; resorbs leaving no permanent device;
- ***Efficacy*:** Restores and maintains blood flow; artery's natural movement is restored as the scaffold resorbs;
- ***Drug Eluting*:** Delivers standard anti-restenotic drug to the stented artery;
- ***Standard Deployment*:** Catheter mounted; does not require presoaking; deliverable using metal stent clinical practices including deployment in a one-step continuous inflation and deliverability through the radial artery;
- ***Storage and Handling*:** Clinical handling and storage the same as metal stents with no refrigeration required;
- ***Size*:** Treats arteries with diameters of 2.5 to 3.5 millimeters, the diameters most commonly treated;
- ***Expansion Range*:** Expands within a clinically relevant range of the sized artery; allows for taper of the artery and other implant procedure needs and variations;
- ***Recoil*:** Limited stent recoil, which we believe decreases the risk of restenosis;
- ***Radiopaque*:** Visible by x-ray during and after implant, allowing verification of placement in the artery;
- ***Strength*:** Maintains adequate "hoop" strength for at least three months during an artery's healing period; and,
- ***Manufacturing*:** Produced with conventional repeatable processes in compliance with applicable standards.

We believe that due to risks associated with bare metal and drug-eluting metal stents, and with the introduction of a next-generation bioresorbable scaffold such as ours, the coronary stent market will continue to convert from metal stents to fully bioresorbable polymer scaffolds. To help ensure our scaffolds are commercially competitive, we designed them with the following features:

- ***Proprietary Strong and Resilient Polymer*:** Our proprietary polymer, and the manner in which we process it, allows our scaffold to maintain its strength during the critical 90-day healing period following implant, offers standard clinical deliverability, and is less prone to breaking than other polymers we tested for this application.

- ***No Change to Clinical Practice*:** Our scaffolds are implanted using a standard balloon catheter and the profile of the device is compatible with a standard 6-french delivery catheter size. Our scaffolds do not require any change to traditional storage or handling or to the method of deployment.
- ***Visible Using Standard Imaging Techniques*:** Our scaffolds are visible under x-ray, thereby allowing physicians to see the scaffold during implant and at early patient follow-up.
- ***Standard Resorption Rate*:** Our polymer is designed to degrade and clear from the body in approximately the same timeframes as other polymer-based bioresorbable scaffolds. Our scaffolds lose their molecular weight within approximately one year after implant, which allows restoration of the natural vessel movement. They lose their mass over the next three years, with total resorption taking approximately four years. We have the ability to, and may, adjust the degradation profile of future polymer formulations if it is determined that a shorter or longer degradation period could lead to improved patient outcomes.
- ***Biocompatible and Safe*:** We use a combination of desaminotyrosine polycarbonate with polylactic acid as the base polymer in our scaffolds. Polylactic acid is widely used for medical implant purposes. Desaminotyrosine polycarbonate has been demonstrated to be biocompatible in preclinical testing; in a 12-month study during which the scaffold was degrading, it showed no indication of adverse biological reactions, consistent with the other tests of the polymer.

We have extensively tested our bioresorbable scaffolds during their development, a period spanning over 12 years. Our preclinical tests show the technology to be safe and effective, with over 1,000 scaffolds tested across various animal models. Our bench tests confirm the intended product features, with over 30,000 scaffolds tested in various manners. Our preclinical tests generally comprise the following:

- ***Comparative Testing*:** We compared our scaffolds to commercially available metal stents and, to a lesser extent, bioresorbable scaffolds. Our tests show that our scaffolds maintain the openness of the artery in the 90 days following implant and allow the lumen size (the inside area of the artery) to increase during resorption. Comparatively, the lumen size of arteries implanted with metal stents was almost unchanged.
- ***Strength and Fatigue Testing*:** We conducted engineering and life cycle tests with equipment that replicates both the physiological conditions in the coronary artery as well as measures the maximum stress levels that our technology can withstand. These tests demonstrated satisfactory scaffold design and polymer strength, low levels of polymer embrittlement, and resistance to fatigue failure prior to significant degradation of the scaffold.
- ***Biocompatibility Testing*:** The biological response to our scaffold has been evaluated by assessing healing in animal coronary arteries using standard microscopy for stented arteries (where the vessel is examined under a microscope). These tests have demonstrated that the polymer is safe and no adverse response occurs in the artery, including while the polymer degrades.
- ***Rate of Degradation Testing*:** Our degradation rate tests demonstrate that our scaffolds maintain their structural integrity and strength for at least 90 days, the healing time of an artery following the implant procedure. By design, at 12 months the scaffold no longer has significant mechanical strength and the polymer continues to resorb and be eliminated from the body for approximately four years. A study of the byproducts resulting from the resorption of our scaffold showed no accumulation in key organs or tissues of the animal's body and that the byproducts are cleared from the body.
- ***Toxicity Testing*:** Among other tests, we performed an ISO-10993-1 test for genotoxicity. Our test showed that there is no change to the DNA or chromosomes of cells tested and that our polymer is not genotoxic. We have conducted preclinical tests for several other types of toxicity that also demonstrated the polymer is safe.
- ***Drug Testing*:** Implanting a stent can injure an artery and the body's wound-healing process can cause excessive scar tissue to form inside the stent, referred to as "in-stent restenosis." The drug sirolimus minimizes overgrowth of tissue, thereby minimizing in-stent restenosis. It has been used in drug-eluting stents, has a demonstrated safety profile, and is proven effective at reducing restenosis. We tested the effects of sirolimus, which we apply to the surface of our scaffold in a coating. Our studies demonstrated no major drug toxicity.

In addition to the significant laboratory and preclinical testing that has shown the technology to be safe and effective, we have conducted human clinical trials. We enrolled a total of 165 patients in three clinical studies between 2007 and 2014 with predecessor scaffolds, which combined our proprietary "slide and lock" designs with our proprietary polymer formulations. While these predecessor scaffolds demonstrated viability of the technology, we believed enhanced characteristics were needed and, therefore, developed our *Fantom* scaffold during 2014.

Our *Fantom* scaffold is made from our proprietary polymer and is implanted in a coronary artery using a balloon-mounted angioplasty catheter during a minimally invasive procedure. We manufacture the scaffold device, apply a drug coating, assemble it onto the balloon catheter system, and package and sterilize it. The handling and storage requirements of *Fantom* are similar to those of metal stents, with no refrigeration required. Also, *Fantom's* clinical procedure for implant does not vary from that commonly used in clinical practice with metal stents. Because of *Fantom's* unique full x-ray visibility and other polymer properties, it allows for single-step inflation during implant and provides visual confirmation of the complete scaffold structure upon implant, correct placement over a lesion, and successful expansion of the scaffold against the artery wall. While *Fantom* contains features that overcome a number of limitations of other bioresorbable scaffolds, it is not designed for the smallest or largest diameter vessel applications or highly calcified lesions. As a result, it will not be able to initially address the needs of all patients requiring a coronary stent.

Following bench and laboratory testing, we implanted *Fantom* in humans for the first time in December 2014. Following the successful acute results in these first patients, we initiated our pivotal trial of *Fantom*, enrolling a total of 240 patients, who will be followed for a total trial period of five years, between March 2015 and March 2016. We used follow-up data at a six-month time point from approximately 100 of the patients in our CE Mark application in August 2016. CE Marking is the regulatory approval that would allow us to sell our scaffolds in Europe and other countries that recognize the CE Mark. We are currently awaiting *Fantom's* approval from the European notified body; based on recent inquiries, we expect approval early this year. We plan to commercially sell *Fantom* shortly after, and if, we receive CE Mark approval.

Concurrently, with developing and testing *Fantom*, we have been testing feasibility of additional technologies in our patent portfolio. As we commercialize *Fantom*, we will continue our feasibility testing as our resources allow and, if feasibility is proven, determine a course of development for additional products. Subject to our ability to raise adequate capital to successfully commercialize and initiate sales of *Fantom*, we anticipate devoting resources to new product testing in 2017, with the goal to identify at least one technology for development by year end.

Our Product Strategy

Our goal is to become a world leader in the production and sale of bioresorbable cardiovascular products for use in humans. To achieve this goal, we are pursuing the following business strategies:

- ***Demonstrate Clinical Safety and Efficacy and Gain Regulatory Approval for our Products*:** Our strategy is to develop safe and effective products and to demonstrate that safety and effectiveness through human clinical trials, followed by application for regulatory approval to commercialize. We believe the data from our clinical trial of *Fantom*, including six-month results showing a MACE rate of 2.1 percent and In-Scaffold Late Lumen Loss (an indication of the effectiveness of the device) of 0.25mm (±0.40mm), demonstrate the safety and efficacy of our *Fantom* technology. We used six-month data from approximately 100 of the patients in our application for CE Marking, our first application for regulatory approval.
- ***Develop Follow-on Products*:** We intend to enhance existing products, by refining or adding features, and to develop and commercialize additional technologies in our patent portfolio, if feasibility is proven. Once feasibility of a new product is proven, we will determine a course of product development and seek to provide follow-on products.
- ***Commercialize and Drive Adoption of our Products*:** As we have conducted clinical studies and applied for CE Marking, we have also focused on commercialization readiness. We have developed a sales and marketing strategy that contemplates a targeted roll-out, with subsequent expansion after proven acceptance of our product. We believe we currently can meet supply demands for anticipated sales should we receive regulatory approval in the European Union. As we expand to other markets, such as Australia, we intend to refine and expand our manufacturing capabilities to required levels. We have also granted BSC an option to negotiate exclusive rights to market, distribute, and sell our products, subject to certain requirements. See "— Distribution and License Agreements" below for additional information.
- ***Build Awareness and Support among Leading Physicians*:** Our commercial strategies include collaboration with key opinion leaders in the field of interventional cardiology. We believe these key physicians will be advocates of our technology and important in the market adoption of our products once approved. We also will look to these physicians to generate and publish scientific data that further supports the benefits of our scaffolds.

- ***Leverage Our Technology Platform into Other Therapeutic Areas*:** We believe our technology is applicable to therapies beyond coronary artery disease. For example, we intend to pursue the use of our technology to treat peripheral artery disease, which is an expanding market. We believe current treatments for peripheral artery disease have demonstrated only marginal benefit and the application of our technology to the development of a bioresorbable peripheral scaffold could be significant.
- ***Provide the Highest Quality Products for Our Customers and Patients*:** We have assembled a team of employees and consultants who are experienced professionals in the medical device industry and who are focused on patient safety and product quality. We incorporate these principles in every aspect of our products, including development, manufacturing, quality assurance, and clinical research. We intend to offer only the highest quality products to patients and physician customers.
- ***Expand and Strengthen Our Intellectual Property Portfolio*:** We plan to continue to expand our current intellectual property portfolio. While we believe that our current portfolio will allow us to effectively market our products for the treatment of coronary artery disease, we plan to create, originate, license, and acquire additional intellectual property to enhance our existing position and enable us to more effectively expand and protect our technology.
- ***Explore Licensing Opportunities*:** We intend to explore opportunities to leverage our intellectual property portfolio by out-licensing our technology to third parties or through the establishment of partnerships. For example, we may seek a partner to license our polymer for use as embolic beads or as a drug-delivery device for pharmaceutical applications.

Our Technology

Our *Fantom* scaffolds are drug-eluting fully bioresorbable polymer scaffolds that are implanted using a balloon catheter. The underlying technology primarily consists of a standard deformable stent design fabricated from our proprietary polymer that we coat with a widely used anti-restenotic drug that we purchase.

The polymer, which we use for both the body of the scaffold and for the drug coating, is a patented technology based on an iodinated, tyrosine-derived polycarbonate compound. We license the polymer technology and related improvements from Rutgers, The State University of New Jersey, or "Rutgers." See "— Distribution and License Agreements" for additional information. We work in collaboration with Rutgers to continually develop and enhance the polymer technology. The polymer formulation used in *Fantom* is a combination of our desaminotyrosine polycarbonate polymer and other polymeric components.

We believe our polymer offers the following advantages as compared to other polymer-based stents and scaffolds:

- ***Strength*:** We have developed our polymer so that, in conjunction with our scaffold design and our method of processing, it maintains the strength and structural integrity necessary to support an artery during the critical 90-day healing period after implant. We believe our specific polymer formulation is inherently less prone to cracking and breakage than other polymers.
- ***Biocompatibility*:** The *Fantom* polymer formulation has been tested for biocompatibility in a variety of preclinical and clinical studies and has not shown any adverse results. In a 12-month preclinical study of our desaminotyrosine polycarbonate polymer, no adverse biological reactions occurred during the scaffold material degradation. Additionally, the *Fantom* polymer has demonstrated equal biocompatibility in preclinical testing to our earlier polymer formulations. Between 2007 and 2014, we performed human clinical trials with earlier designs of our scaffold; none of those earlier versions has shown any adverse biological reactions.
- ***Degradation and Resorption*:** Our polymer degrades into benign metabolites (consisting of monomers and carbon dioxide) that are cleared from the body. Our polymer also allows us to change the formulation to allow for a more rapid degradation process to occur that could facilitate, for example, the short-term treatment of vulnerable plaque with drugs.
- ***Visibility*:** The use of covalently-bound iodine in our polymer enables our entire scaffold to be visible under x-ray, including standard fluoroscopy, providing visibility approximating that of metal stents. Other commercially available bioresorbable scaffolds utilize metal "markers" at each end of a scaffold; under x-ray, these metal markers are the only visible portion of those scaffolds and they remain in the vessel wall permanently. Our improved visibility allows interventional cardiologists to more accurately assess the implant quality and position.

Our bioresorbable scaffolds are drug-eluting to help reduce restenosis of the artery in the treatment location. *Fantom* delivers sirolimus, an anti-restenotic drug used in commercial drug-eluting stents. This drug is available from a number of different sources and has been approved by both European and U.S. regulatory bodies. We coat the outside surface of our scaffold using a polymer solution containing a target dose of sirolimus. The polymer used for the coating solution is the same polymer used in the scaffold structure. Through our preclinical studies, we have demonstrated a controlled release of the drug over 30 days; most of the drug is released within 90 days. We believe our release characteristics optimize the efficacy of the drug.

The deformable design of our *Fantom* scaffold allows for delivery to, and deployment in, the artery utilizing a standard balloon-mounted angioplasty catheter and a standard 6-french guide catheter. Facilitated by our polymer's properties, our scaffold is designed to maintain its strength during the critical 90-day healing period following implant, to exhibit minimal recoil, and to allow expansion within a clinically relevant range of the sized artery in order to ensure sufficient apposition to the vessel wall and to allow for taper of the artery and other implant procedure needs and variations. *Fantom's* design also provides standard clinical use features.

Preclinical Testing

We have undertaken significant laboratory and preclinical testing during the development of our technology, with tests of more than 1,000 scaffolds in various animal models and more than 30,000 scaffolds in various bench tests. This testing has shown that our technology was sufficiently safe and effective in animals to support continued product development. Our preclinical tests have included strength, embrittlement, and fatigue tests; biocompatibility and toxicity tests; drug release tests; deployment and degradation tests; and, tests of comparability to commercial metal stents and bioresorbable scaffolds. We used the data from our preclinical tests in our application for CE Marking of *Fantom*.

Clinical Studies and Regulatory Strategy

We have targeted Europe, and other countries that recognize the European CE Mark, as our initial commercial markets. After we have achieved initial sales in Europe we intend to expand to additional markets, including the United States, India, and Japan after we complete regulatory requirements and obtain clearance for commercial sales in such jurisdictions. For each jurisdiction in which we perform clinical studies or commercialize products, we are subject to significant regulatory requirements, with which we intend to fully comply.

The European Medical Devices Directive ("MDD") 93/42/EEC sets out the essential requirements for clinical studies, product approval, and CE Marking in the European Union (the "EU"); there are numerous other directives and standards regulating the design, manufacture, clinical trials, and labeling for medical devices. We will need to receive CE Mark approval and to comply with the other requirements of the MDD before we can label our products for sale.

In order to obtain the data we used in our European CE Mark application, which we submitted in 2016, we enrolled 240 patients in eight countries, including Australia, Brazil, and Europe, in a clinical trial of our *Fantom* scaffold. Based on the outcome of our *Fantom* trials, we plan to apply for and conduct a clinical trial in the United States, which is expected to be a randomized trial of between 1,800 and 2,000 patients. Pursuant to our clinical and regulatory strategy, the timing of this trial will be determined based on our capacity to manage multiple trials concurrently and the availability of funding. Additionally, we intend to design and conduct follow-on trials of *Fantom* for regulatory and marketing purposes.

Manufacturing

Manufacturing of medical devices is subject to strict quality requirements imposed by regulators, referred to as Good Manufacturing Practices ("GMPs"). We intend to continue to follow GMPs for production of our scaffolds as we are responsible for the quality and compliance of products we introduce in the clinic and, if we successfully commercialize our product, to the market. Accordingly, we utilize a quality management system that is designed to comply with the ISO standards and U.S. Food and Drug Administration ("USFDA" or "FDA") regulations that govern medical device products in areas such as design, manufacture, testing, product and product component release, and raw material receipt and control. We have developed controlled methods and processes for the consistent manufacture of our products. All key outsourcing partners are ISO-certified to help ensure a continual supply of high quality components.

Our operations take place at our facility in San Diego, California, an approximately 37,000 square foot building dedicated to development and manufacturing under a lease that expires in January 2018. The facility includes laboratories for polymer development and synthesis, chemistry, engineering, and product assembly, including clean rooms and quality control laboratories. Our facility has the capacity to produce the quantities of *Fantom* that will be needed for initial commercial sales and for ongoing clinical trials; the facility is currently certified to ISO 13485:2012, with such certification made by an independent third-party. We may expand our manufacturing beyond our current facility to allow for continued sales growth after our initial product introduction in Europe.

We develop and test our products, including the underlying manufacturing capabilities and processes, with a goal to sell commercially. We believe our manufacturing methods and processes for *Fantom* have been fully developed and tested and we are ready for commercial production. To help ensure that we produce a high quality product that will be commercially competitive, however, we plan to continue to make improvements to our manufacturing processes.

The process to manufacture *Fantom* involves seven main steps, some of which involve a degree of manual intervention and some of which are outsourced. Our strategy to outsource selected processes is intended to minimize capital and operating costs while maintaining required quality standards. The manufacturing steps are as follows:

- ***Polymer Manufacture*:** Performed at our facility.
- ***Polymer Tube Fabrication*:** Performed at our facility.
- ***Lasing of Polymer Tubes*:** Outsourced to a domestic third party.
- ***Drug Coating*:** Drug purchased from a foreign supplier; coating prepared and applied at our facility.
- ***Catheter System*:** System purchased from a domestic supplier; coating purchased from a foreign supplier.
- ***Assembly, Mounting on the Catheter, Quality Assurance, and Packaging*:** Performed at our facility.
- ***Sterilization*:** Outsourced to a domestic laboratory.

Although certain materials used in our product are purchased and certain portions of our manufacturing process are completed by external parties, we generally have not entered into supply agreements with any third parties. While we are not obligated to make purchases, we also are not guaranteed supply of components, which may result in supply interruptions. We intend to continue to assess our need for supplier contracts and will secure such contracts as we consider necessary. Additionally, we currently source some of our component materials and many of our contracted services from single suppliers. While we have identified alternative suppliers, and we believe there are a number of qualified suppliers readily available, any interruption or delay in obtaining products from our currently used suppliers, or our inability to obtain products from alternative sources or at acceptable prices in a timely manner, could impair our ability to meet the demand for our products.

Competition

The coronary stent industry is highly competitive. Many of our competitors have significantly greater financial resources, human resources, and expertise in research and development, manufacturing, preclinical and clinical testing, regulatory applications, and marketing of approved products than we do. Many of these competitors also have developed worldwide distribution channels and have more established reputations with our target customers. These competitors include Abbott Vascular, Boston Scientific Corporation ("BSC"), and Medtronic. Smaller or early-stage companies may also prove to be competitors to us, particularly if they enter into collaborative arrangements with the large and established companies. These companies compete with us in recruiting and retaining qualified scientific, production, sales, and management personnel. They also compete with us in establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business. As a result, we cannot provide assurances that we will be able to compete effectively against these competitors or their products.

Although the field of interventional cardiology is extremely competitive with requirements for high-performance products, we believe interventional cardiologists historically have been rapid adopters of new technology. While physicians may recommend alternative treatments such as drug therapy, bypass surgery, angioplasty, or bare metal stenting, we expect the primary competition for our products to be drug-eluting stents and other bioresorbable scaffolds. The market leaders for metal stents (bare and drug-eluting) are Abbott, BSC, and Medtronic. Of the three, only Abbott currently offers a bioresorbable scaffold.

Abbott began selling its *Absorb* bioresorbable scaffold outside of the United States approximately four years ago and received FDA approval in July 2016; it is currently available in approximately 100 countries worldwide and generated an estimated $127.0 million in revenue in 2016. *Absorb* is made with a polylactic acid ("PLLA") polymer. In November 2016, Abbott released three-year data from its ABSORB II trial that showed a 1.8 percent rate of very late stent thrombosis; these finding are creating a cause for concern among physicians and explanations are being sought. Abbott is currently enrolling 3,000 patients in a follow-on trial to evaluate angina rates at one year and target lesion failure rates between one and five years. Abbott's ability or inability to obtain reimbursement for, and secure adoption of, the *Absorb* scaffold may play a significant role in the market adoption for bioresorbable scaffolds over the next several years.

In May 2013, Elixir Medical announced CE Mark approval of their *DESolve* bioresorbable scaffold, also a PLLA polymer stent; their first commercial implant was performed in January 2014. Additionally, during 2014, Elixir received CE Mark approval for a second, thinner strut bioresorbable scaffold that we believe they are not marketing. In November 2016, Elixir indicated they had received CE Marking of a third bioresorbable scaffold with a size between the other two and that planned commercialization of that mid-sized device is first quarter of 2017. Elixir's ability or inability to obtain reimbursement for, and secure adoption of, its scaffolds may further define the marketing potential for bioresorbable scaffolds.

In June 2016, Biotronik, a Germany entity, received CE Mark for its *Magmaris* magnesium bioresorbable scaffold. Biotronik has initiated a controlled and limited launch of this product and their ability or inability to obtain reimbursement for, and secure adoption of, their magnesium scaffolds may further define the marketing potential for bioresorbable scaffolds.

A number of other companies are developing bioresorbable scaffolds; they have not yet obtained regulatory approval to sell their products. These include Amaranth Medical, Boston Scientific Corporation, and Meril Life Sciences, all of which we believe utilize PLLA polymers for their scaffolds. These companies are conducting clinical trials and have, or will, release clinical data at industry conferences.

Because of the prevalence of coronary artery disease and the resulting market opportunities, competitors continue to dedicate significant resources to promote their products. New product developments that could compete with us are likely as this industry is characterized by extensive research efforts and technological progress. Accordingly, competitors may develop technologies and products that are safer, more effective, easier to use, or less expensive than ours. We believe our success is likely to be driven by, and depends on, our ability to innovate, manufacture in commercial quantities, obtain regulatory approvals and reimbursement, and successfully market and sell our products. We expect to encounter potential customers who, due to existing relationships with our competitors, are committed to or prefer the products offered by these competitors. To compete effectively, we must demonstrate that our products are attractive alternatives to other devices and treatments by differentiating our products on the basis of safety, efficacy, performance, ease of use, brand and name recognition, reputation, service, and cost-effectiveness.

Research and Development

Since inception, we have devoted a significant amount of resources to develop our technology. Our research and development expenses, which include the costs to conduct our human clinical trials, were $14.3 million in 2014, $16.8 million in 2015, and $18.2 million in 2016. We expect our research and development expenditures to decrease in 2017 as we dedicate a significant portion of our resources to the commercialization of *Fantom*. We expect our research and development expenses to increase once we've successfully established commercial sales of our product, as we then redirect resources toward determining the feasibility of additional technologies and begin new product development, and as we initiate future clinical trials of *Fantom*, including the planned FDA trial when, and if, we receive regulatory approval of the trial and have secured funding for the trial.

Sales and Marketing

We intend to sell our products once we receive full regulatory approval. We believe we could initiate European sales of *Fantom* during the second quarter of 2017. As a pre-revenue company, we have had a limited sales and marketing focus and have not been in a position to commercially distribute products. Accordingly, we have been working to determine our sales and marketing strategies, determine and arrange our distribution options, and identify the resources needed to carry out our strategies.

Since we will not know until later in 2017 whether BSC will elect to exercise their option to distribute under the Distribution Option Agreement (see "— Distribution and License Agreements" below), and even if they do elect, whether we will be successful in negotiating distribution terms, we have begun to build a small direct sales solution. We intend that our sales force will initially focus on a small number of targeted accounts to drive adoption and prove the commercial viability of *Fantom*. We plan a broader roll-out following the initial sales efforts, and once we know the outcome of the BSC distribution option. If BSC does ultimately distribute, we intend to retain our sales force for additional product and clinical support. If BSC does not ultimately distribute our products, we may sell our products through a combination of independent distributors and direct sales.

Generally, our planned targeted roll-out will occur as follows:

- ***Initial Markets*:** The EU will be our initial commercial market target since the CE Marking is our first planned regulatory approval.
- ***Follow-on Markets*:** Other countries that accept the CE Mark, including Australia and many countries in the Middle East, will be our second commercial market targets. Countries that require additional clinical trials will follow, including India and Japan.
- ***United States*:** The United States will be a later commercial market since completion of FDA trials and premarket approval ("PMA") requires extensive, and expensive, clinical trial results.

We have considered many aspects of commercial sales, including product pricing. In most countries, a significant portion of medical expenses is covered by third-party payors. Reimbursement in the EU varies by country and often by hospital. We believe that numerous hospitals have established budgets to purchase coronary stents and the purchase decision is often driven by the interventional cardiologists.

We will continue to revise and update our sales and marketing plans based on market changes, competitor activities, and timing of regulatory approval.

Intellectual Property

We rely on a combination of patents, trade secrets, and copyrights, together with non-disclosure and confidentiality agreements, to establish and protect our proprietary rights in our technologies. Our patents and patent applications covering the fundamental technology underlying our "slide and lock" design have been developed internally, while the technology underlying our polymer has been either licensed or developed by us.

As of February 15, 2017, on a worldwide basis, our patent portfolio comprised approximately 290 issued and pending U.S. and foreign patents that we own directly or for which we are the licensee. Our latest patent expiration date with respect to these patents is 2036. We have been issued 56 U.S. patents and have nine U.S. patent applications that are pending examination or have been allowed by the United States Patent and Trademark Office. For these 65 technology patents and applications, we have sought intellectual property protection outside the United States and have been granted 192 foreign patents and have 34 pending foreign applications. We do not know if any of our pending patent applications will be issued, nor do we know whether our patents, if issued, will adequately cover our technology or will be able to be successfully enforced. Even if valid and enforceable, our patents may not be sufficiently broad to prevent others from inventing a scaffold like ours, despite our patent rights. We have received no communications from third parties concerning the patentability, validity, or enforceability of our patents or patent applications. We believe that the remaining lives of our patents provide adequate time to generate revenues from sales, subject to timing of the clinical pathway and regulatory approvals.

We actively monitor our intellectual property position and review new developments to identify prudent extensions to our patent portfolio to ensure protection of our key technology, as well as to maximize our defensive strategy through the coverage of similar technology developments. We employ an in-house patent attorney and utilize external patent counsel to assist us in managing our intellectual property portfolio. The stent industry has been subject to numerous patent filing and infringement lawsuits. Whether we would, upon commercialization, infringe any patent claim will not be known with certainty unless and until a court interprets a patent claim in the context of litigation. If an infringement allegation is made against us, we may seek to invalidate the asserted patent claim and may allege non-infringement of the asserted patent claim. In order for us to invalidate a U.S. patent claim, we would need to rebut the presumption of validity afforded to patents issued in the United States with clear and convincing evidence of invalidity, which is a high burden of proof. To date, none of our patents or patent applications has been subject to reexamination, interference, or other legal challenge.

We require all employees to sign confidentiality and invention assignment agreements under which they are bound to assign to us inventions made during the term of their employment. These agreements prohibit our employees from using, disclosing, or bringing onto the premises any proprietary information belonging to a third party. In addition, our consultants are required to sign agreements under which they must assign to us any inventions that relate to our business. These agreements also prohibit our consultants from incorporating into any inventions the proprietary rights of third parties without informing us. It is our policy to require all employees to document potential inventions and other intellectual property in laboratory notebooks and to disclose inventions to patent counsel in written form.

We also rely on confidentiality restrictions and trade secrets to protect our technology. We generally require our consultants and other parties who may be exposed to our proprietary technology to sign non-disclosure agreements which prohibit such parties from disclosing or using our proprietary information except as may be authorized by us.

Distribution and License Agreements

BSC Agreement

In 2007, we entered into a Distribution Option Agreement with Boston Scientific Corporation ("BSC") in which we granted BSC an option to negotiate country-by-country or worldwide exclusive rights to sell, market, and distribute our scaffolds. If BSC exercises its option, we will negotiate to enter into a mutually acceptable distribution agreement that will include the following provisions: (i) the agreement shall last at least five years; (ii) the transfer price for our products shall be 50 percent of BSC's average selling price for such products; (iii) other than the transfer price, BSC shall not be required to pay us for the sale, marketing, or distribution of such products; (iv) we shall meet all legal and regulatory requirements, as well as BSC quality standards, with respect to the design, development, and manufacturing of products; (v) BSC shall have sole discretion over all marketing and sales decisions relating to the products; and, (vi) BSC shall be the exclusive distributor of such products and distribution becomes non-exclusive in locations where BSC sells, markets, or distributes a directly competitive stent product. If we are unable to agree on the terms of a distribution arrangement within 90 days after BSC exercises its option to distribute, then we may sell, market, and distribute our products to a third party, provided that the terms of an offer to, and any definitive agreement with, a third party are not on terms more favorable than those offered to BSC.

BSC's option to distribute on a worldwide basis terminates 90 days after we deliver clinical data to BSC that contains all the following: (i) imaging, death, acute myocardial infarction, target lesion revascularization, and stent thrombosis data from one year follow-up of at least 200 patients implanted with our resorbable drug-coated scaffolds; (ii) core lab acute gain, late loss, and binary angiographic restenosis data from eight- to nine-month angiographic follow-up of at least 100 of the implanted scaffolds; and, (iii) eight- to nine-month optical coherence tomography of at least 40 of the implanted scaffolds. We expect to be able to provide this clinical data to BSC during the second or third quarter of 2017. If BSC has elected country distribution, but does not elect worldwide distribution prior to expiration of their worldwide right, they may continue to distribute in countries under the terms of distribution agreements that had been previously negotiated and agreed.

Under the Distribution Option Agreement, we have also agreed not to take certain actions that would prevent BSC from exercising its distribution option; however, we may market, sell, or distribute any product on a non-exclusive basis in any country or territory where BSC directly competes with our product. In addition, if we receive regulatory approval for a product in any country or territory outside the United States prior to our FDA submission, and BSC does not exercise its distribution option within 90 days following written notice of the approval, then we may sell, market, and distribute the product in that foreign country or territory, provided however, that any distribution or other arrangements we make must be terminable without cost to BSC on no more than 90 days' written notice.

Rutgers License

In July 2010, we entered into an Exclusive License Agreement ("License") with Rutgers, The State University of New Jersey ("Rutgers") that superseded our 2004 Exclusive License Agreement with Rutgers. Under the 2010 License, we have an exclusive, worldwide right, including sublicensing rights, to develop and commercialize products that utilize certain polymers in the vascular field. Terms of the License require us to pay annual license fees until a product is commercially sold in a major market. Also, in order to maintain our rights under the License, we must achieve certain development and commercialization milestones. The term of the Rutgers License continues until the expiration of the last to expire of the patents licensed to us, which we believe is 2036. The License allows Rutgers to sublicense certain technology that Rutgers invented, we jointly invented with Rutgers, or that we solely invented, outside our field of use. If Rutgers sublicenses inventions and improvements solely owned by us, Rutgers will pay us a percentage of all income and consideration Rutgers receives from such sublicenses.

The royalties due under the Rutgers License vary depending upon type of product, use of product, stage of product, location of sale, and ultimate sales volume and price. We believe the royalties will range from a minimum of approximately $15 to a maximum of approximately $50 per product sale, with license provisions for escalating minimum royalties that could be as high as $2.2 million per year. Additionally, in the event we receive certain milestone payments related to this technology, the license requires that up to 40 percent of the milestone amount be paid to the licensors. The license requires annual licensing payments of $175,000 until the underlying technology has been commercialized and royalties would be due. The license also requires other payments to occur during commercialization that could total $950,000, payment of $350,000 upon a change in control of ownership, payments of up to $300,000 annually to extend regulatory filing periods related to certain technology (of which, payments totaling up to $250,000 per year during the years 2016, 2017, and 2018 may be deferred to January 1, 2019), and payment of patent filing, maintenance, and defense fees.

Third-Party Reimbursement

In most countries, a significant portion of patient medical expense is covered by third-party reimbursement, consisting of both government-funded and private insurance programs. While each payor develops and maintains its own coverage and reimbursement policies, the vast majority of payors have established policies for stents. We believe that our products generally will fall within existing reimbursement guidelines, or within new reimbursement guidelines that are being established by competing bioresorbable scaffold companies, although some refinement in policies may be needed for our products. Before we can obtain reimbursement for our products in Europe, Australia, Japan, India, China, or the United States, we will need to obtain appropriate regulatory approvals for product sales.

There are many reimbursement programs through private payors as well as government programs. In some countries, government reimbursement is the predominant program available to patients and hospitals. While the vast majority of countries have existing reimbursement for stents, a number of countries may require us to gather additional clinical data before agreeing to coverage and reimbursement for our scaffolds. We intend to complete the requisite clinical studies and obtain coverage and reimbursement approval in countries where it makes economic sense to do so.

In certain regions, such as Europe, innovative pricing and reimbursement agreements are used to balance the interests and objectives of medical technology manufacturers, payors, parties assessing health technology, clinicians, and patients. Payors are increasingly using health technology assessors/assessments, or "HTAs," to evaluate the cost-effectiveness of new technologies and to determine reimbursement. Risk sharing and value-based reimbursement schemes are increasingly being employed. HTAs typically have two elements: clinical effectiveness and cost effectiveness. Some countries in Europe have national HTA (for example, France, Germany, and Sweden) and others have regional ones (such as, Italy, Spain, and the United Kingdom). Some manufacturers who proactively propose such schemes to HTAs may gain competitive advantage. Each country within Europe has its own system of pricing and reimbursement for medical devices and products.

Government Regulation

United States

Our products are considered combination products because they comprise two regulated components in a single product: a drug and a medical device. In the United States, the FDA assigns the review of a combination product, based on the product's "primary mode of action," to one of its centers, such as the Center for Drug Evaluation and Research ("CDER") or the Center for Devices and Radiological Health ("CDRH"). The center to which the product is assigned will have primary jurisdiction over the PMA of the product.

Because the primary mode of action for our products is that of a medical device, we anticipate that when, and if, we apply for approval in the United States, our products will be reviewed by the FDA under the Federal Food, Drug, and Cosmetic Act with CDRH having primary responsibility for review and regulation of our products. As a result, we expect our clinical trial of drug-eluting scaffolds to be conducted under an IDE application in accordance with 21 CFR Part 812. However, it is possible the FDA may assign our products to CDER. Based on FDA precedent and jurisdictional statements to date, we believe that the drug component of our products will not require separate FDA approval and that it will be reviewed in the context of our PMA, with CDRH consulting with CDER as needed. Even if the FDA assigns our products to be regulated by CDER, the drug component of the product will, in all likelihood, not require separate CDER approval but will be evaluated in the context of our PMA as a whole, with application of drug standards as deemed appropriate by FDA based on the circumstances.

FDA regulations govern the following activities that we and our suppliers, licensors, and partners perform and will continue to perform to ensure that the products we distribute domestically or export internationally are safe and effective for their intended uses:

- product design, development, and testing;
- product manufacturing and production;
- product safety;
- product labeling and storage;
- record keeping;
- premarket approval;
- advertising and promotion;
- product sales and distribution; and,
- postmarketing requirements including monitoring for and reporting of adverse events and malfunctions.

***Clinical Trials*:** Clinical trial data is almost always required to support a PMA application. Clinical trials of our scaffolds in the United States will require submission of an IDE application, supported with appropriate data, and approvals by the FDA and institutional review boards. Clinical trials must be conducted in accordance with applicable regulations and must adhere to extensive record keeping and reporting requirements. We, the FDA, or the institutional review board at a clinical site may suspend a clinical trial at any time for any reason, including a belief that the risks to the patients in a trial outweigh the anticipated benefits. U.S. clinical trials of the scope we anticipate for our products can typically take years to complete and may encounter challenges at any stage that may require a trial to be halted.

***Premarket Clearance and Approval Requirements*:** The FDA classifies medical devices into one of three classes. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices or devices not substantially equivalent to a previously cleared 510(k) device, are placed in Class III, requiring PMA. Our scaffolds are Class III devices and will require FDA approval. A PMA must be supported by extensive data, including but not limited to, technical, preclinical, clinical, manufacturing, and labeling to demonstrate to the FDA's satisfaction the safety and efficacy of the device. A PMA must also contain a full description of the device and its components and a full description of the methods, facilities, and controls used for manufacturing of the device.

***Product Modifications*:** New PMAs or PMA supplements are required for all significant modifications to a manufacturing process, labeling, use, or design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as an initial application, except the supplement is limited to information needed to support the device changes. Certain modifications may not require as extensive clinical data or the convening of an advisory panel.

***Pervasive and Continuing Regulation*:** When a device is approved for sale, numerous regulatory requirements apply to the commercial product. These include:

- Good Manufacturing Practices ("GMP") and Quality System Regulations ("QSR") that require manufacturers, including third-party suppliers, to follow stringent design, testing, control, documentation, and other quality assurance procedures during all aspects of the manufacturing process;
- labeling and promotion regulations, which limit the manner in which companies can market their products and impose requirements for content and format of labeling and promotional materials, and FDA prohibitions against promotion of products for unapproved or "off-label" uses;
- medical device reporting regulations, which require manufacturers to report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- post-market surveillance regulations, which will apply when necessary to protect the public health or to provide additional safety and efficacy data for the device; and,
- specific conditions of approval that may be imposed on a specific PMA.

The FDA has broad post-market and regulatory enforcement powers. When, and if, we are approved to sell in the United States, we will be subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Health Services to determine our compliance with QSR and other regulations. The manufacturing facilities of our suppliers may also be inspected by the FDA or other regulatory authorities to determine their compliance with GMP regulations. The FDA monitors marketing and promotional activities for matters of concern, and may receive complaints from competitors or other third parties regarding our products.

In addition, discovery of previously unknown problems with a medical device, manufacturer, or facility may result in restrictions on the manufacturing or marketing of an approved device, including costly recalls or withdrawal of the device from the market. The FDA also has the authority to require repair, replacement, or refund of any medical device that has been manufactured or distributed. Failure to comply with applicable regulatory requirements may result in enforcement action being taken by the FDA, which may include any of the following sanctions:

- inspectional observations or warning letters, identifying concerns that must be corrected;
- fines, injunctions, consent decrees, and civil penalties;
- recall or seizure of our products;
- operating restrictions, partial suspension, or total shutdown of production;
- refusing our requests for PMA or new intended uses;
- withdrawing PMA approval; and/or,
- criminal prosecution.

***Fraud and Abuse*:** We are directly, or indirectly through our business associates, subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the False Claims Act. These laws may impact, among other things, our proposed sales and marketing programs. The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving, or providing payments, directly or indirectly, in exchange for, or to induce, either the referral of an individual, or the furnishing or arranging for a good or service, for which payment is made under a federal program such as Medicare or Medicaid. This statute is broad and prohibits many arrangements and practices that are lawful outside the health care industry. Recognizing that this statute is broad and may technically prohibit many innocuous or beneficial arrangements, Congress authorized a series of safe harbor regulations. The safe harbors set forth provisions that give some assurance to health care providers and others that they will not be prosecuted. The failure of a transaction or arrangement to fit precisely within a safe harbor does not necessarily mean that it is illegal or that prosecution will be pursued; however, conduct and arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by enforcement authorities. All parties to a prohibited transaction may be prosecuted, whether any party sought or received payment from any federally funded program. Penalties for violations of the Anti-Kickback Statute include criminal and civil sanctions such as fines, imprisonment, and possible exclusion from Medicare, Medicaid, and other federal health care programs. Many states have adopted laws similar to the federal statute.

The U.S. False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim or using false statements to obtain payment from the federal government. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly referred to as "whistleblowers," may share in any amounts paid to the government in fines or settlement. The frequency of filing of qui tam actions has increased significantly in recent years, causing more health care companies to defend False Claims. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties ranging from $5,500 to $11,000 for each separate False Claim. Various states have also enacted laws modeled after the federal False Claims Act. Similarly, the federal Civil Monetary Penalty statute imposes penalties of up to $50,000 per violation for filing certain types of proscribed claims or engaging in prohibited acts.

In addition to the laws described above, the Health Insurance Portability and Accountability Act of 1996 created two new federal crimes: health care fraud and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including those of private payors. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from government sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of, or payment for, health care benefits, items, or services. A violation of this statute is a felony and may result in fines or imprisonment.

The penalties for violating any of the laws described above or other applicable state and federal fraud and abuse laws, include civil and criminal penalties, damages, fines, exclusion from government health care programs, and the operating sanctions.

***Patient Protection and Affordable Care Act*:** Our operations may be impacted by the federal Patient Protection and Affordable Care Act of 2010, as modified by the Health Care and Education Reconciliation Act of 2010, which is referred to as the Affordable Care Act ("ACA"). Among other things, the ACA imposed a 2.3 percent excise tax on sales of medical devices sold in the United States and intended for human use; such excise tax is suspended through 2017 and we are unable to predict whether the suspension will be continued beyond 2017. There is no exemption for small companies. If not permanently eliminated, we believe the tax will apply to our scaffolds when we begin commercial sales of our products in the U.S. The ACA also requires (under what are referred to as "Sunshine" or "Open Payments" requirements) manufacturers of covered devices to report details regarding certain payments and other financial arrangements with physicians and teaching hospitals. These reporting provisions preempt state laws that require reporting of the same information, but not those that require reports of different or additional information. Failure to comply results in significant civil monetary penalties. We expect compliance with the ACA to impose significant administrative and financial burdens on us.

***Environmental Regulation*:** We are subject to numerous federal, state, and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous substances. Some of these laws require us to obtain licenses or permits to conduct our operations. We have numerous policies and procedures in place to ensure compliance with these laws and to minimize the risk of occupational exposure to hazardous materials. We do not expect our operations to produce quantities of hazardous or toxic waste or radiation that would require the use of extraordinary disposal practices. Although the costs to comply with these laws and regulations have not been material, we cannot predict the impact of new or amended laws or regulations or any changes in the way existing and future laws and regulations are interpreted or enforced, nor can we ensure we will be able to obtain or maintain any required licenses or permits.

International

International sales of medical devices are subject to foreign governmental regulations, which vary substantially from country to country. The time required to obtain clearance or approval by a particular country may be longer or shorter than that required for FDA clearance or approval, and the requirements may be different. We expect to be subject to foreign regulations prior to the time we would be subject to the United States regulations.

The primary regulatory environment in Europe is the EU, which consists of 28 countries. Three members of the European Free Trade Association, Iceland, Norway, and Liechtenstein have voluntarily adopted medical device laws and regulations that mirror those of the EU. Other countries, such as Switzerland, have entered into Mutual Recognition Agreements ("MRA") and allow the sale of medical devices that meet EU requirements.

The EU has three core directives concerning medical devices: Medical Devices Directive ("MDD"), In-Vitro Diagnostic Medical Devices Directive, and Active Implantable Medical Devices Directive. Also, the European Committees for Standardization have set forth voluntary standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Prior to marketing or using a medical device in the EU, it must undergo a conformity assessment process as set forth in the relevant medical devices directives (*Conformité Européenne*, or "CE"). Once a medical device is approved for CE Marking, it can be commercially distributed in the EU, the member states of the European Free Trade Association, and countries with MRAs. The method of assessing conformity varies depending on the type and class of product, but normally involves a self-assessment by the manufacturer and an assessment by a third-party notified body, an independent and neutral institution appointed in an EU country. The assessment may also include an audit of the manufacturer's quality system and specific testing of the device for compliance with ISO 13485, which are voluntary harmonized standards. Each EU member country implements the MDD into national laws that are enforced by a competent authority in that country. For example, the authority in the United Kingdom is the Medicines and Healthcare Products Regulatory Agency. In addition to obtaining CE Marking, many EU countries require completion of a formal registration process before products can be commercially sold. This in-country process may delay our ability to commercialize after obtaining CE Marking.

Before any medical device can be supplied within Australia, it must be included on the Australian Register of Therapeutic Goods and comply with the provisions of the Australian Therapeutic Goods Act. While much of the documentation produced for obtaining the CE Marking in Europe can be used to obtain registration in Australia and the regulatory requirements are similar to European regulations, compliance generally requires the following:

- full technical documentation demonstrating compliance to all relevant standards and regulations;
- full quality assurance certification to the key international standard; and,
- the ability of the manufacturer to undertake post market surveillance processes.

Employees

As of December 31, 2016, we had 59 employees, 58 of whom were full-time. A total of 50 were in research and development and nine were in general and administrative functions. We have never had a work stoppage and none of our employees are covered by collective bargaining agreements or are represented by a labor union.

Executive Officers

Our executive officers and their ages and backgrounds as of February 15, 2017, are as follows:

Regina E. Groves, age 58, was appointed as our Chief Executive Officer in September 2015. Her background encompasses over 30 years in medical devices, executive leadership, and financial management. Prior to joining REVA, from 2008, Ms. Groves served as Vice President and General Manager of AF Solutions, Cardiac Rhythm and Heart Failure division of Medtronic, a leading global medical technology company. Previously she held other senior positions at Medtronic, McKinsey & Company, Inc., and several health care companies. Ms. Groves received her M.B.A. from Harvard Graduate School of Business Administration and her B.S. in Pharmacy from the University of Florida.

Robert K. Schultz, Ph.D., age 60, has served as our President and Chief Operating Officer since 2003. His background comprises over 30 years in pharmaceutical, medical device, and combination products. Prior to joining REVA, Dr. Schultz held positions of Vice President of Research and Development and Vice President of Technology Strategy and Licensing for Dura Pharmaceuticals, a specialty respiratory pharmaceutical and pulmonary drug delivery company, and Research Specialist for 3M Pharmaceuticals, a diversified international technology company. He obtained his Ph.D. in Pharmaceutics and his B.S. in Pharmacy from the University of Minnesota.

Katrina L. Thompson, age 58, has served as our Chief Financial Officer and Corporate Secretary since 2003. Her experience encompasses over 30 years in accounting, finance, and corporate administration. Prior to joining REVA, Ms. Thompson held senior financial positions in the telecommunications, commercial real estate development, commercial nursery, and high technology industries. She spent the early part of her career as an auditor with Price Waterhouse, a provider of tax, audit and advisory services. Ms. Thompson received her B.S. in Business Administration from San Diego State University.

Jeffrey A. Anderson**,** age 50, has served as our Senior Vice President of Clinical and Regulatory affairs since December 2013 and as our Vice President of Clinical and Regulatory affairs since February 2011, a position he previously held at REVA from 2004 to 2008. He has over 25 years of experience in the medical device industry, including his positions of Vice President of Clinical & Regulatory Affairs and Vice President of Research & Development for Neomend, a biomedical device company engaged in the development and commercialization of surgical wound healing products, where he served from October 2008 through February 2011. Additionally, Mr. Anderson has held senior positions at Abbott Vascular, Jomed, CRS Clinical Research, and Medtronic. He received his B.S. in Physics from California State University at Fullerton.

Richard M. Kimes**,** age 55, has served as our Senior Vice President of Operations since January 2016. His background comprises over 25 years of medical device operations. Prior to joining REVA, Mr. Kimes was President of Advantage Consulting, a firm specializing in operations management, since December 2013. From May 2013 to December 2013, he was Executive Vice President of Operations for Elixir Medical Corporation, a stent company. Prior to that, from 2009 through May 2013, he was Senior Vice President of Operations for Volcano Corporation, a medical imaging equipment company. He has also held senior positions with mNemoscience GmbH, Guidant Corporation, IMED Corp., and Becton Dickinson Corporation, all medical device companies. Mr. Kimes received his B.S. in Mechanical Engineering from the University of Utah.

Item 1A. Risk Factors

You should carefully consider the risks described below and all of the other information set forth elsewhere in this Form 10-K, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in evaluating our business and our prospects. If any of the events or developments described below occurs, our business, financial condition, or results of operations could be negatively affected. In that case, the market price of our CDIs or common stock could decline.

Risks Related to Our Business

Our available cash is limited and we will need additional funding to continue operations; there can be no assurance that we will be able to raise funds. If we are unable to raise additional funds, there would be a significant adverse effect on the Company, including our ability to remain in business.

As of December 31, 2016, we had cash of approximately $6.7 million, which we believe will be sufficient to fund our operating and capital needs through the first quarter of 2017. As of December 31, 2016, we had current liabilities of approximately $98.8 million, of which approximately $32.2 million could become due and payable in 2017. Although our convertible notes payable mature in November 2019 and do not require installment payments, the holders of the Notes have a one-time right to redeem them on June 30, 2017 for their face value plus accrued interest, a total of approximately $30.3 million. While we have the ability, upon receipt of CE Marking and listing of our securities on NASDAQ, to cause the notes to be converted to equity prior to a redemption event, if the noteholders were to collectively exercise the early redemption option, which we believe they will not do, and if the notes were not otherwise converted, the Company would be unable to make the redemption payment.

To fund our ongoing operating and capital needs, we have been actively pursuing a financing that we intend to complete by March 31, 2017. There can be no assurance, however, that we will be successful in completing a financing on a timeframe that coincides with our cash needs, on acceptable terms, or completing it at all. Additionally, since we do not currently anticipate raising funds to redeem the Notes, if we were required to redeem the notes on June 30, 2017 and they could not be converted, we would most likely be unable to repay the notes, or, if we were able to make the redemption payment, we would not have sufficient funds for ongoing operations.

If we are unable to secure additional capital when needed or if we are required to redeem the notes and do not have the cash resources to make the redemption payment, we may be required to reduce 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 we default on any material provision of our convertible Notes, there could be a significant adverse effect on the Company, including our ability to remain in business.

We issued $25.0 million in convertible notes in November 2014, bearing interest at 7.54 percent per annum, with no interest required to be paid until redemption. While the notes have a five-year maturity, their terms allow the noteholders a one-time election to be repaid in full (face value plus accrued interest) on June 30, 2017, or at any time we become in default of the notes. The notes are convertible into common stock at any time. The conversion rate of the notes of $2.17275 per share is favorable for the noteholders, as it is below the $7.89 market price of our common stock as of December 31, 2016.

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

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

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

We are a pre-revenue stage medical device company. We have incurred net losses since our inception, including net losses of approximately $51.0 million, $82.6 million, and $54.1 million for the fiscal years ended December 31, 2014, 2015, and 2016, respectively. As of December 31, 2016, our accumulated deficit was approximately $389.2 million. Currently, we have no products approved for sale in any jurisdiction. We expect to continue to incur significant operating losses and cash outflows through at least 2017 and into 2018 as we incur costs associated with:

- following patients in our current clinical trials and initiating additional trials of our *Fantom* scaffold;
- seeking regulatory approvals in the EU, Australia, India, Japan, and United States for *Fantom*;
- 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 in order 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 payable if they were to become due and payable before their maturity date or conversion to common stock. 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 attain profitability. If we do achieve profitability, we may not be able to sustain it.

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 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. Even if we are successful in our current efforts to raise capital, we may need to raise additional capital in the future to achieve net cash inflows.

Any current or future equity or debt financing, if available at all, may be on terms that are not favorable to us. Equity financings could result in dilution to our existing securityholders, and the securities issued in any financings may have rights, preferences, and privileges that are senior to those of our existing securityholders. 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.

Our ability to generate revenue depends upon receipt of regulatory approval and successfully commercializing our scaffolds, which we may be unable to accomplish.

While we have applied for European CE Marking of our *Fantom* scaffold, it has not yet been approved for sale. Once approved, if approved, our products will also require significant marketing and distribution efforts before they can generate any revenue. Our efforts to generate revenue may not succeed for a number of reasons including:

- we may not receive regulatory approvals in the markets we seek;
- our products may not be accepted in the marketplace by physicians and patients;
- by offering only one product, we would not have the ability to bundle products to drive sales;
- physicians may not receive adequate coverage and reimbursement for procedures using our products;
- we may not be able to manufacture or distribute our products in commercial quantities at an acceptable cost;
- new product introductions by our competitors or any rapid technological change may make our technology and product candidates obsolete;

- our *Fantom* scaffold may not continue to demonstrate the same safety and efficacy results in the long-term that we have seen in the short-term and, therefore, may not be commercially supported; and,
- we may be sued for infringement of intellectual property rights which could prevent us from manufacturing or selling our products.

We cannot market our products in the EU until we receive a CE Mark or in the United States until we receive a PMA. Our operating plan is based in part on our expectations regarding the timing for receipt of regulatory approvals and if we experience delays in the approval process, or ultimately do not receive approval, we may be unable to reduce our expenditures in a timely manner to compensate for such delay or denial, and we may not have adequate financial or other resources to complete the approval process or continue in business. Accordingly, a significant delay in the regulatory approval process, or a denial of approval, would have a material adverse effect on our ability to successfully sell our products and on our financial condition. We may be required to raise additional financing, including equity or debt financing, to fund our operations, which could be dilutive to existing securityholders or require us to relinquish important rights to our technology or products.

We will depend on our Fantom scaffold's success and factors that negatively impact its sales potential, including failures by our competitors, will adversely affect our business, financial condition, and results of operations.

Since *Fantom* will be our first commercial product, our ability to successfully generate revenues and to consider additional products for commercialization will depend on our ability to market and sell *Fantom*. The degree of market acceptance for this scaffold will depend on a number of factors, including:

- its perceived advantages and disadvantages compared to existing stents and other treatments and technologies;
- its safety and efficacy and the prevalence and severity of any adverse events or side effects;
- its ease of use compared to existing products and competitive treatments and technologies;
- our ability to provide additional clinical data regarding its potential long-term benefits;
- the strength of our sales and marketing initiatives;
- 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; and,
- the selling price and the third-party coverage and reimbursement for procedures using *Fantom*.

If our *Fantom* scaffold does not achieve an adequate level of acceptance by physicians, patients, and health care payors, or if competing bioresorbable scaffolds being marketed ultimately prove to be unsuccessful or cause continuing negative sentiments about bioresorbables, we may not be able to successfully commercialize *Fantom*, generate sufficient revenues, or generate or maintain positive gross margins. Additionally, we may not become profitable, or be able to sustain profitability, and we may not commercialize additional products. Even if *Fantom* does achieve market acceptance, we may not be able to sustain it or otherwise achieve it to a degree that would support the ongoing viability of our operations.

We compete against companies that have longer operating histories, more established or approved products, and greater resources, which may prevent us from achieving market penetration or improving operating results.

Competition in the stent industry is intense. Our products will compete against products offered by substantial, global, public companies, as well as smaller and private companies. Global stent sales are dominated by Abbott, BSC, and Medtronic, who together recorded an estimated 94 percent of the $3.9 billion worldwide stent sales in 2016. All three companies have significantly greater technical, regulatory, financial, manufacturing, and human resources than we do. They also have established reputations, approved metal stents and bioresorbable scaffolds (Abbott), significantly greater name recognition, and distribution channels and sales and marketing capabilities that are well established. Our ability to compete effectively depends upon our ability to distinguish our Company and our products from our competitors and their products. We believe the factors affecting our competitive position include:

- name and brand recognition;
- relationships with physicians and patients;
- the availability of other products and procedures, including bundled product offerings;
- product performance and design;

- product safety and the availability of supporting clinical data;
- sales, marketing and distribution capabilities;
- success and timing of new product development and introductions; and,
- intellectual property protection.

The stent industry has a history of rapid and significant technological change and competition intensifies as technical advances are made. Our competitors may develop and commercialize stents or other medical device or pharmaceutical products that are safer or more effective, have fewer side effects, or are less expensive than products we may develop. For example, development of less-invasive technologies for treating cardiovascular disease could limit the market potential for our scaffolds. We also compete to recruit and retain qualified scientific and management personnel, establish clinical trial sites and patient registrations, and acquire technologies complementary to our programs or advantageous to our business. For all these reasons, we may not be able to compete successfully against current and future competitors.

Product liability claims could damage our reputation or adversely affect our business.

The design, manufacture, and sale of medical devices for human use, particularly implantable life-sustaining devices like our scaffolds, carry inherent risks of product liability and other damage claims. A product liability or other claim against our product, a product recall, or a product misuse, regardless of the ultimate outcome, could require us to spend significant time and financial resources in litigation or to pay damages and could seriously harm our business. We maintain clinical trial and limited product liability insurances; we cannot be certain that such insurance will be sufficient to cover all claims that may be made against us. Our insurance policies generally renew on an annual basis; we may not be able to maintain or increase such insurance on acceptable terms or at reasonable costs. A successful claim brought against us in excess, or outside, of our insurance coverage could seriously harm our business, financial condition, results of operations, and prospects and could also materially and adversely damage our reputation and affect our ability to attract and retain customers, whether or not such claim had merit.

We have limited manufacturing capabilities and personnel, and if we are unable to provide an adequate supply of our scaffolds, we may not be able to meet our commercial demands.

We currently manufacture our scaffolds at our facility in San Diego, California. If we encounter a disruption to the facility, we would have no means to manufacture until we were able to restore our facility or procure alternative facilities. Assuming we receive regulatory approval, we currently have limited resources and have not previously manufactured commercial products. We believe we can manufacture quantities of *Fantom* to support initial sales volumes, but in order to achieve larger volumes or to manufacture additional products offerings, we will need to enhance our production operations. The significant technical and regulatory challenges to increasing manufacturing capacity and efficiency will require additional capital investment and the addition of experienced personnel. We may not successfully enhance our manufacturing in a timely or economical manner, or at all. In addition, we may not receive or continue the necessary regulatory approvals for our manufacturing facilities. If we are unable to manufacture a sufficient or consistent supply, or if our manufacturing processes yield substandard product or do not conform to regulatory standards, our revenues, business, and financial prospects would be adversely affected.

If we are unable to retain or hire key personnel, we may not be able to sustain or grow our business.

Our ability to operate successfully and manage our potential future growth depends upon our ability to attract, retain, and motivate highly skilled and qualified research, technical, clinical, regulatory, sales, marketing, manufacturing, managerial, and financial personnel. We compete for talent with numerous companies, as well as universities and non-profit research organizations. Our future success also depends on the personal efforts and abilities of the principal members of our senior management and scientific staff to provide strategic direction, manage our operations, and maintain a cohesive and stable environment.

Except with respect to our agreements with our Chief Executive Officer, President and Chief Operating Officer, Chief Financial Officer, and Senior Vice President of Clinical and Regulatory Affairs, we have not entered into any employment agreements with our employees, nor do we maintain key person life insurance on any of our senior team. Although we have a stock option plan pursuant to which we provide our key personnel with various economic incentives to remain employed with us, these incentives may not be sufficient to retain them. The loss of key personnel for any reason or our inability to hire, retain, and motivate additional qualified personnel in the future could prevent us from sustaining or growing our business.

BSC has an option to distribute our products. Until we know whether we will enter into distribution with BSC, we will need to develop our own sales force. Any delay or problems associated with developing our own sales force or in executing a distribution agreement with BSC could have a serious impact on our product sales.

We have limited experience in marketing, selling, or distributing products. In December 2007, we entered into an agreement that provides BSC an option to negotiate to be the worldwide, exclusive distributor of our scaffold products. If BSC exercises its option, we are required to negotiate with BSC to enter into a mutually acceptable definitive distribution agreement. If we are unable to agree on the terms of a distribution agreement with BSC, we are limited in our ability to negotiate more favorable terms with any other potential distribution partners.

Since we do not yet know the outcome of distribution by BSC, we have developed a sales and marketing launch strategy that involves engaging a small direct sales force that we would retain for product and clinical support if BSC does enter into distribution of our product, or that would be the basis for our future sales and marketing solution if BSC does not enter into distribution. The development of our own sales and marketing network, especially if it will need to be expanded, requires significant amounts of financial and management resources and we will face a number of risks, including:

- our ability to locate, retain, and interact with foreign sales and marketing professionals and comply with foreign employment and other laws since our initial target markets are outside the U.S.;
- the cost to train and provide regulatory oversight for a marketing or sales force; and,
- our ability to comply with legal and regulatory requirements for product sales.

Any delay or problems associated with a distribution partner or our own sales and marketing force could have a material adverse impact on our sales and our financial performance. Also, any problems associated with compliance could result in enforcement actions, jeopardize our ability to market our products, or subject us to liability, any of which could have an adverse impact on our sales and financial condition.

We intend to commercialize outside the U.S. and will be subject to the risks of operating in foreign markets.

Our research and development operations are located in the United States. We are seeking European CE Marking approval of *Fantom* and intend to seek additional regulatory approvals for our products in the EU, Australia, India, Japan, and elsewhere prior to seeking a PMA in the United States. If and when we expand into these foreign markets, we will be subject to new business risks, including:

- failure to fulfill foreign regulatory requirements on a timely basis, or at all, to market our products;
- availability of, and changes in, reimbursement within prevailing foreign health care payment systems;
- differing laws and regulations, business and clinical practices, and patient preferences in foreign countries;
- difficulties managing foreign relationships and operations, including relationships with foreign partners, sales or marketing agents, or distributors, and the costs of enforcing contractual obligations in foreign jurisdictions;
- limited protection for intellectual property rights in some countries;
- difficulty in collecting accounts receivable and longer collection periods;
- recessions, political instability, and changes in diplomatic and trade relationships in foreign countries;
- currency exchange rate fluctuations; and,
- potentially adverse tax consequences.

If we are successful in introducing *Fantom* or future products into foreign markets, we will be affected by these additional business risks, which may adversely impact our business, financial condition, and results of operations. In addition, expansion into foreign markets imposes additional burdens on our executive and administrative personnel, research and sales departments, and general managerial resources. Our efforts to introduce our current or future products into foreign markets may not be successful, in which case we may have expended significant resources without realizing the expected benefit. Ultimately, the investment required for expansion into foreign markets could exceed the results of operations generated from this expansion.

Risk Factors Related to Regulation

We cannot predict if there will be long-term issues from use of our products in patients. If our products cause adverse or unexpected results, our Company will be significantly negatively impacted.

Even though the results from our clinical trials have been favorable, the long-term use of our products could produce unexpected results. If our *Fantom* scaffold, or any future product, should demonstrate adverse issues such as restenosis, stroke, thrombosis, and/or death, we may need to suspend or terminate clinical trials or cease commercial sales until, and if, we can address the issues. There is no guarantee that we will be able to successfully address and overcome any adverse issues arising from our products, which may significantly impair the product value, as well as the underlying technology value.

Completion of current clinical trials or initiation of future trials could be impacted by regulatory or other factors. Any delay in completing clinical trials could have an adverse effect in bringing products to market.

Our clinical trials could be substantially delayed or prevented by several factors, including the failure of patients to complete the clinical trial or our inability to monitor patients adequately after implant and other factors such as:

- governmental and regulatory delays or changes in regulatory requirements, policies, or guidelines;
- varying interpretation of data by regulatory agencies; and,
- perceived lack of product efficacy during clinical trials.

Any delay in initiating clinical trials, or in obtaining data from the trials, could have an adverse impact on our commercialization timelines, which would have an adverse impact on our ability to generate revenue, which will adversely affect our business, financial condition, and results of operations.

Even with successful data from clinical trials, we may not receive regulatory approval to market and sell our products, which could negatively impact our future prospects.

The process of obtaining marketing approval or clearance from regulatory authorities to market and sell our *Fantom* scaffold or any future products or enhancements or modifications to any products, could:

- take a significant period of time or more time than we expect;
- require the expenditure of substantial resources;
- involve rigorous preclinical and clinical testing; and,
- require changes to our products and/or result in limitations on the indicated uses of the products.

There can be no assurance that we will receive the required approvals from the regulatory authorities or, if we do receive the required approvals, that we will receive them on a timely basis or that we otherwise will be able to satisfy the conditions of such approval, if any. The failure to receive product approvals by the regulatory authorities will have a material adverse effect on our business, financial condition, and results of operations.

We plan to operate in multiple regulatory environments that require costly and time consuming approvals.

We will need to obtain regulatory approval in each jurisdiction in which we intend to commercialize our products. The regulatory requirements will vary from country to country. In addition, the laws and regulations regarding the manufacture and sale of our products will be subject to future changes, as are administrative interpretations and policies of regulatory agencies. If we fail to comply with applicable laws or regulations, we could be subject to enforcement actions. Enforcement actions could include product seizures, recalls, withdrawal of clearances or approvals, and civil and criminal penalties, which, in each case, would harm our business.

We may not meet regulatory quality standards applicable to our manufacturing and quality processes, which could have an adverse effect on our business, financial condition, or results of operations.

Even after products receive marketing approval, they can be withdrawn due to failure to comply with regulatory standards or the occurrence of problems following initial approval. As a device manufacturer, we will be required to demonstrate and maintain compliance with a variety of regulatory requirements. In the EU, we are required to maintain certain ISO certifications in order to sell our products and must undergo periodic inspections by notified bodies to obtain and maintain these certifications. Additionally, suppliers of components and products that we use in the manufacture of our products must also comply with applicable regulatory requirements.

We have received a Certificate of Registration certifying that our Quality Management System complies with the requirements of ISO 13485:2012 and we have undertaken to ensure our suppliers comply with applicable regulatory requirements. In the future, if we or our suppliers fail to comply with a regulation, the relevant regulatory authority may withdraw our approval to market, require a product recall, or take other enforcement action. Compliance is subject to continual review and is rigorously monitored through periodic inspections. If we fail to take satisfactory corrective action in response to an adverse inspection, we could be subject to enforcement actions, including a public warning letter, a shutdown of or restrictions on our manufacturing, delays in approval of a product, refusal to permit the import or export of our products, a recall or seizure of our products, fines, injunctions, civil or criminal penalties, or other sanctions, any of which could cause our business and operating results to materially suffer.

Our operations involve hazardous materials and we must comply with environmental laws and regulations, which can be expensive.

Our research, development, and manufacturing activities involve the controlled use of hazardous chemicals. Our operations also produce hazardous waste products. We are subject to a variety of federal, state, and local regulations relating to the use, handling, storage, and disposal of these materials. We generally contract with third parties for the disposal of such substances. We cannot eliminate the risk of accidental contamination or injury from these materials. We may be required to incur substantial costs to comply with current or future environmental and safety regulations. If an accident or contamination occurred, we would likely incur significant costs to remedy the situation and also may be subject to civil penalties or criminal fines. Current or future environmental regulation may impair our research, development, or production efforts.

If we fail to obtain and maintain adequate reimbursement for our products by third-party payors, there may be no commercially viable markets for our products or the markets may be much smaller than expected.

The markets for our products depend on the availability and levels of reimbursement by governmental and other health care payment systems including private insurance, which vary significantly by country. Government and other third-party payors continually attempt to contain or reduce health care costs by challenging prices charged for products and services and they may attempt to limit coverage and level of reimbursement of new products, such as ours. To obtain reimbursement or pricing approval in some countries, we may be required to produce additional clinical data, which may involve one or more clinical trials, that compares the cost-effectiveness of our products to other available therapies. In addition, the efficacy, safety, performance, and cost-effectiveness of our products in comparison to any competing products may determine the availability and level of reimbursement for our products.

We believe that future reimbursement may be subject to increased restrictions both in the United States and in international markets. Future legislation, regulation, or reimbursement policies of third-party payors may adversely affect the demand for our products and limit our ability to sell our products on a profitable basis. We cannot predict how pending or future legislative and regulatory proposals will influence the manner in which medical devices, including ours, are purchased or covered and reimbursed. If reimbursement for our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, sales of our products would be impaired and our future revenues would be materially adversely affected.

Health care reform legislation could adversely affect our future revenue and financial condition.

In recent years in the United States and other countries, there have been numerous initiatives for reforms affecting the availability of, and reimbursement for, health care services. These initiatives have ranged from proposals that would fundamentally change health care reimbursement programs, to minor modifications of existing programs, to requirements for comparative effectiveness analysis. The ultimate content or timing of any future health care reform legislation, and its impact on medical device companies such as ours, is impossible to predict. If significant reforms are made to the United States or other health care systems, they may have a material adverse effect on our financial condition and results of operations.

Our future operations may also be impacted by the U.S. Affordable Care Act ("ACA"), if it remains in effect, or any replacement health care legislation. Among other things, we believe the 2.3 percent excise tax on sales of medical devices intended for use by humans, which is currently suspended, would apply to our scaffolds when we sell in the U.S. We are unable to predict whether the suspension will be continued beyond 2017 or eliminated entirely.

The ACA also requires (under what are referred to as "Sunshine" or "Open Payments" requirements) manufacturers of covered devices to report details regarding certain payments and other financial arrangements with physicians and teaching hospitals. These reporting provisions preempt state laws that require reporting of the same information, but not those that require reports of different or additional information. Failure to comply subjects the manufacturer to significant civil monetary penalties. Recently, Congress and the new administration have proposed various steps to revise, repeal, or delay implementation of various aspects of the ACA. If the ACA is significantly changed, or repealed, or if any replacement health care legislation is enacted, our business, including our financial results could be negatively impacted. We expect compliance with the ACA, or any future healthcare regulations, to impose significant administrative and financial burdens on us.

We are subject to various federal and state laws pertaining to health care fraud and abuse. Any violations of such laws could result in fines, penalties, or other criminal prosecution. In addition, compliance with these laws may result in significant additional expense to us and limit our ability to commercialize our products.

Our commercial, research, and other financial relationships with health care providers and institutions are subject to various federal and state laws intended to prevent health care fraud and abuse. We are also subject to regulation by other regional, national, state, and local agencies, including the Department of Justice, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies. Violations of any of these laws and regulations could result in penalties or fines being assessed against us, significant additional compliance expense, or even a limitation on our ability to commercialize our products.

The federal Anti-Kickback Statute prohibits the knowing offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid, or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. Many states have similar laws that apply to their state health care programs as well as private payors. Violations of the anti-kickback laws can result in exclusion from federal health care programs and substantial civil and criminal penalties.

The U.S. False Claims Act ("FCA") imposes liability on persons who, among other things, present false or fraudulent claims for payment by a federal health care program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, including services that are not medically necessary. The FCA includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share in a portion of the recovery of successful claims. If our marketing or other arrangements were determined to violate anti-kickback or related laws, including the FCA, then our revenues could be adversely affected, which would likely have a material adverse effect on our business, financial conditions, and results of operations. Similarly, the federal Civil Monetary Penalty statute imposes significant penalties for filing certain types of improper claims or engaging in prohibited acts related to federal program integrity.

State and federal authorities have aggressively targeted medical device companies for alleged violations including improper research or consulting contracts with doctors, certain marketing arrangements that rely on volume-based pricing, off-label marketing schemes, and other improper promotional practices. Compliance with the federal and state laws is difficult and time consuming and companies that violate them may face substantial penalties. Because of the breadth of these laws and the lack of extensive legal guidance in the form of regulations or court decisions, it is possible that some of our business activities or those of our commercial partners could be subject to challenge under one or more of these laws, which could have a material adverse effect on our business and financial condition and growth prospects. Companies targeted in prosecutions have paid fines in the hundreds of millions of dollars or more, have been forced to implement extensive corrective action plans, and have often been subject to consent decrees severely restricting the manner in which they conduct business. If we become the target of such an investigation or prosecution based on our contractual relationships with providers or institutions, or our marketing and promotional practices, we could face similar sanctions which would materially negatively affect our business.

If we are found to have violated laws protecting the privacy or security of patient information, we could be subject to civil suits and civil or criminal penalties, which could result in liability and harm our reputation or business.

We are subject to privacy laws in the countries in which we do business. We have in place a specific Australian Privacy Policy and plan to expand our privacy policies to cover the privacy laws we are, or will be, subject to. These laws, including the federal and state privacy laws in the United States, are designed to protect the privacy and security of personally identifiable information, including patient health information and patient records, by, among other things, limiting its use and disclosure, establishing patient rights, requiring security safeguards, and mandating notice to the government and individuals if information is compromised (i.e., a breach).

Many local jurisdictions also have similar laws protecting the privacy and security of personally identifiable information, including breach notification requirements. If we violate applicable privacy laws, we could be subject to civil lawsuits based on state law or tort (including class actions) and civil or criminal penalties, which could increase our liabilities, harm our reputation, and have a material adverse effect on our business, financial condition, and results of operations.

Risk Factors Related to Intellectual Property

We rely on certain licenses for patents and other technology related to our products. The termination of these license agreements could delay or prevent us from being able to commercialize our products.

We have licensed certain patent rights and other technology that we use for our scaffolds. For example, we have licensed a majority of the polymer technology that we use from Rutgers University. In order to maintain our rights under the Rutgers License Agreement, we must satisfy certain development and commercialization obligations. If we fail to satisfy these obligations, Rutgers might license some or all of this technology to one or more of our competitors and our ability to compete may be diminished. Furthermore, if we fail to comply with material obligations under the license agreement or if the license were terminated for any reason, we could lose license rights that are important to our business. The license agreement expires on the expiration date of the last patent to expire under this agreement, which we believe is currently approximately 2036; if we need to renew the license, there is no guarantee we will be able to renew it on commercially reasonable terms, if at all.

In addition, we expect that we may need to license other technology or patents to commercialize our scaffolds or future products. These licenses may not be available to us on commercially reasonable terms, or at all, which could adversely affect our results of operations and growth prospects.

If we are unable to obtain, maintain, and enforce intellectual property protection covering our products, others may be able to make, use, or sell products similar to ours, which could adversely affect our ability to compete.

Our success depends in part on obtaining, maintaining, and enforcing the intellectual property rights, including patents, that cover our scaffolds and future products. If we are unable to protect our intellectual property, others may make, use, or sell products that are substantially the same as ours without incurring the sizeable development and licensing costs we have incurred, which would adversely affect our ability to compete in the market.

Currently, our patent portfolio comprises approximately 290 issued and pending U.S. and foreign patents that we own directly or license and that expire as late as 2036. Pending patent applications could further extend our patent portfolio life. However, we might not receive approval of pending applications or future patent applications and issued patents may be found by a court to be invalid or otherwise unenforceable. Even if our patents are determined to be valid and enforceable, they may not be sufficiently broad to prevent others from marketing products similar to ours, or designing around our patents despite our patent rights, nor do they provide us with freedom to operate unimpeded by the patent rights of others.

As we have licensed certain intellectual property from third parties, we rely on them to file and prosecute patent applications, maintain patents, and otherwise protect that intellectual property. We cannot be certain that such third parties have or will comply with applicable laws and regulations and that their activities will result in valid and enforceable patents and other intellectual property rights. In addition, we cannot be certain that our licensors will allocate sufficient resources or enforce or defend their patents, so as to protect our interests in the licensed patents.

The patent positions of medical device companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in patents in these fields has emerged to date in the United States or in many foreign jurisdictions.

Both the U.S. Supreme Court and the Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the U.S. patent laws are interpreted. In addition, Congress is currently considering legislation that would change provisions of the patent law. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law. Those changes may materially affect our patents, our ability to obtain patents, or the patents and applications of our collaborators and licensors. The patent situation in the medical device and disease diagnostic fields outside the United States is even more uncertain.

We have numerous foreign patents and applications. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as laws in the United States and many companies have encountered significant difficulties in obtaining, protecting, and defending such rights in foreign jurisdictions. If we encounter such difficulties or we are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

We rely on trade-secret protection for certain processes for which patents are difficult to obtain or enforce. We may not be able to protect our trade secrets adequately as we have limited control over our licensors, collaborators, and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, suppliers, scientific collaborators, and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and used any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. We rely, in part, on non-disclosure and confidentiality agreements with our employees, consultants, and other parties to protect our trade secrets and other proprietary technology. These agreements may be breached and we may not have adequate remedies for any breach. Moreover, others may independently develop equivalent proprietary information or third parties may otherwise gain access to our trade secrets and proprietary knowledge. Any disclosure of confidential data into the public domain or to third parties could allow our competitors to use the information against us.

Claims that our current or future products infringe or misappropriate the proprietary rights of others could adversely affect our ability to sell those products and cause us to incur additional costs.

Intellectual property rights play a critical role in stents and stent delivery systems. We face significant risks relating to our patents and to patents held by others. If any intellectual property claim against us is successful, we could be prevented from commercializing our scaffolds or other future product candidates. There are numerous U.S. and foreign-issued patents and pending patent applications owned by third parties with patent claims in areas that relate to our scaffolds. Also, because patent applications can take many years to be issued, there may be other pending applications, unknown to us, that may result in future patents that pose a material risk to us. We are aware of patents owned by others, to which we do not have licenses, that relate to, among other things:

- stent structures, materials, and designs;
- catheters used to deliver stents; and,
- polymer and stent manufacturing and coating processes.

We expect that we could be increasingly subject to third-party infringement claims as we receive regulatory approval to sell products, our revenues increase, we are faced with more competitors, or the functionality of products and technology in different industry segments overlaps. Third parties may currently have, or may eventually be issued, patents on which our current or future products or technologies may infringe. Any of these third parties might make a claim of infringement against us.

All of the major companies in the stent and related markets, including BSC, Abbott, and Medtronic have been involved in patent litigation relating to stents since at least 1997. The stent and related markets have experienced rapid technological change and obsolescence in the past, and our competitors have strong incentives to stop or delay the introduction of new products and technologies by their competitors. We may pose a competitive threat to many companies in the stent and related markets. Accordingly, many of these companies will have a strong incentive to take steps, through patent litigation or otherwise, to prevent us from commercializing our products.

Any litigation, regardless of its outcome, would likely result in significant expenses and the diversion of resources and management time. In addition, litigation in which we are accused of infringement may cause negative publicity, adversely impact prospective customers, cause product shipment delays, prohibit us from manufacturing, marketing, or selling our products, require us to develop non-infringing technology, make substantial payments to third parties, or enter into royalty or license agreements, which may not be available on acceptable terms, or at all.

If a successful claim of infringement were made against us and we could not develop non-infringing technology, invalidate the claim, or license the infringed or similar technology on a timely and cost-effective basis, our revenues may decrease substantially and we could be exposed to significant liability. A court could enter orders that temporarily, preliminarily, or permanently prevent us or our customers from making, using, selling, offering to sell, or importing our current or future products, or could enter an order mandating that we undertake certain remedial activities. Claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our reputation, business, financial condition, or results of operations.

We may need to initiate lawsuits to protect our patents or other intellectual property rights, which could be expensive and which, if lost, could result in loss of intellectual property rights, which would harm our business.

We rely on patents to protect a portion of our intellectual property and competitive position. Patent law relating to the technology fields in which we operate is still evolving and, consequently, patent positions in the medical device industry are generally uncertain. In order to protect or enforce our patent rights, we may initiate patent litigation against third parties, such as infringement suits or interference proceedings. Litigation may be necessary to:

- assert claims of infringement;
- enforce our patents;
- protect our trade secrets or know-how; or,
- determine the enforceability, scope, and validity of the proprietary rights of others.

Any lawsuits that we initiate could be expensive, take significant time, and divert management's attention from other business concerns. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially valuable. The occurrence of any of these events may have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Our CDIs and Common Stock

The market price of our CDIs and common stock may be volatile and fluctuate significantly, which could result in substantial losses for investors.

Our securities are listed for sale only on the Australian Securities Exchange (the "ASX") in the form of CHESS Depositary Interests ("CDIs"). We are a pre-revenue stage company. Until we achieve commercialization, start generating revenues and cash receipts, have the ability to service our convertible Notes payable, demonstrate regular measureable performance, or list our securities for sale on an additional stock exchange, the market for our CDIs may continue to be illiquid and the market price of our CDIs may continue to be volatile. In addition to the matters described in this "Risk Factors" section, the market price of our CDIs may fluctuate due to other risks and factors, such as changes in general economic, industry, and market conditions and other factors including:

- our development progress, including delays or advancements in our timelines;
- changes to the regulatory status of our scaffolds and future product candidates;
- any reported adverse events in our human clinical trials;
- technology innovations, new products, contracts, acquisitions, or strategic alliances by our competitors or us;
- changes in the estimates of the future size and growth rate of our markets;
- changes in market valuations or earnings of our competitors;
- changes in legislation or regulatory policies, practices, or actions;
- the commencement or outcome of litigation involving our company, our general industry, or both;
- recruitment or departure of one or more members of our executive management team or board of directors;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- actual or expected sales of our CDIs or common stock by existing holders;
- the overall trading volume of our CDIs; and,
- failure to service our debt or complete additional financings to fund our operations when needed or on terms favorable to us or on terms that are not overly dilutive to our current securityholders.

Stock markets in general, and submarkets for medical technology companies in particular, have experienced volatility that has often been unrelated to the operating performance of companies. These broad market and industry factors may materially affect the market price of our CDIs. Litigation has often been brought against companies whose securities have experienced volatility in market price. Class-action litigation, even if unsuccessful, could be costly to defend and divert management's attention and resources, which could materially harm our financial condition and results of operations.

Investors may experience difficulty in trading our CDIs due to their relatively limited liquidity on the ASX.

Although our CDIs are listed on the ASX, there can be no guarantee of a readily liquid market for them, particularly since a small number of securityholders own a majority of our outstanding shares. It may be more difficult for an investor to realize an investment on the ASX than it would be to realize an investment in a company whose shares or other securities are quoted on NYSE, NASDAQ, or any other stock exchange.

We may not retain our ASX listing and we may not qualify for listing on another securities exchange.

We cannot assure investors that we will always retain a listing on ASX and our common stock is not currently listed for trading on a U.S. or any other securities exchange. The provisions of the Note Deed we signed in 2014 call for us to use reasonable efforts to list on NASDAQ, which we plan to pursue in 2017. If we fail to retain our ASX listing or if we do not list on another securities exchange, certain investors may decide to sell their securities and/or there may not be a market for the securities, which could have an adverse impact on the price of the securities. There is no assurance that we can qualify in the future for listing any of our securities on the New York Stock Exchange, the NASDAQ Stock Market, or any other exchange.

Some of our existing stockholders can exert control over us and may not make decisions that are in the best interests of all stockholders.

As of February 15, 2017, officers, directors, and stockholders holding more than five percent of our outstanding shares collectively controlled approximately 70 percent of our outstanding common stock. As a result, these stockholders, if they act together, would be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. Accordingly, this concentration of ownership may harm the market price of our shares by delaying or preventing a change in control, even if a change is in the best interests of our other stockholders. In addition, the interests of this concentration of ownership may not always coincide with the interests of other stockholders and, accordingly, they could cause us to enter into transactions or agreements that we would not otherwise consider.

Future sales of our common stock may depress the market price of our CDIs.

The holders of an aggregate of approximately 19.2 million shares of our outstanding common stock, as well as the holders of our convertible notes, if such notes are converted into common stock, have certain rights to cause us to file a registration statement on their behalf and to include their shares in registration statements that we may file on behalf of other stockholders. In addition, shares of common stock reserved for issuance under our 2010 Equity Incentive Plan, as amended (the "Plan"), have been registered and, accordingly, any vested and exercised shares of stock issued in accordance with the Plan may be freely sold under the federal securities laws and may be tradable under state securities laws if a holder satisfies such laws or is exempt from them. Additionally, the Plan provides for annual increases in the number of shares available for issuance under the Plan, which we intend to register annually. From time to time, we also may sell additional common stock in subsequent public offerings or private placements. Sales of a substantial number of common shares or CDIs in the public market, whether by us or by our stockholders, or the perception that these sales may occur, could cause the market price of our CDIs to decline and make it more difficult for holders to sell CDIs or shares of common stock in the Company.

We have broad discretion in the use of our assets and our investment of these assets may not yield a favorable return, which could harm our business and depress the market price of our securities.

Our management has discretion in the application of our assets and other resources and may use them for a broad range of purposes. Accordingly, securityholders will have to rely upon our management's judgment with respect to the use of the Company's assets. Management may spend a portion or all of our assets in ways that holders of our securities may not desire or that may not yield a significant return, or any return at all. The failure by our management to apply these funds effectively could harm our business and depress the market price of our securities. Pending their use, we may also invest our assets in a manner that does not produce income or that loses value.

We do not currently intend to pay dividends on our CDIs or common stock; consequently, the return on an investment in our securities will depend on appreciation in the market price of our CDIs.

We currently intend to invest our future earnings, if any, to fund the development and growth of our business. The payment of dividends will be at the discretion of our Board and will depend on our operating results, capital needs, financial condition, future prospects, debt covenants, contractual arrangements, restrictions imposed by applicable law, and other factors our Board may deem relevant.

In addition the Notes contain a negative covenant that may limit our ability to pay dividends. If we do not pay dividends, the ability to achieve a return on an investment in REVA will depend on any future appreciation in the market price of our CDIs or other securities. There is no guarantee that our CDIs will appreciate or even maintain the price at which they were purchased.

We incur exchange rate risks relating to our listing on the ASX.

Our securities, in the form of CDIs, are listed on the ASX and priced in Australian dollars. However, we report in U.S. dollars. As a result, movements in foreign exchange rates may cause the price of our securities to fluctuate for reasons unrelated to our financial condition or performance and may result in a discrepancy between our actual results of operations and investors' expectations of returns on our securities expressed in Australian dollars.

Failure to comply with U.S. public company laws and regulations as well as the listing requirements of the ASX could cause investors to lose confidence in our Company and could have a material adverse effect on our business and on the market price of our CDIs.

As an SEC-registered U.S. public company with securities listed on the ASX, we incur substantial legal, accounting, and other shareholder and reporting compliance expenses. In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure, including SEC regulations, may increase legal and financial compliance costs and make some corporate activities more time consuming. Since our securities are traded on the ASX, we must comply with ASX Listing Rules. We believe our policies and procedures are designed to provide reasonable assurance of ASX Listing Rules compliance; however, if we do not follow those procedures and policies, or they are not sufficient to prevent non-compliance, we could be subject to delisting, liability, fines, and lawsuits. These laws, regulations, and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We expend significant management resources to comply with securities regulations, which may divert attention from revenue-generating activities. If our efforts to comply with new laws, regulations, and standards are unsuccessful, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404") to maintain internal control over financial reporting and to assess and furnish reports as to the effectiveness of those controls. Additionally, our independent auditors are required to report to the SEC on, among other things, the effectiveness of our internal controls. The controls are designed to ensure that information disclosed by us in reports that we file with the SEC is accurate and recorded, processed, summarized, and reported within the time periods specified by the SEC. Although we believe we have developed and maintain effective controls, they may become inadequate because of changes in conditions or our degree of compliance, or weaknesses may be discovered. If we, or our auditors, are unable to certify that our internal controls over financial reporting are effective and in compliance with Section 404, or we are unable to produce timely or accurate financial reports, we may be subject to sanctions or investigations, and investors may lose confidence in our financial reports, which would have a material adverse effect on our business, the market price of our CDIs, and our ability to access the capital markets. Failure to comply with the SEC and ASX rules and regulations might also make it more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors, or as members of senior management.

As a Delaware corporation, an acquisition of us, which may be beneficial to our stockholders, and attempts by our stockholders to replace or remove the current members of our board and management may be more difficult.

We are a Delaware corporation, subject to the provisions of Delaware General Corporation Law. Those laws, in addition to certain provisions of our certificate of incorporation and our bylaws, could discourage, delay, or prevent a merger, acquisition, or other change of control that stockholders may consider favorable. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove members of our board of directors (the "Board"). These provisions also could limit the price that investors might be willing to pay in the future for our CDIs, thereby depressing the market price of our CDIs. These provisions:

- allow the authorized number of directors to be changed only by resolution of our Board and provide that our stockholders may only remove our directors for cause;
- establish a classified Board so that not all members of the Board may be elected at one time;

- authorize our Board to issue, without stockholder approval but subject to ASX Listing Rules, up to 100,000,000 shares of common stock or up to 5,000,000 shares of preferred stock, that, if issued, would dilute ownership and operate as a "poison pill" to help prevent an acquisition that is not approved by the Board;
- require that stockholder actions occur at a duly called stockholder meeting or by unanimous written consent;
- establish advance notice requirements for stockholder nominations to our Board or for stockholder proposals that can be voted at stockholder meetings;
- limit who may call stockholder meetings; and,
- require approval from 80 percent of the outstanding shares of our capital stock in order to amend certain provisions of our certificate of incorporation and bylaws.

In addition, provisions of Section 203 of the Delaware General Corporation Law may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15 percent or more of the voting rights on our common stock, from merging or combining with us for a prescribed period of time.

Item 1B. Unresolved Staff Comments

We do not have any unresolved staff comments relating to our periodic or current reports.

Item 2. Properties

Our primary facility is located at 5751 Copley Drive, San Diego, California, where we lease and occupy approximately 37,000 square feet of research, lab, and office space. We lease an entire building and are the only tenant in the building. The lease on this facility expires in January 2018.

We do not own any real property. We believe that our leased facility is adequate to meet our current needs, as well as our future office, lab, and manufacturing needs through at least initial commercial sales of our *Fantom* scaffold. We may consider additional or different facilities and locations for manufacturing after we have commenced commercial sales.

Item 3. Legal Proceedings

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

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities

Market Information

Shares of our common stock began trading in the form of CHESS Depositary Interests ("CDIs"), each CDI representing one-tenth of a share of our common stock, on the Australian Securities Exchange ("ASX") under the symbol "RVA" on December 23, 2010. Prior to such time, there was no public market for our securities.

Between January 1, 2016 and December 31, 2016, the price of our CDIs ranged from a low of A$0.81 to a high of A$1.35, or a low price per share of common stock of $5.89 and a high of $10.34 after giving effect to the ten-for-one CDI-to-common stock exchange ratio and after converting to U.S. dollars using the closing exchange rate applicable on the relevant date as reported by the Reserve Bank of Australia. The high and low sales prices for our CDIs during each quarter, and on an equivalent basis as converted to common stock and U.S. dollars, were as follows:

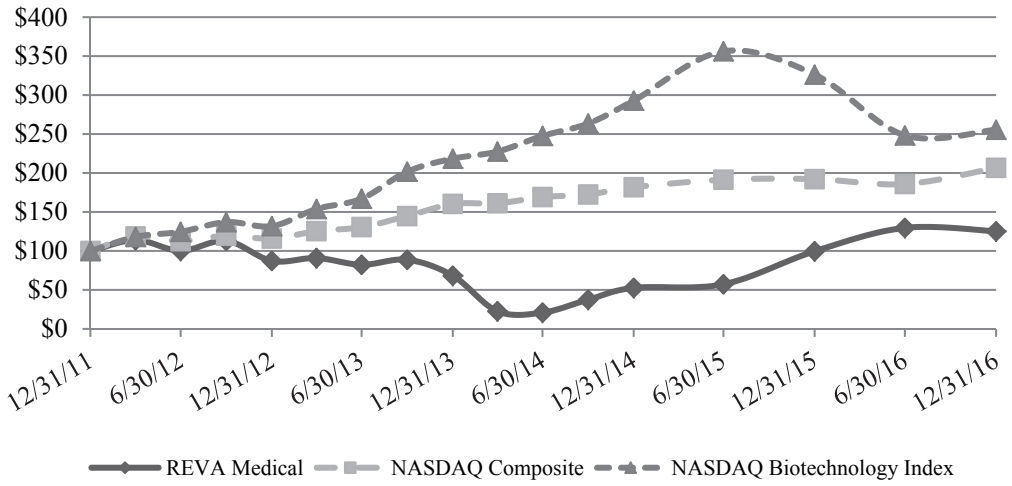
	CDI Price Range		Stock Price Range	
	Low	High	Low	High
Year Ended December 31, 2015:				
First quarter	$0.40	$0.58	$3.23	$ 4.56
Second quarter	0.45	0.55	3.46	4.33
Third quarter	0.40	0.80	2.92	5.61
Fourth quarter	0.73	0.94	5.28	6.84
Year Ended December 31, 2016:				
First quarter	$0.81	$1.22	$5.89	$ 8.65
Second quarter	0.95	1.28	7.02	9.32
Third quarter	1.04	1.35	7.73	10.34
Fourth quarter	0.95	1.32	7.05	10.06

As of February 15, 2017 we had 42,851,477 shares of common stock issued and outstanding with 882 holders of record. The holders included CHESS Depositary Nominee Pty Limited, which held 26,986,968 shares of our common stock, or approximately 63% of the outstanding shares, in the form of CDIs on behalf of the CDI holders; there were 822 registered owners of our CDIs on February 15, 2017.

Stock Price Performance Graph

The following graph compares the total return on our common stock (after giving effect to the ten-for-one CDI-to-common stock ratio and after converting to U.S. dollars using the spot rate on the relevant date) to (i) the NASDAQ Composite Index and (ii) the NASDAQ Biotechnology Index for the five years ending December 31, 2016:

RVA 5-Year Stock Performance



The performance graph was prepared based on an initial investment of $100 in our common stock at the closing price of $6.30 per share on January 1, 2012, and in the NASDAQ Composite and Biotechnology Indexes on that date. The comparisons in the table are disclosures in accordance with SEC requirements and are not intended to forecast or be indicative of possible future performance of our common stock. The graph shall not be deemed "soliciting material" or to be "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act or the Exchange Act.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support operations and finance the growth and development of our business and do not intend to pay cash dividends on our common stock or CDIs for the foreseeable future. In addition, the Notes contain a negative covenant that may limit our ability to pay dividends. Any future determination related to our dividend policy will be made at the discretion of our board of directors.

Recent Sales of Unregistered Securities

On November 14, 2014, we issued 8,750,000 warrants to purchase shares of our common stock. On October 1, 2015, half the warrants were exercised for cash. Upon receipt of the exercise proceeds in the amount of $9.5 million, we issued 4,375,000 shares of unregistered common stock. On February 12, 2016, the remaining warrants were exercised for cash. Upon receipt of the exercise proceeds in the amount of $11.4 million from this second exercise of warrants, we issued 4,375,000 shares of unregistered common stock.

Item 6. Selected Financial Data

We derived our statements of operations data for the years ended December 31, 2012 and 2013 and our balance sheet data as of December 31, 2012, 2013, and 2014 from our audited financial statements, which are not included in this Form 10-K. We derived our statements of operations data for the years ended December 31, 2014, 2015, and 2016 and our balance sheet data as of December 31, 2015 and 2016 from our audited financial statements appearing elsewhere in this Form 10-K. Our financial information is prepared and presented in accordance with generally accepted accounting principles in the United States, or US GAAP. Our selected financial data should be read together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included elsewhere in this Form 10-K. The following tables (this page and the following page) present our selected financial data for the five-year period ended December 31, 2016.

	Year Ended December 31,				
	2012	2013	2014	2015	2016
Consolidated Statements of Operations Data:	(in thousands, except per share data)				
Operating Expense:					
Research and development	$ 15,822	$ 19,212	$ 14,318	$ 16,760	$ 18,171
General and administrative	8,043	8,731	7,645	7,210	8,609
Loss from operations	(23,865)	(27,943)	(21,963)	(23,970)	(26,780)
Other Income (Expense):					
Interest income	92	30	8	9	3
Interest expense	—	—	(986)	(1,904)	(2,053)
Loss on issuance of convertible notes payable and warrants to purchase common stock	—	—	(15,627)	—	—
Loss on change in fair value of convertible notes payable and warrant liability	—	—	(12,542)	(56,788)	(25,247)
Other income (expense)	(3)	(9)	73	59	(21)
Net Loss	$ (23,776)	$ (27,922)	$ (51,037)	$ (82,594)	$ (54,098)
Net Loss Per Share: [1]					
Net loss per share, basic and diluted	$ (0.72)	$ (0.84)	$ (1.53)	$ (2.38)	$ (1.28)
Shares used to compute net loss per share, basic and diluted	33,072,058	33,124,655	33,382,381	34,680,634	42,120,545

(1) See Note 3 to our consolidated financial statements for an explanation of the method used to compute the net loss per share and the number of shares used in the computation of the per share amounts.

	Year Ended December 31,				
	2012	2013	2014	2015	2016
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 38,876	$ 19,229	$ 25,814	$ 16,895	$ 6,674
Short- and long-term investments	5,223	1,492	995	—	—
Working capital (deficit)	42,323	17,656	24,351	13,996	(91,664)
Total assets	47,397	24,785	30,195	20,071	9,483
Convertible notes payable	—	—	37,780	75,365	91,655
Common stock warrant liability	—	—	15,389	19,622	—
Total liabilities	2,771	3,960	56,644	100,635	99,076
Accumulated deficit	(173,587)	(201,509)	(252,546)	(335,140)	(389,238)
Total stockholders' equity (deficit)	44,626	20,825	(26,449)	(80,564)	(89,593)

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the "Selected Financial Data" and our consolidated financial statements and related notes thereto included elsewhere in this Form 10-K. In addition to historical information, the following discussion and analysis includes forward-looking statements that involve risks, uncertainties, and assumptions. 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" included elsewhere in this Form 10-K. Also see "Forward-Looking Statements" included elsewhere in this Form 10-K.

Overview

We are a pre-revenue stage medical device company working toward commercialization of our proprietary technologies to provide minimally invasive medical devices for treating conditions in humans. We are in the later stages of developing and clinically testing bioresorbable drug-eluting coronary stents, which are called "scaffolds" because they are not permanent devices like metal stents. We completed an application for CE Marking of our *Fantom* scaffold in August 2016 and are currently awaiting notification as to approval. If approved, we intend to commercially sell *Fantom*, which would be our first commercial product, in Europe and other countries that recognize the CE Mark. If approved, we anticipate first sales of *Fantom* during the second quarter of 2017.

Our scaffolds are made from our proprietary bioresorbable polymer and have been designed to offer unique scaffold features that include full x-ray visibility, standard clinical delivery, low profile, and a wide expansion range. Our scaffolds also contain standard features of relevant sizing, robust strength during the healing period, and safe resorption. Due to the positive clinical results we've obtained from *Fantom* so far, along with its unique features and ease of clinical use, we believe we will be able to compete effectively in the stent market, which had approximately $3.9 billion in worldwide revenues during 2016, and, in particular, with other bioresorbable scaffolds, which had estimated annual revenues of approximately $127.0 million in 2016. Use of fully bioresorbable scaffolds, and the number of patients receiving them, has continued to increase since becoming commercially available outside the United States a little over four years ago.

Our scaffolds combine our proprietary polymer with various designs, including conventional designs and internally developed designs. In addition to the clinical studies we are currently conducting, we have invested significant time and funds in development, having performed scientific research, engineering development, and testing in laboratory and preclinical studies. We have developed, tested, and selected the polymer formulation, tested and selected the anti-restenotic drug and coating process, created and iterated the device design, and identified and implemented methods and processes to produce and test the scaffold. We designed and performed extensive preclinical tests that ranged from bench and engineering studies to in vitro and in vivo laboratory studies. We also enrolled approximately 165 patients in prior clinical studies between 2007 and 2014 that showed the viability of the technology.

We enrolled 240 patients in a clinical trial of *Fantom* between March 2015 and March 2016, obtained data on approximately 100 of the patients at a six-month time point to use in our CE Mark application, and will continue to follow the patients for a total trial period of five years. We have been preparing for commercialization, including planning and implementing our sales and marketing approach, finalizing our manufacturing processes, arranging warehousing and distribution capabilities, and preparing our back office resources. We believe our current manufacturing facilities will accommodate our commercial needs through at least 2017.

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

We perform all of our manufacturing, research, and development activities from one location in San Diego, California. We have three clean rooms, a polymer manufacturing lab, and multiple engineering and chemistry labs at our facility, which is also our corporate and administrative office. We are ISO certified to the medical device standard 13485:2012 and intend to maintain that certification. We had 59 employees as of December 31, 2016; a significant number are degreed professionals and five are PhDs. We leverage our internal expertise with contract research and preclinical laboratories, catheter manufacturing, outside lasing, and other outside services as needed.

We have not yet brought a product to a saleable stage and have not generated any revenue in our history. While we expect *Fantom* to be approved for sale in 2017, our efforts to generate substantial revenue and achieve positive cash flows from operations may take several years, if ever, even if our clinical results continue to be favorable.

We have funded our research and development with a variety of private, strategic, and public investments, including our $84.3 million Initial Public Offering ("IPO") on the Australian Securities Exchange ("ASX") in December 2010 and, prior to the IPO, investments from health care venture capital funds and global medical device manufacturers including Medtronic, Inc. ("Medtronic") and Boston Scientific Corporation ("BSC"). Most recently, in November 2014, we issued convertible notes and warrants to purchase our common stock. We received cash proceeds of $25.0 million from the convertible notes in November 2014 and cash proceeds totaling $20.9 million from the exercise of the warrants in October 2015 and February 2016.

We believe our cash balance at December 31, 2016 of $6.7 million will fund our operating and capital needs through the first quarter of 2017. We are currently pursuing a financing that we intend to complete by March 31, 2017. Additionally, we intend to pursue a listing of our common stock on NASDAQ, with the intention to be accepted for listing by June 30, 2017.

We have incurred substantial losses since our inception; as of December 31, 2016, we had accumulated a deficit of approximately $389.2 million. We expect our losses to continue as we continue research and development, conduct clinical studies, and commercialize *Fantom* in 2017, when and if we receive regulatory approval. In order to successfully transition to profitable operations and generate positive cash flows, we will need to achieve a level of revenues and product margins to support the Company's cost structure.

Our current financial condition, pre-revenue stage of operations, history of losses and cash outflows, and the uncertainty of the timing of receipt of a financing, if any, raise substantial doubt about our ability to continue as a going concern. Additionally, holders of our convertible notes have a one-time option to redeem the notes on June 30, 2017 for face value plus accrued interest. Based on the Company's existing cash balances, if the noteholders were to individually or collectively exercise this option, which management believes they will not do, the Company would be unable to make the redemption payment of approximately $30.3 million.

Key Components of our Results of Operations

We are still in a pre-revenue stage and our activities have been focused on product development, clinical studies, and preparation for commercial sales. We additionally have performed minimal research and feasibility tests for future product development. Through December 31, 2016, we have not sold a product or generated revenue; we anticipate selling our first product, if it receives regulatory approval, in approximately the second quarter of 2017. Our operating results, therefore, have consisted of research and development expenses, including the costs to perform clinical trials, and general and administrative expenses. We additionally incur other non-operating expenses that primarily arise from the convertible notes and warrants that we issued in November 2014.

We anticipate our first commercial sales of *Fantom* during the second quarter of 2017, if we receive regulatory approval, and will begin to record revenue and costs of goods sold at that time. We also expect to incur sales and marketing expenses during the first quarter of 2017 as we build our sales force and prepare for the commercial product launch. Since we are planning a targeted sales launch to prove commercial viability of the product, we anticipate small to modest revenues and costs of goods sold in 2017 and selling and marketing costs corresponding to a small sales force.

***Research and Development Expenses*:** Our research and development expenses arise from a combination of 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 study expenses, regulatory consulting, and license fees paid for the technology underlying our polymer materials. All research and development costs are expensed when incurred.

Historically, our research and development expenses have represented between 70 and 75 percent of our total operating expenses; they were 70 percent and 68 percent of total operating expenses for the years ended December 31, 2015 and 2016, respectively. We expect our research and development expense to decrease slightly in 2017, and decrease as a percentage of our total expenses, as we transition to the commercial sales of *Fantom*. We expect our research and development expenses to continue to be a significant portion of our operating expenses as we continue to research, prove feasibility, and develop additional products.

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

Historically, our general and administrative expenses have represented between 25 and 30 percent of our total operating expenses; they were 30 percent and 32 percent of total operating expenses for the years ended December 31, 2015 and 2016, respectively. We anticipate that we will expand our corporate infrastructure in 2017 to support the commercialization of *Fantom* and the ongoing needs of being a public company, which will increase our general and administrative expenses accordingly. We anticipate that we will continue to invest in patents at similar levels as we have in the past.

***Other Income and Expense*:** Following our issuance of convertible notes ("Notes") and warrants in November 2014, the components of other income and expense primarily comprise interest expense on the Notes and losses related to the changes in fair values of the Notes and warrants. We account for the Notes, and the warrants until they were exercised in full in February 2016, 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. During 2016, due to a variety of factors including our clinical progress, application for CE Marking, and increase in the trading price of our common stock of approximately 25 percent, the value of the Notes and warrants increased and we recorded a $25.2 million loss on the change in value.

Until the 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 notes at the rate of 7.54 percent per annum until they are either converted or repaid.

We have reported net losses for all periods through December 31, 2016; therefore no provision for income taxes has been recorded. While we had deferred tax assets of approximately $100.7 million as of December 31, 2016, we have established a valuation allowance against the entire balance of deferred tax assets due to the uncertainty surrounding our ability to generate future taxable income to be able to realize those tax assets.

Critical Accounting Policies and Significant Estimates

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States. 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.

While our significant accounting policies are described in more detail in Note 3 to our consolidated financial statements included elsewhere in this Form 10-K, 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.

***Research and Development Costs*:** We expense research and development costs as incurred. Our preclinical and clinical study costs are incurred on a contract basis and generally span a period from a few months to several years. We record costs incurred under these contracts as the work occurs and make payments according to contractual terms. Until a contract is completed, we estimate the amount of work performed and accrue for estimated costs that have been incurred but not paid. As actual costs become known, we adjust our accruals. We expect our clinical expense accruals to fluctuate, and possibly increase, as we continue to initiate and enroll patients in clinical trials. We expect to make estimates of work performed throughout the term of these trials, each of which is expected to be three years or longer. If our estimates are inaccurate, possible material changes to our accruals could be required, which could materially affect our results of operations within any fiscal period. To date, there have been no material changes in our research and development expense estimates, including our estimates for accrued clinical costs.

Stock-Based Compensation: We recognize stock-based compensation expense in connection with equity grants and awards to employees, directors, and consultants. Most of these grants and awards vest based on the passage of time; in 2015 we awarded restricted stock units ("RSU") and stock options that vest based on achievement of performance milestones.

For awards to employees and directors, we determine the amount of compensation expense by estimating fair value on the date of award and recording the resulting stock-based compensation over the vesting period, which ranges from one to four years, on a straight-line basis. For awards that vest upon achievement of performance milestones, we record compensation expense for only the performance milestones that are probable of being achieved, on a straight-line basis over the vesting period. Through December 31, 2015, we determined that two of the three milestones for the performance-based awards were probable of being achieved and, therefore, recorded expense for those two milestones only. During the year ended December 31, 2016, we determined that all three performance milestones were probable of being achieved and, therefore, recorded approximately $367,000 in cumulative expense for the third milestone, as well as straight line expense for all three performance milestones during the year. We reverse cumulative expense recorded whenever unvested performance based awards are cancelled; during the year ended December 31, 2016, we reversed a total of $163,000 in compensation expense that had been recorded during the year ended December 31, 2015.

Stock-based compensation expense has been recorded as either research and development or general and administrative expense based on a recipient's work classification. For stock options, we estimate the grant date fair value by using the Black-Scholes option pricing model. For the model inputs, we use the fair value of the underlying common stock, a risk-free interest rate that corresponds to the expected life of the option, an expected option life ranging between 5.50 and 6.25 years, and an estimate of volatility based on the market trading prices of comparative peer companies. We use peer group data due to the fact that we have limited historical trading data but adjusted the 2016 volatility upward by approximately ten percent to allow us to move toward using our trading history, which is more volatile than our peer group. The fair value of restricted stock awards is equal to the closing market price of our common stock on the date of award. Additionally, we reduce the amount of recorded compensation expense to allow for potential forfeitures of awards; the forfeiture rate is based on actual historical forfeitures and has ranged from approximately 1.7 percent to 3.4 percent.

We occasionally grant options to consultants; no consultant options remained subject to vesting at either December 31, 2015 or December 31, 2016. When we grant or have unvested consultant options, we estimate the fair value at date of grant and at each subsequent reporting date until vesting is complete and record compensation expense based on the fair value during the service period of the consultant. We estimate the fair value by using the Black-Scholes option pricing model with the same approach to inputs and assumptions as we use to estimate the fair value of options granted to employees, except we use the remaining term as the expected life of the option.

As a result of our use of estimates for the fair value calculations and the performance-based achievement probabilities, if factors change and we use different assumptions, the amount of our stock-based compensation expense could fluctuate materially in the future. Also, we may increase the level of awards in 2017 as we expand our workforce, including the addition of a direct sales force, and begin commercial sales, which could result in an increase of our stock-based compensation in the future.

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

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

***Common Stock Warrants*:** Whenever we have a warrant liability, we remeasure the fair value of the underlying warrants at each reporting date and record a gain or loss based on the change in fair value. Following the exercise of warrants in February 2016, we no longer have any outstanding warrants. Prior to their exercise, through September 30, 2015, the warrants were valued utilizing a binomial valuation model since two exercise prices were possible; we moved to a Black-Scholes valuation model thereafter because the exercise price became fixed. This change in models did not have a material effect on the fair value of the warrants. Inputs to the valuation models were of the same nature as those used for the Notes and involved the use of subjective assumptions.

Results of Operations

During 2016, our operating activities primarily consisted of completing enrollments in the clinical trial of *Fantom*, which were completed in March 2016 with a total of 240 patients, performing follow-up assessment of the patients, collecting the related clinical data to support our CE Mark application that was completed in August 2016, and continuing to refine our manufacturing processes in preparation for the commercialization of *Fantom* that is planned during the second quarter of 2017, if we receive regulatory approval early in 2017. This compares to 2015 activity that primarily consisted of clinical enrollments, which were initiated in March 2015, and testing and refining *Fantom* and its related manufacturing processes.

We issued the Notes and warrants in November 2014, receiving cash proceeds of $25.0 million. Half the warrants were exercised in October 2015 for cash proceeds of $9.5 million and the other half were exercised in February 2016 for cash proceeds of $11.4 million. We account for the Notes and, until the time of exercise, the warrant liability at fair value and have recognized non-cash losses in the consolidated statement of operations for the increases in fair values since their issuance date.

Comparison of the Years Ended December 31, 2015 and 2016

	Year Ended December 31,		Change	
	2015	2016	$	%
	(dollars in thousands)			
Research and development expense	$ 16,760	$ 18,171	$ 1,411	8%
General and administrative expense	$ 7,210	$ 8,609	$ 1,399	19%
Interest expense	$ 1,904	$ 2,053	$ 149	8%
Loss on change in fair values of convertible notes payable and warrant liability	$ 56,788	$ 25,247	$ (31,541)	(56)%
Interest and other income (expense)	$ 68	$ (18)	$ (86)	>(100)%

Research and development expense increased $1,411,000, or eight percent, for the year ended December 31, 2016 compared to the year ended December 31, 2015 due to a combination of factors. Personnel costs increased $552,000 between years primarily due to an approximate 11 percent increase in average headcount to support our commercialization efforts, offset by a $202,000 decrease in stock compensation. Direct materials that include polymer costs, polymer lasing, and purchased catheters increased $965,000 between years, and testing and non-recurring verification costs increased $447,000, as we made process improvements and performed verification activities in advance of commercialization. We incurred an additional $90,000 in 2016 in connection with our technology license from Rutgers, The State University of New Jersey, in accordance with license terms. Clinical costs decreased $209,000 in 2016 compared to 2015; the clinical trial initiated in March 2015 completed enrollment in March 2016 and the patient follow-up assessment activity that primarily occurred in 2016 resulted in comparatively lower costs. Preclinical costs decreased $579,000 between years due to the timing of studies and related analyses; a majority of preclinical tests for *Fantom* began in 2014 and 2015 and concluded by the first quarter of 2016. The remainder of the change in research and development expenses between years resulted from individually immaterial changes in lab supplies, engineering services, depreciation, and facilities expenses.

General and administrative expense increased $1,399,000, or 19 percent, for the year ended December 31, 2016 compared to the year ended December 31, 2015, primarily as a result of a $1,491,000 increase in stock-based compensation between years, due to equity grants to our Chief Executive Officer in September 2015 and February 2016 and equity awards to our Board members in May 2016 and July 2016. Offsetting the increase, non-recurring severance costs of $210,000 and recruiting costs of $132,000 recorded in 2015 were not repeated in 2016. Also, travel costs decreased approximately $181,000 in 2016, primarily as a result of less clinical support travel following completion of study enrollment. The remainder of the change in general and administrative expenses between years was due to individually immaterial changes in investor relations costs, office supplies, marketing and tradeshow costs, audit and tax fees, legal fees, facilities costs, depreciation, insurance, and other overhead expenses.

Our other non-operating expenses during the year ended December 31, 2016 primarily arose from the convertible notes and warrants issued in November 2014. Interest expense was comparable between years. We recorded a loss of $16,290,000 from the change in fair values of the Notes during 2016 and a loss of $8,957,000 from the change in fair value of the warrants during the period January 1, 2016 to the exercise date of February 12, 2016. Interest income was $3,000 and other expense, which primarily arose from exchange rate losses, was $21,000 during 2016.

Comparison of the Years Ended December 31, 2014 and 2015

	Year Ended December 31,		Change	
	2014	2015	$	%
	(dollars in thousands)			
Research and development expense	$ 14,318	$ 16,760	$ 2,442	17%
General and administrative expense	$ 7,645	$ 7,210	$ (435)	(6)%
Interest expense	$ 986	$ 1,904	$ 918	93%
Loss on issuance of convertible notes payable and warrants	$ 15,627	$ —	$ (15,627)	(100)%
Loss on change in fair values of convertible notes payable and warrant liability	$ 12,542	$ 56,788	$ 44,246	>100%
Interest and other income	$ 81	$ 68	$ (13)	(16)%

Research and development expense increased $2,442,000, or 17 percent, for the year ended December 31, 2015 compared to the year ended December 31, 2014, primarily as a result of our change in product development to the *Fantom* scaffold in late March 2014, a related reduction in headcount at that time, and the initiation of a preliminary *Fantom* clinical trial in December 2014. Clinical costs increased $1,130,000 as a result of the difference in timing and number of *Fantom* patient enrollments in 2015 compared to the predecessor product patient follow-ups in 2014; approximately 200 patients were treated in 2015 compared to 100 in 2014. Direct materials, including purchased catheters and polymer lasing costs, increased $528,000 because of increased product needs for preclinical and clinical purposes and our initiation of process improvement efforts during 2015. Preclinical costs increased $306,000 in 2015 as compared to 2014 due to the timing and scope of such work; numerous studies were undertaken in 2015 to test and validate *Fantom*. We paid licensing fees of $200,000 for certain polymer technology in 2015 for which we had no corresponding expense in 2014. Our personnel costs, including benefits and stock-based compensation, increased $58,000 in 2015; the $237,000 in severance benefits and payroll taxes recorded in 2014 was not repeated in 2015 and was offset by an increase of $291,000 in stock-based compensation in 2015 due to non-recurring performance-based grants made in 2015. The remainder of the change in research and development expenses between periods resulted from individually immaterial changes in lab supplies, quality control, engineering services, depreciation, and facilities expenses.

General and administrative expense decreased a total of $435,000, or six percent, for the year ended December 31, 2015 compared to the year ended December 31, 2014. A combination of items contributed to this decrease. Personnel costs decreased $654,000 due to a decrease of $373,000 in stock-based compensation upon final vesting of stock option grants made in 2010 and 2011 for which comparative grants were not made in 2015. Additionally, we recorded $178,000 in severance benefits in 2014 upon headcount reductions; we recorded $210,000 in severance benefits in 2015 upon our transition to a new Chief Executive Officer. The remainder of the decrease in personnel costs was due to the approximate 44 percent decrease in headcount during March 2014. Offsetting the personnel decreases, travel and entertainment increased $237,000 between years as a result of travel required for clinical studies, new executive travel, and numerous in-person board meetings. The remainder of the change in general and administrative expenses between periods was due to individually immaterial changes in investor relations costs, office supplies, marketing and tradeshow costs, audit and tax fees, facilities costs, depreciation, insurance, franchise taxes, legal fees, and other overhead expenses.

Our other non-operating expenses during the year ended December 31, 2015 primarily arose from the Notes and warrants issued in November 2014. Interest expense of $1,904,000 on the convertible notes accrued during 2015 compared to $986,000 in interest expenses recorded during 2014. We additionally recorded a $56,788,000 loss on the change in fair value of the notes and warrants during 2015. The loss on issuance of the convertible notes and warrants in 2014 was non-recurring so we had no corresponding loss in 2015. Interest income was $9,000 and other income, which primarily arose from exchange rate gains, was $59,000 during 2015.

Liquidity and Capital Resources

Sources of Liquidity

We are conducting clinical trials and have submitted an application for regulatory approval to commercially sell our *Fantom* scaffold under a European CE Marking. If and when approved, *Fantom* would be our first commercial product; we have not previously commercialized any products or generated any revenue since our inception in June 1998. Our future operating and capital requirements will depend on many factors, including the timing and achievement of regulatory approval of *Fantom* or any other product, growth of revenue, amount of intellectual property and technology expenditures, number and size of future clinical trials, extent of new product development, and the timing of repayment of our convertible notes, should they become due and payable. We anticipate that we will continue to incur substantial net losses and cash outflows through at least the remainder of this year and into 2018 as we continue research and development, conduct clinical trials, and begin commercial sales. While we expect *Fantom* to be approved for sale in 2017, our efforts to generate substantial revenue and achieve positive cash flows from operations may take several years, if ever, even if our clinical results continue to be favorable.

Our development, clinical, and operating activities have been funded with a variety of capital received from angel investors, venture capitalists, strategic partners, hedge funds, our IPO in 2010, issuance of convertible notes in November 2014, and the cash proceeds from warrant exercises in October 2015 and February 2016. Since our inception through December 31, 2016, we have received approximately $175.9 million in equity proceeds and $53.5 million from issuances of notes payable (of which, $28.5 million converted to common stock upon our IPO).

In November 2014, we completed a financing that comprised the issuance of 250 senior unsecured convertible notes (the "Notes"), each with a face value of $100,000 and a five-year maturity, and warrants to purchase 8,750,000 shares of our common stock. We received cash proceeds of $25.0 million from the Notes in November 2014 and $20.9 million from the exercise of the warrants between October 2015 and February 2016. In February 2016, we entered into an amendment to the Note Deed that governs the Notes. The amendment, which was approved by our stockholders on March 22, 2016, provided two modifications. The first modification extended the date of an optional redemption right of the noteholders to June 30, 2017 if the Notes have not otherwise been converted or redeemed; the prior optional redemption date had been January 14, 2017. The second modification added a third condition, being that the Company list its common stock on the NASDAQ stock exchange (or another exchange approved by the noteholders), before the Notes will automatically convert into common stock. The prior conditions to an automatic conversion of the Notes were the receipt of a CE Mark on *Fantom* combined with a market trading price of the Company's securities of at least A$0.60 per CDI for 20 or more consecutive trading days. We are pursuing the CE Mark, our securities have traded above A$0.60 for over a year, and we intend to pursue NASDAQ with the intention to be accepted for listing by June 30, 2017.

As of December 31, 2016 we had cash of $6,674,000, all of which is available for operations and which reflects receipt of $11,407,000 cash proceeds from warrant exercises in February 2016. Based on our current operating plans and projections, we believe this cash balance will be sufficient to fund our operating and capital needs through the first quarter of 2017. We have generated losses and negative cash flows since our inception and, as of December 31, 2016, we had an accumulated deficit of $389,238,000 and current liabilities of $98,810,000 (of which $32,155,000 could become due and payable in 2017). The holders of our convertible notes have a one-time option to redeem the notes on June 30, 2017 for face value plus accrued interest, a total of approximately $30,286,000. If the noteholders were to collectively exercise the early redemption option, which management believes they will not do, and if the notes were not otherwise converted under either the automatic conversion feature of the notes or at the election of a noteholder, the Company would be unable to make the redemption payment.

We have been actively pursuing a financing to secure additional capital to continue our operations, with the intention to finalize the financing by March 31, 2017. There can be no assurance, however, that we will be successful in completing a financing on a timeframe that coincides with our cash needs, or completing it at all, or that it will be on terms that are acceptable to us.

While we believe we will receive CE Mark regulatory approval and initiate commercial operations by mid-2017, until we generate revenue, and at a level to support our cost structure, we expect to continue to incur substantial operating losses and net cash outflows. Even if we do attain revenue, we may never become profitable and even if we do attain profitable operations, we may not be able to sustain profitability or positive cash flows on a recurring basis.

Our current financial condition, pre-revenue stage of operations, and history of losses and cash outflows, as well as the magnitude of the redemption payment if the holders of our convertible notes exercise the early redemption option and the uncertainties surrounding the outcome of our current fundraising efforts, raise substantial doubt about our ability to continue as a going concern.

Additionally, even if we are successful in our current fundraising and commercialization efforts, we may need to raise further capital in the future to service our debt or fund our operations until the time we can sustain positive cash flows. If we are unable to raise sufficient additional capital when needed, now or in the future, we may be compelled to reduce the scope of our operations and planned capital expenditures or sell certain assets, such as our intellectual property assets. 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, and, as such, the financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the company be unable to continue in existence.

Cash Flows

Below is a summary of our cash flows for the periods indicated.

	Year Ended December 31,		
	2014	2015	2016
		(in thousands)	
Net cash used for operating activities	$ (17,930)	$ (19,082)	$ (21,259)
Net cash provided by (used for) investing activities	$ (44)	$ 138	$ (729)
Net cash provided by financing activities	$ 24,559	$ 10,025	$ 11,767
Net increase (decrease) in cash and cash equivalents	$ 6,585	$ (8,919)	$ (10,221)

Net Cash Flow from Operating Activities

Net cash used for operating activities during 2014 primarily reflects the loss from operations of $21,963,000 and the changes in operating assets and liabilities of $610,000. These items were offset by non-cash expenses of $3,516,000 for stock-based compensation, $1,027,000 of depreciation and amortization, interest and other income of $81,000, and $19,000 of other non-cash expense. The loss from issuance of convertible notes payable and warrants and the change in fair value of convertible notes payable and warrant liability that were recorded during 2014 were non-cash items that had no effect on cash flows.

Net cash used for operating activities during 2015 primarily reflects the loss from operations of $23,970,000, offset by non-cash expenses of $3,434,000 for stock-based compensation, $1,096,000 of depreciation and amortization, $244,000 from changes in operating assets and liabilities, and $46,000 of other non-cash expense. The loss from the change in fair value of convertible notes payable and warrant liability and the interest on convertible notes payable recorded during 2015 were non-cash items that had no effect on cash flows.

Net cash used for operating activities during 2016 primarily reflects the loss from operations of $26,780,000 and $344,000 used for changes in operating assets and liabilities, offset by non-cash expenses of $4,723,000 for stock-based compensation, $1,139,000 of depreciation and amortization, and $21,000 of other non-cash expense. The loss from the change in fair value of convertible notes payable and warrant liability and the interest on convertible notes payable recorded during 2016 were non-cash items that had no effect on cash flows.

Net Cash Flow from Investing Activities

Net cash used for investing activities during 2014 consisted of property and equipment purchases of $541,000, offset by $497,000 in net maturities of investments.

Net cash was provided by investing activities during 2015, which consisted of $995,000 in net maturities of investments offset by $857,000 in purchases of property and equipment.

Net cash used for investing activities during 2016 consisted of property and equipment purchases of $729,000.

Net Cash Flow from Financing Activities

Net cash provided by financing activities in 2014 consisted of $247,000 in proceeds from the issuance of common stock upon exercise of employee stock options and $25,000,000 in proceeds from the issuance of convertible notes payable, offset by payment of $688,000 in issuance costs.

Net cash provided by financing activities in 2015 consisted of $9,506,000 in proceeds from the issuance of common stock upon the exercise of 4,375,000 warrants originally issued in 2014 and $569,000 in proceeds from the issuance of common stock upon exercise of employee stock options. These receipts were offset by a $50,000 payment in 2015 for issuance costs incurred in 2014 in connection with the issuance of convertible notes payable.

Net cash provided by financing activities in 2016 consisted of $11,407,000 in proceeds from the issuance of common stock upon the exercise of 4,375,000 warrants originally issued in 2014 and $360,000 in proceeds from the issuance of common stock upon exercise of employee stock options.

Operating Capital and Capital Expenditure Requirements

We are conducting clinical studies and have applied for approval to commercially sell our *Fantom* scaffold under a European CE Marking. If we receive regulatory approval, *Fantom* would be our first commercial product; we anticipate we could begin commercial sales during the second quarter of 2017. We have incurred substantial losses since our inception and anticipate that we will continue to incur substantial net losses and cash outflows during 2017 and into 2018 as we continue our clinical trials, expand our corporate infrastructure, prepare to commercially manufacture and sell our products, and collect cash from sales of our product(s).

Until we commercialize a product and reach a sales volume to generate positive cash flow, we plan to fund our operating and capital needs by utilizing our current cash resources and by raising additional capital through equity or debt financings. We have been actively pursuing a financing to secure additional capital to continue our operations, with the intention to finalize the financing by March 31, 2017. There can be no assurance, however, that we will be successful in completing a financing on a timeframe that coincides with our cash needs, or completing it at all, or that it will be on terms that are acceptable to us. Additionally, we anticipate that in order to conduct a U.S. FDA clinical trial of *Fantom*, which we believe is critical to our ultimate success, the associated costs would be at least $70 million, or more, and we would need to secure additional funding for the trial.

To provide additional liquidity to our stockholders and to position the Company for a potential future public offering of our securities, we intend to pursue listing of our common stock on NASDAQ, or another exchange approved by our noteholders, with the intention to be accepted for listing no later than June 30, 2017. We intend to utilize our current cash balances, and any additional proceeds received from financings, to fund our operating and capital needs.

While our noteholders have the right to request an early redemption of the Notes on June 30, 2017, which management believes they will not do, we believe that, as a result of our intentions to list our securities on NASDAQ, combined with our efforts to receive CE Marking of *Fantom*, we can cause the Notes be converted to equity prior to the time we would be required to redeem and, therefore, do not currently anticipate requiring additional capital to redeem the Notes.

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

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

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

Contractual Obligations, Commitments, and Contingencies

The following table summarizes our outstanding contractual obligations as of December 31, 2016:

	Payments Due by Period		
	Less than 1 Year	1-3 Years	Total
		(in thousands)	
Operating lease obligations	$ 711	$ 60	$ 771
Deferred technology license fees	—	250	250
Purchase obligations	157	4	161
Total contractual obligations	$ 868	$ 314	$ 1,182

We have not included our convertible notes in the table as we believe they will be converted into common stock rather than repaid. Our operating lease obligations represent the contractual rental payments due under our facility lease, as amended in August 2011, which matures in January 2018.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Recent Accounting Pronouncements

We have set forth the applicable recent accounting pronouncements in Note 3 to our consolidated financial statements included elsewhere in this Form 10-K. We adopted ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, in 2016 and, accordingly, provide the disclosures required by that pronouncement. We do not believe adoption of other applicable pronouncements will result in a material effect on our financial statements or related disclosures.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Sensitivity

As of December 31, 2016, we had no investments and our convertible notes payable bear interest at a fixed rate; therefore, we do not believe we have any current material exposure to changes in interest rates.

Foreign Currency Risk

We believe we currently have minimal exposure to foreign currency rate fluctuations, although we do conduct a number of transactions in foreign currencies. We purchase goods and services from foreign suppliers and consultants in their native currencies; such purchases have been minimal to date. The costs we incur to the hospitals and doctors that conduct our clinical trials, denominated primarily in the currencies of Australia and the European Union, are anticipated to remain constant or reduce slightly in 2017. We anticipate that our initial commercial sales, which could begin in 2017, will be based in Europe and will most likely be denominated in European currencies; therefore, we will become more sensitive to exchange rate fluctuations in the future. We do not currently enter into foreign currency hedging transactions. Our German subsidiary is non-operational; until such time as it conducts operations, the effects of exchange rate fluctuations on its net assets are immaterial to our financial statements.

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements, and accompanying notes, and the Report of Grant Thornton LLP, our Independent Registered Public Accounting Firm, are included in this Annual Report on Form 10-K on pages F-1 through F-22.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

Item 9A. Controls and Procedures

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the Company's board of directors, management and other personnel, 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 and includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the Company's assets;
- provide reasonable assurance that transactions are recorded as necessary to permit the preparation of financial statements in accordance with generally accepted accounting principles, and that the receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and,

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, including our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of the end of the fiscal year covered by this Annual Report on Form 10-K. In making this assessment, our management used the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework), or "COSO." Based on their assessment, management has concluded that, as of December 31, 2016, our Company's internal control over financial reporting is effective based on the COSO criteria.

Evaluation of Disclosure Controls and Procedures

Our management, including our Chief Executive Officer and Chief Financial Officer, have evaluated the effectiveness of our "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) as of the end of the period covered by this Annual Report on Form 10-K. Based on their evaluation, they have concluded that our disclosure controls and procedures are effective as of the end of the period covered by this report.

Remediation of Previously Reported Material Weakness

In our Quarterly Reports on Form 10-Q/A for the quarter ended June 30, 2016 and Form 10-Q for the quarter ended September 30, 2016, as filed with the SEC on November 8, 2016 and November 9, 2016, respectively, we reported a material weakness in our internal controls over the accounting and reporting for infrequent, unusual, or complex technical accounting issues, specifically those related to the balance sheet classification of our convertible notes payable.

We have taken actions to improve our internal controls over financial reporting and remediate the material weakness previously reported, specifically those related to the accounting and disclosure of existing or new infrequent, unusual, or complex technical accounting transactions. During the three months ended December 31, 2016, we implemented additional internal review procedures and engaged an external qualified technical accounting resource to review, evaluate, and advise as to our accounting for complex transactions and the related disclosures for those transactions, including our accounting and disclosures related to our convertible notes payable. Based on our evaluation and testing of the controls implemented, we believe they are designed appropriately, operating effectively, and provide reasonable assurance that our financial statements are fairly presented in all material respects. As such, management determined that, as of December 31, 2016, our implementation of the enhanced controls fully remediated the material weakness previously reported.

Changes in Internal Control Over Financial Reporting

Other than as previously described, there have not been any changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) that occurred during the quarterly period ended December 31, 2016 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
REVA Medical, Inc.

We have audited the internal control over financial reporting of REVA Medical, Inc., a Delaware corporation, (the "Company") as of December 31, 2016, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements of the Company as of and for the year ended December 31, 2016, and our report dated February 27, 2017 expressed an unqualified opinion on those financial statements.

/s/ GRANT THORNTON LLP

San Diego, California
February 27, 2017

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

The information required by this item related to our directors is incorporated by reference to our Definitive Proxy Statement for our 2017 Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission within 120 days of December 31, 2016 (the "2017 Proxy Statement"), under the heading "Election of Directors."

Information concerning our executive officers is set forth under "Executive Officers" in Item 1 of Part I of this Annual Report on Form 10-K and is incorporated herein by reference.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all of our officers, directors, and employees. We have posted a copy of our Code of Business Conduct and Ethics, and intend to post updates to this code, or any waivers of its requirements, in the Corporate Governance section on our website at *www.revamedical.com*. If we make any substantive amendments to the Code of Business Conduct and Ethics or grant any waiver from any of its provisions to any executive officer or director, we will disclose the nature of the amendment or waiver on our website within four business days.

Australian Disclosure Requirements

Because we are listed on the ASX, we are required to comply with various disclosure requirements as set out in the ASX Listing Rules. The following information is provided to comply with the ASX Listing Rules and is not intended to fulfill SEC information required by Part III of this Annual Report on Form 10-K.

Substantial Holders at February 15, 2017

The number of our equity securities held by our substantial securityholders (i.e., those holders, who together with their affiliates, have an interest in at least five percent of our voting securities), assuming the conversion of common stock held by those securityholders into CHESS Depositary Interests, or "CDIs" (ten CDIs are equivalent to one share of common stock), based on our review of our shareholder registers and available public filings, as of February 15, 2017 are as follows:

					Total Holdings	
Security Holder	Number of Common Shares Held	% of Total Common Shares Outstanding	Number of CDIs Held	% of Total CDIs Outstanding	Equivalent Number of CDIs Held	% of Total Securities Outstanding
Brookside Capital and affiliates	—	—	29,650,222	11.0%	29,650,222	6.9%
Cerberus and affiliates	—	—	28,844,260	10.7%	28,844,260	6.7%
Citicorp Nominees Pty Limited	—	—	30,326,928	11.2%	30,326,928	7.1%
Domain Partners and affiliates	3,698,688	23.3%	—	—	36,986,880	8.6%
Elliott Associates, L.P.	3,227,031	20.3%	—	—	32,270,310	7.5%
Goldman Sachs International	4,375,000	27.6%	—	—	43,750,000	10.2%
Group Outcome Investors/Robert B. Stockman	1,744,906	11.0%	1,199,260	0.4%	18,648,320	4.4%
Kenneth Rainin Trust and affiliates	—	—	13,470,695	5.0%	13,470,695	3.1%
Medtronic, Inc.	379,651	2.4%	13,526,100	5.0%	17,322,610	4.0%
Gordon E. Nye	858,531	5.4%	129,544	0.0%	8,714,854	2.0%
Saints Capital Everest, L.P.	—	—	32,235,131	11.9%	32,235,131	7.5%
Senrigan Capital and affiliates	—	—	62,192,706	23.0%	62,192,706	14.5%
Total securities held by $\geq$ 5% holders	14,283,807	90.0%	211,574,846	78.4%	354,412,916	82.7%
Total securities held by all other holders	1,580,702	10.0%	58,294,834	21.6%	74,101,854	17.3%

Distribution of Security Holders as of February 15, 2017

As of February 15, 2017, we had a total of 42,851,477 shares of common stock issued and outstanding, a portion of which were held as CDIs (ten CDIs are equivalent to one share of common stock). The table below presents the number of shares of common stock (including restricted stock) and CDIs held, as well as the number of shares underlying outstanding stock options to purchase common stock, convertible notes, and restricted stock units.

	Common Stock (includes Restricted Stock)		**CDIs**		**Options** (unlisted)		**Convertible Notes** (unlisted)		**Restricted Stock Units** (unlisted)	
	# of Holders	**# of Shares**	**# of Holders**	**# of CDIs**	**# of Holders**	**# of Shares**	**# of Holders**	**# of Shares**	**# of Holders**	**# of Shares**
1 – 1,000	11	4,114	140	65,315	2	2,000	—	—	—	—
1,001 – 5,000	9	25,000	227	702,712	3	9,000	—	—	—	—
5,001 – 10,000	6	43,963	132	1,120,900	—	—	—	—	7	47,800
10,001 – 100,000	20	627,949	264	8,610,520	19	808,267	—	—	8	278,000
100,001 and over	13	15,163,483	59	259,370,233	12	5,308,925	2	11,506,155	3	428,200
Total holders and securities	59	15,864,509	822	269,869,680	36	6,128,192	2	11,506,155	18	754,000

The number of shareholders holding less than a marketable parcel of CDIs (being a parcel of securities not less than A$500) as of February 15, 2017 was 66.

Top 20 CDI Holders as of February 15, 2017

Following are the top 20 holders of our CDIs on February 15, 2017 (does not include holdings in common stock):

		Number of CDIs Held	**% of CDIs Outstanding**
1.	Citicorp Nominees Pty Limited	60,989,370	22.6%
2.	Merrill Lynch (Australia) Nominees Pty Limited	49,406,739	18.3%
3.	HSBC Custody Nominees (Australia) Limited – GSCO ECA	40,673,612	15.1%
4.	JP Morgan Nominees Australia Limited	38,536,590	14.3%
5.	HSBC Custody Nominees (Australia) Limited <No 2 A/C>	32,619,920	12.1%
6.	DNU Nominees Pty Limited	4,774,821	1.8%
7.	HSBC Custody Nominees (Australia) Limited – A/C 3	4,540,405	1.7%
8.	Frederic H Moll	3,345,610	1.2%
9.	Trienos Group LLC	3,000,000	1.1%
10.	UBS Nominees Pty Ltd	2,000,000	0.7%
11.	HSBC Custody Nominees (Australia) Limited	1,595,051	0.6%
12.	Warman Investments Pty Ltd	1,451,771	0.5%
13.	Lightstorm Pty Ltd <Hotspice A/C>	1,332,000	0.5%
14.	Viking Management Services Pty Ltd <VHK Superannuation Fund A/C>	1,159,121	0.4%
15.	Mr Robert Thomas + Mrs Kyrenia Thomas <Rob Thomas Super Fund A/C>	1,100,000	0.4%
16.	Mrs Danielle Susan Borgas	1,006,000	0.4%
17.	Mr Antony Richard Kerr + Mr Peter Michael Clerk <AR Kerr Family A/C>	900,000	0.3%
18.	BT Portfolio Services Limited <Wade Family Super Fund A/C>	646,394	0.2%
19.	CS Fourth Nominees Pty Limited <HSBC Cust Nom AU Ltd 11 A/C>	636,919	0.2%
20.	Dr. Philip James Currie + Mrs. Anne Jennifer Currie <Currie Family Superfund A/C>	561,361	0.2%
	Total CDIs held by top 20 CDI holders	250,275,684	92.7%
	Total CDIs held by all other CDI holders	19,593,996	7.3%
	Total CDIs outstanding	269,869,680	100%

The table at the top of the next page provides a list of the top 20 holders of our securities as of February 15, 2017, taking into account securities held in the form of both common stock and CDIs and prepared on the assumption that all CDIs are held as common stock. Related but separate legal entities are not aggregated for the purposes of the table below.

	Security Holder	Shares of Common Stock Held	CDIs Held (common stock equivalent)	Total Number of Securities Held	% of Outstanding Capital
1.	Senrigan Capital	—	6,219,271	6,219,271	14.5%
2.	Goldman Sachs International	4,375,000	—	4,375,000	10.2%
3.	Domain Partners V, L.P.	3,606,002	—	3,606,002	8.4%
4.	Elliott Associates, L.P.	3,227,031	—	3,227,031	7.5%
5.	Saints Capital Everest, L.P.	—	3,223,513	3,223,513	7.5%
6.	Citicorp Nominees Pty Limited	—	3,032,693	3,032,693	7.1%
7.	Brookside Capital Partners Fund, LP	—	2,783,204	2,783,204	6.5%
8.	Medtronic, Inc.	379,651	1,352,610	1,732,261	4.0%
9.	Group Outcome Investors I, LLC	1,341,175	—	1,341,175	3.1%
10.	Cerberus Series Four Holdings, LLC	—	1,046,486	1,046,486	2.4%
11.	Cerberus International, Ltd	—	995,553	995,553	2.3%
12.	Gordon E. Nye	858,531	12,954	871,485	2.0%
13.	HSBC Custody Nominees (Australia) Limited – GSCO ECA	—	567,361	567,361	1.3%
14.	Cerberus Partners, L.P.	—	520,641	520,641	1.2%
15.	HSBC Custody Nominees (Australia) Limited <No 2 A/C>	—	478,788	478,788	1.1%
16.	DNU Nominees Pty Limited	—	477,482	477,482	1.1%
17.	Merrill Lynch (Australia) Nominees Pty Limited	—	364,551	364,551	0.9%
18.	Frederic H. Moll	—	334,561	334,561	0.8%
19.	Robert K. Schultz	311,500	—	311,500	0.7%
20.	Trienos Group LLC	—	300,000	300,000	0.7%
	Total securities held by top 20 holders (stated as common stock)	14,098,890	21,709,668	35,808,558	83.6%
	Total securities held by all other holders (stated as common stock)	1,765,619	5,277,300	7,042,919	16.4%

Unlisted Options, Unlisted Convertible Notes, and Unlisted Restricted Stock Units

As of February 15, 2017, we had 6,128,192 unlisted options to purchase shares of common stock on issue under the 2010 Equity Incentive Plan and the 2001 Stock Option/Stock Issuance Plan. These options are held by 36 individuals. With the exception of our Chief Executive Officer, Regina E. Groves, who holds 2,000,000 options representing 32.6 percent of the outstanding options, no other single person holds 20 percent or more of the outstanding options.

As of February 15, 2017, we had issued 250 unlisted convertible notes, each with a face value of $100,000, and each of which is convertible into 46,024.62 shares of common stock. The convertible notes are held equally by two entities, Goldman Sachs International and Senrigan Master Fund.

As of February 15, 2017, we had 754,000 unlisted restricted stock units on issue; each restricted stock unit entitles the holder to one share of common stock upon vesting. These restricted stock units are held by 18 individuals. The only individuals holding 20 percent or more of the RSUs are Robert K. Schultz, who holds 158,400 RSUs, and Katrina L. Thompson, who holds 151,800 RSUs.

Restricted Stock

As of February 15, 2017, we had 11,875 unlisted shares of restricted stock on issue under our 2010 Equity Incentive Plan, all of which was held by Robert B. Stockman.

Voting Rights

Our amended and restated certificate of incorporation and by-laws provide that each stockholder has one vote for every share of common stock entitled to vote and held by such stockholder on a record date. In addition, although holders of restricted stock are subject to restrictions on transfer until vesting, holders of restricted stock have the same voting rights as holders of shares of common stock.

If holders of CDIs wish to attend our general meetings, they will be able to do so. Under the ASX Listing Rules, REVA Medical, Inc., as an issuer of CDIs, must allow CDI holders to attend any meeting of the holders of the underlying securities unless relevant U.S. law at the time of the meeting prevents CDI holders from attending those meetings. In order to vote at such meetings, CDI holders have the following options:

- instructing CHESS Depositary Nominee or "CDN," as the legal owner, to vote the shares of REVA Medical common stock underlying their CDIs in a particular manner. The instruction form must be completed and returned to our share registry prior to the meeting;
- informing REVA Medical that they wish to nominate themselves or another person to be appointed as CDN's proxy for the purposes of attending and voting at the general meeting; and,
- converting their CDIs into a holding of shares of REVA Medical common stock and voting these at the meeting (however, if thereafter the former CDI holder wishes to sell their investment on ASX, it would be necessary to convert shares of common stock back to CDIs). This must be done prior to the record date for the meeting.

Because holders of CDIs do not appear on REVA Medical's share register as the legal holders of the common stock, they will not be entitled to vote at our stockholder meetings unless one of the above steps is undertaken. Proxy forms and details of these alternatives will be included in each notice of meeting sent to CDI holders by REVA Medical.

Holders of options and warrants to purchase stock, convertible notes, and restricted stock units are not entitled to vote.

Required Statements

REVA Medical makes the following disclosures:

- There is no current on-market buy-back of the Company's securities.
- REVA Medical, Inc. is incorporated in the state of Delaware in the United States of America.
- REVA Medical, Inc. is not subject to Chapters 6, 6A, 6B, or 6C of the Corporations Act dealing with the acquisitions of shares (including substantial shareholdings and takeovers).
- Under the Delaware General Corporation Law, shares are generally freely transferable subject to restrictions imposed by U.S. federal or state securities laws, by our certificate of incorporation or bylaws, or by an agreement signed with the holders of the shares at issue. Our amended and restated certificate of incorporation and bylaws do not impose any specific restrictions on transfer. Delaware General Corporation Law prohibits a publicly held Delaware Corporation from engaging in a "business combination" with an "interested shareholder" for a period of three years following the time the person became an interested shareholder, unless the business combination or acquisition of shares that resulted in a shareholder's becoming an interested shareholder is approved in a prescribed manner. A "business combination" can include a merger, asset or share sale, or other transaction resulting in a financial benefit to an interested shareholder. Generally, an interested shareholder is a person who, together with its affiliates and associates, owns (or within three years prior to the determination of interested shareholder status did own) 15 percent or more of a corporation's voting shares. The existence of this provision would be expected to have an anti-takeover effect with respect to transactions not approved in advance by the Board, including discouraging attempts that might result in a premium over the market price for the shares of common stock held by shareholders.
- The securities of REVA Medical, Inc. are not quoted on any exchange other than the ASX.

General Information

The name of the Company Secretary is Katrina Thompson. The address of our office in the United States, which is our principal administrative office, is REVA Medical, Inc., 5751 Copley Dr., San Diego, California 92111, telephone +1 (858) 966-3000.

The address of our registered office in Australia is c/o Buchan Pty Ltd, Suite 4, Level 14, 6 O'Connell Street, Sydney NSW 2000, telephone +61 2 9237 2800.

Registers of CDI securities are held at Computershare Investor Services Pty Limited, Level 3, 60 Carrington Street, Sydney NSW 2000, Australia, Investor Enquiries 1300 855 080. Registers of common stock securities are held at Computershare Trust Company, N.A., 250 Royall Street, Canton, MA 02021, USA, Investor Inquiries (800) 962-4284.

Quotation has been granted for CDIs (and the underlying shares of common stock) on the ASX Limited.

Australian Corporate Governance Statement

Our Board of Directors (the "Board") is committed to promoting and strengthening good corporate governance practices and a culture of good corporate governance and ethical conduct throughout the Company. The Board has evaluated the Company's corporate governance policies and practices in light of the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations 3rd Edition ("ASX Recommendations") for the Company's financial year ended December 31, 2016 and confirms that the Company's corporate governance framework is generally consistent with the ASX Recommendations, other than as set forth below. Following is a summary of the approach adopted and used by the Company during the year ended December 31, 2016, using the same numbering sequence as contained in the ASX Recommendations.

Principle 1 — Lay solid foundations for management and oversight

Recommendation 1.1 — Establish the roles and responsibilities of the board and management; disclose those matters expressly reserved to the board and those delegated to senior executives

The roles and responsibilities of the Board and of management have been established. The Board's responsibilities are defined by the Company's Corporate Governance Guidelines, a copy of which is available in the Corporate Governance section on the Company's website at *www.revamedical.com*. Management is responsible for implementing the strategic objectives set by the Board, to carry out the day-to-day operations of the Company, and to make accurate, timely, and clear reports to the Board. There is a clear delineation between the Board's responsibility for the Company's strategy and activities and management's responsibilities for the day-to-day management of operations.

Recommendation 1.2 — Undertake appropriate assessments prior to appointing a board member; provide all relevant material information to stockholders regarding a candidate proposed for election to the board

The Company's Corporate Governance Guidelines provide general criteria for Board member qualification. Additionally, the Nominating and Corporate Governance Committee of the Board is responsible for assessing the qualifications and background of Board candidates and appointees. Prior to recommending a new Board candidate, the Committee undertakes to check a candidate's independence, experience, education, and general character. Annually and prior to recommending re-election of a director, the Committee assesses performance, interests and independence, outside commitments, and availability for Board responsibilities. Only qualified candidates are recommended for appointment or candidacy. The backgrounds and qualifications of directors who are recommended for election or re-election are provided to stockholders in the Company's proxy statement. A partial list of the evaluations to be made of Board candidates is contained in the Nominating and Corporate Governance Committee's charter, which is available on the Company's website at *www.revamedical.com* in the Corporate Governance section Each Board member's background is also available on the Company's website in the Corporate Governance section.

The skills, experience, expertise, diversity, independence, and related information for each of our directors holding office as of February 15, 2017 are set forth below:

Ross Breckenridge, MD, MRCP, PhD, age 47, has served as a director since January 2015. Dr. Breckenridge is the Chief Executive Officer of Silver Creek Pharmaceuticals, Inc., since September 2016. Prior to that, he was a senior clinical lecturer and Programme Director for the Masters Programme in Clinical and Experimental Medicine at University College London since 2006. He was a Fellow of the Royal College of Physicians (London) and a Consultant Physician at University College London Hospital from 2006 until September 2016. Dr. Breckenridge has provided consultation services to investors in the biotech and healthcare sector since 1998. He is a current board member of the Cornelia de Lange Society of Great Britain and has sat on numerous other medical and corporate boards. He obtained his medical degree from Oxford University, followed by his PhD in Developmental Biology at the University of Cambridge. He then completed his training in Clinical Pharmacology at University College London. Dr. Breckenridge is qualified to sit on our Board due to his extensive medical background, particularly as it relates to research of cardiac disease, his experience serving on multiple other boards of directors, and his general business proficiency.

Brian H. Dovey, age 75, has served as a director since June 2001 and as Chairman of the Board since March 2016. Since 1988, Mr. Dovey has been a partner of Domain Associates, LLC, a private venture capital management firm focused on life sciences, where he has led innovative investments not only in life science companies, but also has established and directed new initiatives such as the collaboration between Domain and Rusnano. Since joining Domain, he has served on the board of directors of over 35 private and public companies and has been chairman of six, including REVA.

Mr. Dovey currently sits on the board of three public companies: REVA, Orexigen Therapeutics, Inc., and Miramar Labs, Inc. (since May 2016). Prior to joining Domain, Mr. Dovey spent six years at Rorer Group, Inc. (now part of Sanofi-Aventis), a pharmaceutical and medical device company listed on the NYSE. As president of Rorer from 1986 to 1988, he was the primary architect of the company's strategic shift to pharmaceuticals. Previous to that, he was President of Survival Technology, Inc., a start-up medical products company. Mr. Dovey serves on the board of directors and is also chairman at the Center for Venture Education (Kauffman Fellows Program) and serves on the La Jolla Playhouse board of trustees. He was the former chair and currently serves on the board of trustees of the Wistar Institute, a leader in preclinical biomedical research in the non-profit sector. Mr. Dovey has served as both president and chairman of the National Venture Capital Association. He is a former board member of the industry association representing the medical device industry, as well as the association representing consumer pharmaceuticals. He is a trustee emeritus of Germantown Academy and is a former trustee of the University of Pennsylvania School of Nursing and the Sanford-Burnham Institute for Medical Research. Mr. Dovey received his B.A. in mathematics from Colgate University and his MBA from the Harvard Business School. Mr. Dovey is qualified to sit on our Board due to his extensive financial background, his experience in corporate governance and risk management, his service as a director on over 35 private and public companies, his broad executive experience with medical device companies, and his extensive experience at a health care venture capital firm.

Scott Huennekens, age 52, has served as a director since March 2015. Since December 2015 he is President and Chief Executive Officer of Verb Surgical, Inc., a collaboration between Alphabet, Inc. (formerly Google) and Johnson & Johnson, focused on developing a comprehensive robotic surgical solutions platform. Previously, from April 2002 to February 2015, Mr. Huennekens was President and Chief Executive Officer of Volcano Corporation, a manufacturer of intravascular imaging equipment for coronary and peripheral applications. Prior to 2002, he served as President and Chief Executive Officer of Digirad Corporation, a diagnostic imaging solutions provider, and also held senior positions at Baxter International, Inc. in the Edwards Cardiovascular Division and the Novacor division. Mr. Huennekens currently serves on the Medical Device Manufacturers Association ("MDMA") board and he served on the board of EndoChoice until November 2016. He received his B.S. in Business Administration from the University of Southern California and an MBA from Harvard Business School. Mr. Huennekens is qualified to sit on our Board due to his vast experience in executive positions with medical equipment manufacturers, his broad business background, his experience serving on multiple other boards of directors, and his strong financial background, including his work early in his career at Deloitte, a provider of tax, audit, and advisory services.

Anne Keating, age 63, has served as a director since October 2010. Ms. Keating is currently a director of a number of ASX-listed companies in a range of different industries, including GI Dynamics, Inc., a U.S.-based medical device company (since June 2011), and Goodman Group Limited, a global property development and management company (since January 2004). Ms. Keating has been Chairman of Houlihan Lokey Australia, investment bank, since April 2015. Ms. Keating is also a Director of the Garvan Institute of Medical Research since January 2009 and an Inaugural Governor for the Cerebral Palsy Foundation since 2006. From 1993 to 2001, Ms. Keating held the position of General Manager, Australia for United Airlines. She was also a Delegate to the Australian/American Leadership Dialogue for 14 years. Ms. Keating previously served on the board of IAG, Australia's largest general insurer, ClearviewWealth Ltd, life insurance and wealth management, NRMA, Australia's largest mutual, and was an inaugural board member of the Victor Chang Cardiac Research Institute where she served for ten years. She has also held former directorships with Spencer Street Station Redevelopment Holdings Limited, Easy FM China Pty Ltd, Radio 2CH Pty Ltd, and Workcover Authority of New South Wales. Ms. Keating is qualified to sit on our Board due to her extensive business, management, and governance experience, including her positions on a number of boards of ASX-listed companies. Ms. Keating also brings Australian medical research and cardiac experience from her years of service with the Garvan Institute of Medical Research and the Victor Chang Cardiac Research Institute.

Gordon E. Nye, age 62, has served as a director since 1999. Since December 2014, he is Chief Executive Officer of R2 Dermatology, a development stage medical device company. He served as Chief Executive Officer of ZELTIQ Aesthetics, Inc., a medical device company, from September 2009 to April 2012. From August 2003 to July 2009, Mr. Nye served as general partner of Prism Venture Partners, a venture capital firm, where he was a member of the life sciences investment team. Prior to that time, he served as our Chief Executive Officer from 2001 to 2003 and President and Chief Executive Officer of two former Johnson & Johnson divisions ("A" Company Orthodontics, Inc. and Critikon Company, LLC) after they were acquired in management buyouts. He has also held a variety of marketing, sales, and general management roles for L.A. Gear, Inc., Olin Ski Company, Inc., Reebok, Ltd., and The Gillette Company. Mr. Nye received his MBA from the Amos Tuck School of Business at Dartmouth College where he also received his undergraduate degree. Mr. Nye's qualifications to sit on our Board include his knowledge of the medical device business, his broad operating experience as a senior executive, his extensive consumer marketing background, and his other board service.

Robert B. Stockman, age 63, our co-founder and a member of our Board, served as our Board Chairman from 1999 until March 2016; he was our Chief Executive Officer from August 2010 to September 2015. He served as a director of HeartWare Limited/HeartWare International, Inc., a NASDAQ-listed medical device company (formerly also ASX-listed), between December 2006 and August 2016 when they were acquired by Medtronic, Inc. He previously served on the board of ZELTIQ Aesthetics, Inc., a medical technology company listed on NASDAQ, from July 2010 until April 2012. Since 1999, Mr. Stockman has been the President and Chief Executive Officer of Group Outcome LLC, a U.S.-based merchant banking firm that deploys its capital and that of its financial partners in private equity and venture capital investments in medical technology companies. Mr. Stockman also co-founded Centrimed, Inc., an internet-based software company, that was acquired by the Global Healthcare Exchange, LLC, and led the buyouts of Ioptex, an intraocular lens manufacturer, and two Johnson & Johnson divestitures, "A" Company Orthodontics, Inc. and Critikon Company, LLC, each of which was subsequently acquired. Prior to establishing Group Outcome LLC, Mr. Stockman spent 18 years with Johnston Associates, Inc. and Narragansett Capital Corporation, where he focused on venture capital investments and merger advisory work in health care. Mr. Stockman holds a Bachelor's Degree from Harvard College and an MBA from The Tuck School at Dartmouth College, where he serves on Tuck's Board of Overseers. Mr. Stockman is qualified to sit on our Board due to his extensive experience as an entrepreneur driving the growth of five medical products companies, his experience as an executive of several medical device companies, and his experience as an executive in the investment banking industry, particularly in private equity and venture capital investments in medical technology. Mr. Stockman's qualifications also include his strong financial background, including his work early in his career at Price Waterhouse, a provider of tax, audit, and advisory services, and his ability to provide financial expertise to the Board, including an understanding of financial statements, corporate finance, accounting, and capital markets.

Robert Thomas, age 71, has served as a director since July 2010. He was a director and non-executive Chairman of the Board of HeartWare Limited/HeartWare International, Inc., a NASDAQ-listed medical device company (formerly also ASX-listed), between November 2004 and August 2016 when they were acquired by Medtronic, Inc. He is currently a director of a number of Australian public companies, including Virgin Australia Limited, and Biotron Limited; he is Chairman of Starpharma Limited. Between October 2004 and September 2008, Mr. Thomas was a consultant to Citigroup Corporate and Investment Bank. Between March 2003 and September 2004, he was Chairman of Global Corporate and Investment Bank, Citigroup Global Markets, Australia and New Zealand. Prior to that time, Mr. Thomas was Chief Executive Officer of Citigroup's Corporate and Investment Bank (formerly known as Salomon Smith Barney), Australia and New Zealand from October 1999 until February 2003. Mr. Thomas is Chairman of Aus Bio Limited, a director of O'Connell Street Associates, and Chairman of Grahger Capital Resources. Mr. Thomas holds a Bachelor of Economics from Monash University, Australia. He is a member of the Stockbrokers Association of Australia and is a Master Stockbroker. Mr. Thomas is also a Fellow of the Financial Services Institute of Australia and the Australian Institute of Company Directors. He is on the board of the NSW State Library Foundation and serves on NSW State Library's Audit and Risk Committee. Mr. Thomas is qualified to sit on our Board due to his extensive investment banking experience, including his leadership of finance and strategic transactions, his involvement with medical device companies, and his experience in governance and risk management across a wide range of industries. Mr. Thomas also brings capital market and economics expertise to the Board from his years of service as a securities analyst and experience as a director of ASX-listed companies.

Recommendation 1.3 — Provide a written agreement with each director and senior executive setting out the terms of his or her appointment

The terms of Board membership are set forth in the Company's Corporate Governance Guidelines and remuneration to Board members is provided in accordance with stockholder approvals following the Compensation Committee's recommendation. While the Company does not have a separate written agreement with each of its Board members, it believes these guidelines are adequate to provide a clear understanding of the roles and responsibilities of Board members. In the case of senior executives, the Company has provided a letter of employment to each executive detailing the terms of employment and has developed job descriptions setting forth the position, duties, and reporting structure. Where there are any agreed entitlements upon termination, such agreed items are set forth in the employment letters. For the year ended December 31, 2016, there were no material variations to any of the Company's employment letters.

Recommendation 1.4 — The Company secretary is accountable directly to the board on all matters to do with the proper functioning of the board

The role and responsibilities of the Company's secretary are set forth in the Company's bylaws. The Board is responsible for electing or appointing the secretary and for prescribing the duties and powers of the secretary. The secretary is responsible for preparing and maintaining the appropriate corporate records, including such items as meeting notices, meeting minutes, and stock ledgers, and to provide such records to the Board as requested or required. The secretary is accountable to the Board on all matters to do with the proper functioning of the Board. Each director is able to communicate freely and directly with the secretary and vice versa.

Recommendation 1.5 — Establish and maintain a gender-based diversity policy and provide an annual report of the Company's measurable objectives for achieving gender diversity

The Company has adopted a Diversity Policy, which includes measurable objectives for achieving gender diversity and provisions for the Board to annually assess both the objectives and the Company's progress in achieving them. A copy of the Diversity Policy is available in the Corporate Governance section on the Company's website at *www.revamedical.com*.

The Board continued to evaluate the gender diversity of the Company's employees, its senior management, and its Board during 2016 and determined that the gender diversity continued at levels generally consistent with the prior year and in line with expectations. The Board endorsed the Company's objective for diversity to remain at the same relative proportions, if not higher, of females in each category measured. The base level expectations for females are a minimum 15 percent of Board members, 30 percent of senior management, and 40 percent of employees. As of December 31, 2016, the Company reports that women represented 14 percent of its Board members, 40 percent of its senior executives (those positions of vice presidents and higher), and 49 percent of its entire workforce, which was aligned with its Diversity Policy.

Recommendation 1.6 — Establish and maintain a process to periodically evaluate the board, the board committees, and individual directors and provide an annual report of the undertaking of such process

The Company's Corporate Governance Guidelines provide for annual assessments of the performance of the Board and each committee of the Board, to be provided to the Nominating and Corporate Governance Committee. The performance assessments include evaluations of numerous items, including each Board and committee member's independence and skill levels, process and effectiveness in addressing Company, Board, and committee matters, interactions with management and outside service providers, meeting attendance, and governance items, including annual charter reviews. The assessments are to be completed by individual Board members, aggregated by the Nominating and Corporate Governance Committee, and evaluated and discussed by the Board and the individual committees of the Board. Such Board and committee assessments were performed and evaluated for the year ended December 31, 2016 in accordance with the guidelines.

The Company's Corporate Governance Guidelines do not call for evaluation of each individual director. The size of the Board and each committee is relatively small, Board and committee meetings are held frequently throughout the year, and the process to assess the Board and each committee considers the involvement and effectiveness of the individual directors. These factors allow for continuous self-assessment, as well as Board level assessments and feedback, of individual performance and contribution.

Recommendation 1.7 — Establish and disclose the process to evaluate the performance of senior executives and provide an annual report of the undertaking of such process

The Company's employment and personnel policies provide for annual performance evaluations and goal setting for all employees, including senior executives. The Compensation Committee of the Board, in accordance with its charter, annually reviews the performance of each senior executive and reviews and approves each personal performance goal, then subsequently measures attainment of the goals. The assessments made by the Compensation Committee are reported to the Board. In accordance with the established processes, the performance of the senior executives of the Company was evaluated by the Company's Compensation Committee and Board for the year ended December 31, 2016.

Principle 2 — Structure the board to add value

Recommendation 2.1 — Establish a nomination committee and disclose its charter and membership

The Board has established a Nominating and Corporate Governance Committee to oversee the selection and appointment practices of the Company. The Committee consists of three members: Anne Keating (Chair), Dr. Ross Breckenridge, and Gordon Nye. All members of the Committee are non-executives and are considered independent directors for both ASX and SEC purposes. The Committee held two formal and numerous informal meetings during the year ended December 31, 2016; all members attended all meetings. A copy of the Nominating and Corporate Governance Committee Charter is available in the Corporate Governance section on the Company's website at *www.revamedical.com*.

Recommendation 2.2 — Establish and disclose a board skills matrix setting out the mix of skills and diversity the board currently has or is looking to achieve

The Nominating and Corporate Governance Committee of the Board is responsible for developing and recommending the mix of skills and diversity for Board and committee members. The committee continually assesses the needs of the Company and the current mix of skills provided by Board members. While the Company has been, and continues to be, in a pre-revenue stage, the skill mix of the Board has been focused on the needs of a pre-revenue company. As the Company prepares for commercialization, a formal skills matrix is anticipated to be developed by early 2017.

Recommendation 2.3 — Disclose director independence and length of service

The Company considers a director to be independent when that director is free from any interest and any business or other relationship that could, or could reasonably be perceived to, materially interfere with the director's decisions relating to the Company or with the director's ability to act in the best interests of the Company. In accordance with the Corporate Governance Guidelines, a director will not be considered to be independent until the Board affirmatively determines that such director meets all applicable standards. Annually, the Board will review its determinations based on recommendations from the Nominating and Corporate Governance Committee.

At the Company's expense, the Board collectively or the directors acting as individuals are entitled to seek advice from independent external advisors in relation to any matter that is considered necessary to fulfill their relevant duties and responsibilities. Individual directors seeking such advice must obtain approval of the Chairman (which may not be unreasonably withheld). Any advice so obtained will be made available to all Board members.

The composition and tenure of the members of the Board as of December 31, 2016, as well as each member's independence status during 2016, was as follows:

				Committees		
Director	**Director Position**	**Year Appointed**	**Independent**	**Audit**	**Compensation**	**Nominating and Corp. Governance**
Brian H. Dovey	Chairman	2001	(1)	X	X	–
Dr. Ross A. Breckenridge	Non-Executive	2015	Yes	–	–	X
R. Scott Huennekens	Non-Executive	2015	Yes	Chair	–	–
Anne J. Keating	Non-Executive	2010	Yes	–	–	Chair
Gordon E. Nye	Non-Executive	1999	Yes	–	Chair	X
Robert B. Stockman	Non-Executive	1999	No (2)	–	–	–
Robert B. Thomas	Non-Executive	2010	Yes	X	X	–

(1) Mr. Dovey is an Independent Director under the rules of NASDAQ and the SEC, but not considered independent under the ASX.

(2) Mr. Stockman was employed as our Chief Executive Officer until September 18, 2015. Under ASX, NASDAQ, and SEC rules, a director employed by the Company is not independent until three years after such employment terminates.

Recommendation 2.4 — A majority of board members should be independent

A majority of the Company's Board was independent during the year ended December 31, 2016. Mr. Dovey is a principal in a firm that has invested in our Company and for ASX purposes he is not considered to be independent. Mr. Stockman was Chief Executive Officer until September 2015 and, as a result, will not be considered an independent director until September 2018. All other members of our Board are considered to be independent.

Recommendation 2.5 — The Chair of the board should be an independent director and should not be the chief executive officer

Mr. Dovey was appointed Chairman of our Board on March 28, 2016. Mr. Dovey is not considered an independent director under ASX Listing Rules as he is a principal in a firm that has an approximate 8.6 percent ownership interest in REVA. Prior to Mr. Dovey's appointment, Mr. Stockman was the Chairman. Mr. Stockman was also our Chief Executive Officer until September 18, 2015. Because Mr. Stockman was an officer of REVA, he was not an independent director during the time he was Chairman. The Board appointed a new Chief Executive Officer in September 2015, Regina E. Groves, who is not a Board member; see "— Executive Officers" above for Ms. Groves' biography.

We believe that our Board, and in particular the role of Chairman, is able to carry out their responsibilities in an independent manner since the roles of Chairman and Chief Executive Officer have been separate since September 2015 (and for the entire year ended December 31, 2016) and there is adequate segregation of responsibilities between the Board and management. Management continues to be responsible for, and carry out, the day-to-day operations of the Company while oversight and governance functions are addressed by the Board, a majority of who are independent.

Recommendation 2.6 — Establish a program for inducting new directors and ongoing development opportunities for directors

The Nominating and Corporate Governance Committee of the Board continually assesses the needs of the Company and the skills and knowledge required of its Board members. On appointment, new directors are provided with induction information that generally includes historical information about the Company and its operations, details of the Company's directors' and officers' insurance, the Company's Corporate Governance Guidelines, and other Company governance policies. The induction process also involves one-on-one discussions with the Chairman and other directors and briefings from senior management to help new directors participate actively in Board decision making at the earliest opportunity. When it is necessary, resources are provided for the Board as a whole, and for individual Board members as needed, to supplement their skills and knowledge and fill any identified gaps. Any outside expertise guidance or training undertaken by Board members in furtherance of their responsibilities to the Company is generally paid by the Company.

Principle 3 — Act ethically and responsibly

Recommendation 3.1 — Establish a code of conduct and disclose a summary of the code

The Company has adopted a Code of Business Conduct and Ethics, an Insider Trading Policy, and a Related Party Transaction Policy. A copy of each policy is available in the Corporate Governance section on the Company's website at *www.revamedical.com*. These Company codes apply to all directors, senior executives, and employees and, in general, call for personal integrity, ethical conduct, and balanced business approaches and dealings. The policies are reinforced on a regular basis and provide for disciplinary action for any violations.

Principle 4 — Safeguard integrity in corporate reporting

Recommendation 4.1 — Establish an audit committee

The Board has established an Audit Committee to oversee the management of the Company's financial and internal risks and reporting. The Audit Committee has adopted and is governed by a formal charter, a copy of which is available in the Corporate Governance section on the Company's website at *www.revamedical.com*. The Audit Committee regularly reports to the Board about Committee activities, issues, and related recommendations.

The Audit Committee comprises three members, who are Mr. Huennekens (Chair), Mr. Dovey, and Mr. Thomas. All Committee members are non-executive directors and a majority are independent. Mr. Huennekens and Mr. Thomas are considered independent directors for ASX purposes; however, Mr. Dovey is not considered to be independent for ASX purposes but is considered to be independent under SEC rules. The Committee held five meetings during 2016; Mr. Huennekens attended all meetings, Mr. Dovey attended three meetings, and Mr. Thomas attended four meetings.

All members of the Audit Committee are considered to be financially literate and familiar with financial and accounting matters and qualified to adequately understand the financial and accounting matters that relate to the Company. Mr. Huennekens is considered to be a financial professional with appropriate financial and accounting expertise.

Recommendation 4.2 — Receive declarations from the Chief Executive Officer and Chief Financial Officer prior to approving financial statements regarding compliance with accounting standards, accuracy and fairness of disclosures, and the systems of internal controls and risk management underlying the financial statements

The Company is a U.S. SEC registrant and, as such, complies with SEC requirements in addition to the ASX Listing rules. In accordance with SEC requirements, the Company's Chief Executive Officer and its Chief Financial Officer review and assess the financial statements and related disclosures and the underlying financial records, internal controls, and policies and procedures. At each financial reporting date, the Audit Committee of the Board is provided certifications, which are filed with the SEC and lodged with the ASX, by the Chief Executive Officer and the Chief Financial Officer regarding their assessments of the financial statements and underlying internal controls. During the year ended December 31, 2016, such certifications were filed with the SEC and lodged with the ASX.

Recommendation 4.3 — The Company's external auditor should attend its AGM

The Company's policy is to ensure its external auditor attends the Annual General Meeting of stockholders, in person, to have an opportunity to make a statement, if desired, and to respond to appropriate questions from security holders regarding the audit. The Company's auditor for the year ended December 31, 2016 was Grant Thornton LLP, who attended the AGM.

Principle 5 — Make timely and balanced disclosure

Recommendation 5.1 — Establish a policy for continuous disclosure and disclose that policy

The Company is committed to providing timely and balanced disclosure to the market in accordance with its continuous disclosure obligations, as required under ASX Listing Rules. In accordance with its commitment to fully comply with these obligations and to ensure accountability at a senior management level for that compliance, the Company has adopted a Continuous Disclosure Policy, together with other internal mechanisms and reporting requirements. A copy of the Company's Continuous Disclosure Policy is available on its website at *www.revamedical.com* in the Corporate Governance section. In addition, copies of all the Company's ASX announcements, financial reports, and related public information are also available on the Company's website.

Principle 6 — Respect the rights of security holders

Recommendation 6.1 — Provide information about the Company and its governance via a website

The Company is committed to providing ready access to information about the Company, its approach and policies regarding governance, and its reports. Accordingly, the Company hosts and maintains a website at *www.revamedical.com* that includes information about the Company, its products, methods of contact, answers to frequently asked questions, and a separate section with information for Investors. In addition to providing links to the Company's ASX trading information, news releases, and ASX and SEC filings, the Investor section includes information about the Company's directors and senior management, committee composition and charters, and its corporate governance policies.

Recommendation 6.2 — Design and implement a program to facilitate effective two-way communication with investors

The Company has adopted a Shareholder Communication Policy that supports effective two-way communication with its shareholders. The Shareholder Communication Policy is included in the Company's Corporate Governance Guidelines, a copy of which is available in the Corporate Governance section on the Company's website at *www.revamedical.com*. The Company seeks to utilize numerous modes of communication, including electronic communication, to ensure that its communication with Shareholders is frequent, clear, and accessible. Additionally, the Company announces briefing calls in advance of such calls, provides relevant information on its website, and maintains internal records of matters discussed with shareholders. Shareholders are entitled to and encouraged to participate in briefing calls and/or contact the Company directly with questions or concerns. Contact information in both Australia and the U.S. is provided in each communication with shareholders, as well as on the Company's website.

Recommendation 6.3 — Facilitate and encourage shareholder participation at meetings

All shareholders are invited to attend the Company's annual meeting either in person or by proxy. To facilitate attendance, the Company arranges the annual meeting to be held in an easily accessed and well-known public location in Sydney and announces the date and location of the meeting in advance of the meeting. Notices of the meeting are mailed to all securityholders. The Board regards the annual meeting as an excellent forum in which to discuss issues relevant to the Company and accordingly encourages full participation by shareholders. Shareholders have an opportunity to submit questions to the Board and auditors. The meeting may also be audio cast and/or webcast to provide access to those shareholders who are unable to attend the annual general meeting in person.

Recommendation 6.4 — Provide security holders the option to receive communications electronically

The Company's share registry is managed by Computershare Investor Services, who provides security holders the option to receive and send communications from and to the share registry electronically. Additionally, the share registry facilitates electronic distribution of Company materials. In addition, the Company provides ongoing electronic notices and reports to shareholders and other third parties who have provided their electronic contact details to the Company and have requested to receive such notices and reports electronically. The Company provides an e-mail alert subscription form on its website at *www.revamedical.com* under the Investor section that allows the subscriber to select which information to receive about the Company. The selections include press releases, ASX announcements, SEC filings, and webcasts and events.

Principle 7 — Recognize and manage risk

Recommendation 7.1 — Establish a committee to oversee risk

While the Company has adopted a Risk Management Policy that sets forth the process to identify, assess, and manage risk in the Company's business operations, it has not established a formal Risk Committee. A copy of the Risk Management Policy is available in the Corporate Governance section on the Company's website at *www.revamedical.com*. In addition to following its Risk Management Policy, the Board and its committees have developed its charters and policies with a focus on risk identification and management. The Board's role in risk oversight includes receiving reports from external auditors, internal auditors, other independent parties, and from members of management on a regular basis regarding material risks faced by the Company and applicable mitigation strategies and activities. The reports from management are provided at least quarterly. The reports cover the critical areas of operations, research and development, regulatory and quality affairs, intellectual property, clinical developments, and legal and financial affairs, as well as management's assessment of risks facing the Company. The Board and its committees consider these reports, discuss matters with management and independent parties, and identify and evaluate any potential strategic or operational risks and appropriate activity to address those risks, thereby ensuring effectiveness in identifying and managing material business risks.

Recommendation 7.2 — Review the risk management framework and disclose the results of such review

While the Board does not currently conduct a formal annual review of the material risks to the Company and the methods used to identify and communicate those risks, the Board continually assesses these matters and believes this current approach is effective. As the Company prepares for commercialization and anticipates the related additional business risks in 2017, it intends to develop a formal review process of the Company's risk identification and management processes.

Recommendation 7.3 — Disclose the structure and role of internal audit

The Company engages a third party independent firm for its internal audit function. This independent internal audit firm reports directly to the Audit Committee and is responsible for developing independent risk-based reviews and testing of the Company's system of internal controls over financial reporting. The independent internal audit firm shares its results and reports with management and the Company's external auditors and provides recommendations for improvements if necessary.

Recommendation 7.4 — Disclose material exposures to economic, environmental, and social sustainability risks

The Company provides a complete assessment of risks to the business in the "Risk Factors" section of this Annual Report on Form 10-K. Considering its pre-revenue stage, location of facilities, and intended products and markets, the Company does not believe it has exposure to material economic, environmental, or social sustainability risks beyond those discussed in the "Risk Factors" section.

Principle 8 — Remunerate fairly and responsibly

Recommendation 8.1 — Establish a remuneration committee

The Board has established a Compensation Committee to review and assess executive and director compensation. The Compensation Committee has adopted and is governed by a formal charter, a copy of which is available in the Corporate Governance section on the Company's website at *www.revamedical.com*. The Compensation Committee regularly reports to the Board about Committee activities, issues, and related recommendations.

The Committee comprises three members, who are Mr. Nye (Chair), Mr. Dovey, and Mr. Thomas. Mr. Nye and Mr. Thomas are both considered to be independent for ASX purposes; however, Mr. Dovey is not considered to be independent for ASX purposes but is considered to be independent under the SEC rules. The Compensation Committee, therefore, consists of a majority of independent directors and is also chaired by an independent director. The Committee held one formal and numerous informal meetings during 2016. All Committee members attended all meetings.

Recommendation 8.2 — Disclose the policies and practices regarding remuneration of directors and senior executives

In accordance with its charter, the Compensation Committee is responsible for ensuring that the policies and practices regarding compensation for directors and senior executives are defined and disclosed. The Company has adopted a non-executive director compensation policy pursuant to which directors are compensated for their services to the Board. Non-executive director compensation comprises a base fee, committee membership fees, chair fees, and the ability to receive annual equity grants at the Board's discretion (subject to shareholders' approval being obtained as required under the ASX Listing Rules). The Company has adopted a separate executive compensation program that consists of base salary, equity-based incentives, performance-based cash bonuses, severance benefits, and other customary benefits such as health insurance on the same basis as provided to all other employees. None of the Company's non-executive directors are entitled to any retirement benefits.

The Company discloses compensation details, including philosophy, policy, and compensation payments for each director and each executive officer in its annual Proxy Statement as lodged with the ASX, filed with the SEC, and provided to shareholders ahead of the Annual General Meeting. A copy of the prior proxy statements can be found in the Investors section of the Company's website at *www.revamedical.com*.

While the Compensation Committee reviews and reports compensation items to the Board for both non-executive directors and executive management, including each individual's skills, knowledge, and contributions to the Company, the Committee does not provide a separate report of compensation by gender.

Further information regarding the Compensation Committee, as required by Item 10 of this Annual Report on Form 10-K, will be contained in our 2017 Proxy Statement. Such information is incorporated herein by reference.

Recommendation 8.3 — Disclose the policy regarding permitted equity-based transactions

The Company provides compensation in the form of equity-based awards to non-executive directors (upon approval by shareholders), senior executives, and employees of the Company. Awards are made under the Company's 2010 Equity Incentive Plan, as amended, which has been approved by shareholders. The Company's Insider Trading Policy, a copy of which is available in the Corporate Governance section on the Company's website at *www.revamedical.com*, sets out the Company's policy that prohibits certain transactions involving REVA's securities, including short-term or speculative transactions and publicly traded options, short sales, puts and calls, hedging, and other transactions.

Item 11. Executive Compensation

The information required by this item is incorporated by reference to our 2017 Proxy Statement under the headings "Non-Employee Director Compensation" and "Executive Compensation."

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The Information required by this item is incorporated by reference to our 2017 Proxy Statement under the heading "Security Ownership of Certain Beneficial Owners and Management."

The following table sets forth information regarding outstanding options and shares reserved for future issuance as of December 31, 2016 under equity compensation plans approved by our stockholders. We do not have any equity compensation plans that have not been approved by stockholders.

Plan Category	Number of Shares to be Issued on Vesting or Exercise of Outstanding Awards	Weighted Average Exercise Price of Outstanding Stock Options	Number of Shares Remaining Available for Future Issuance [1]
Equity compensation plans approved by stockholders [2]	6,904,067	$6.65	8,028,446

(1) Our 2010 Equity Incentive Plan, as amended, contains a provision for an automatic increase each January 1st of the number of shares available for grant. The automatic increase shall be the lessor of (i) 3% of the number of shares of our common stock issued and outstanding on January 1st or (ii) a number of shares set by our Board.

(2) Consists of grants and awards from our 2001 Stock Option/Stock Issuance Plan and our 2010 Equity Incentive Plan, as amended, including 6,128,192 outstanding options to purchase common stock, 21,875 shares of restricted stock subject to future vesting, and 754,000 restricted stock units that each entitles the holder to one share of our common stock upon vesting.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is incorporated by reference to our 2017 Proxy Statement under the heading "Related Party Transactions."

Item 14. Principal Accounting Fees and Services

The information required by this item is incorporated by reference to our 2017 Proxy Statement under the heading "Audit and Non-Audit Fees."

PART IV

Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as part of this Annual Report on Form 10-K:

1. Financial Statements — The following financial statements are included in this report:

   Report of Independent Registered Public Accounting Firm

   Consolidated Balance Sheets

   Consolidated Statements of Operations and Comprehensive Loss

   Consolidated Statements of Cash Flows

   Consolidated Statements of Stockholders' Equity (Deficit)

   Notes to Consolidated Financial Statements

2. List of Financial Statement Schedules — All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

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

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

REVA Medical, Inc.

Dated: February 27, 2017

By: /s/ Regina E. Groves
Name: Regina E. Groves
Title: Chief Executive Officer
(principal executive officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Regina E. Groves Regina E. Groves	Chief Executive Officer (principal executive officer)	February 27, 2017
/s/ Katrina L. Thompson Katrina L. Thompson	Chief Financial Officer (principal financial and accounting officer)	February 27, 2017
/s/ Brian H. Dovey Brian H. Dovey	Chairman of the Board	February 27, 2017
/s/ Ross A. Breckenridge Dr. Ross A. Breckenridge	Director	February 27, 2017
/s/ R. Scott Huennekens R. Scott Huennekens	Director	February 27, 2017
/s/ Anne J. Keating Anne J. Keating	Director	February 27, 2017
/s/ Gordon E. Nye Gordon E. Nye	Director	February 27, 2017
/s/ Robert B. Stockman Robert B. Stockman	Director	February 27, 2017
/s/ Robert B. Thomas Robert B. Thomas	Director	February 27, 2017

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
REVA Medical, Inc.

We have audited the accompanying consolidated balance sheets of REVA Medical, Inc., a Delaware corporation, (the "Company") as of December 31, 2015 and 2016, and the related consolidated statements of operations and comprehensive loss, cash flows, and stockholders' equity (deficit) for each of the three years in the period ended December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of REVA Medical, Inc. as of December 31, 2015 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2016 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company incurred a net loss of $54,098,000 during the year ended December 31, 2016, and as of that date has a cash balance of $6,674,000, current liabilities of $98,810,000, and an accumulated deficit of $389,238,000. These conditions, along with other matters as set forth in Note 2, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2016, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 27, 2017 expressed an unqualified opinion thereon.

/s/ GRANT THORNTON LLP

San Diego, California
February 27, 2017

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

Assets	December 31, 2015	December 31, 2016
Current Assets:		
Cash and cash equivalents	$ 16,895	$ 6,674
Prepaid expenses and other current assets	397	472
Total current assets	17,292	7,146
Non-Current Assets:		
Property and equipment, net	2,719	2,277
Other non-current assets	60	60
Total non-current assets	2,779	2,337
Total Assets	$ 20,071	$ 9,483
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable	$ 1,054	$ 778
Accrued expenses and other current liabilities	2,242	2,173
Convertible notes payable	—	91,655
Accrued interest on convertible notes payable	—	4,204
Total current liabilities	3,296	98,810
Long-Term Liabilities:		
Convertible notes payable	75,365	—
Common stock warrant liability	19,622	—
Other long-term liabilities	2,352	266
Total long-term liabilities	97,339	266
Total Liabilities	100,635	99,076
Commitments and contingencies (Note 9)		
Stockholders' Deficit:		
Common stock — $0.0001 par value; 100,000,000 shares authorized; 38,155,986 and 42,851,477 shares issued and outstanding at December 31, 2015 and December 31, 2016, respectively	4	4
Class B common stock — $0.0001 par value; 25,000,000 shares authorized; no shares issued or outstanding	—	—
Undesignated preferred stock — $0.0001 par value; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Additional paid-in capital	254,572	299,641
Accumulated deficit	(335,140)	(389,238)
Total Stockholders' Deficit	(80,564)	(89,593)
Total Liabilities and Stockholders' Deficit	$ 20,071	$ 9,483

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

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

	Year Ended December 31,		
	2014	**2015**	**2016**
Operating Expense:			
Research and development	$ 14,318	$ 16,760	$ 18,171
General and administrative	7,645	7,210	8,609
Loss from operations	(21,963)	(23,970)	(26,780)
Other Expense:			
Interest income	8	9	3
Interest expense	(986)	(1,904)	(2,053)
Loss on issuance of convertible notes payable and warrants	(15,627)	—	—
Loss on change in fair value of convertible notes payable and warrant liability	(12,542)	(56,788)	(25,247)
Other income (expense)	73	59	(21)
Other expense	(29,074)	(58,624)	(27,318)
Net Loss and Comprehensive Loss	$ (51,037)	$ (82,594)	$ (54,098)
Net Loss Per Common Share:			
Net loss per share, basic and diluted	$ (1.53)	$ (2.38)	$ (1.28)
Shares used to compute net loss per share, basic and diluted	33,382,381	34,680,634	42,120,545

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

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

	Year Ended December 31,		
	2014	**2015**	**2016**
Cash Flows from Operating Activities:			
Net loss	$ (51,037)	$ (82,594)	$ (54,098)
Non-cash adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	1,027	1,096	1,139
Stock-based compensation	3,516	3,434	4,723
Interest on convertible notes payable	986	1,904	2,053
Loss on issuance of convertible notes payable and warrants	15,627	—	—
Loss on change in fair value of convertible notes payable and warrant liability	12,542	56,788	25,247
Other non-cash expenses	19	46	21
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	9	9	(75)
Accounts payable	(566)	365	(244)
Accrued expenses and other current liabilities	64	33	(90)
Other long-term liabilities	(117)	(163)	65
Net cash used for operating activities	(17,930)	(19,082)	(21,259)
Cash Flows from Investing Activities:			
Purchases of property and equipment	(541)	(857)	(729)
Purchases of investments	(995)	—	—
Maturities of investments	1,492	995	—
Net cash provided by (used for) investing activities	(44)	138	(729)
Cash Flows from Financing Activities:			
Proceeds from issuances of common stock	247	10,075	11,767
Proceeds from (costs of) issuance of convertible notes payable and warrants, net	24,312	(50)	—
Net cash provided by financing activities	24,559	10,025	11,767
Net increase (decrease) in cash and cash equivalents	6,585	(8,919)	(10,221)
Cash and cash equivalents at beginning of period	19,229	25,814	16,895
Cash and Cash Equivalents at End of Period	$ 25,814	$ 16,895	$ 6,674
Supplemental Non-Cash Information:			
Property and equipment in accounts payable	$ 12	$ 50	$ 18
Warrant liability transferred to equity upon exercise	$ —	14,970	$ 28,579

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

REVA Medical, Inc.
Consolidated Statements of Stockholders' Equity (Deficit)
(in thousands, except share and per share amounts)

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance at December 31, 2013	33,270,053	$ 3	$ 222,331	$ (201,509)	$ 20,825
Net loss and comprehensive loss	—	—	—	(51,037)	(51,037)
Common stock issued January through October upon exercise of stock options for cash at $0.61 to $1.40 per share	259,725	—	247	—	247
Stock-based compensation expense	—	—	3,516	—	3,516
Balance at December 31, 2014	33,529,778	$ 3	$ 226,094	$ (252,546)	$ (26,449)
Net loss and comprehensive loss	—	—	—	(82,594)	(82,594)
Common stock issued March through December upon exercise of stock options for cash at $1.25 to $5.60 per share	251,208	—	569	—	569
Common stock issued October upon exercise of warrants for cash at $2.17275 per share	4,375,000	1	9,505	—	9,506
Fair value of warrant liability transferred to equity upon warrant exercise	—	—	14,970	—	14,970
Stock-based compensation expense	—	—	3,434	—	3,434
Balance at December 31, 2015	38,155,986	$ 4	$ 254,572	$ (335,140)	$ (80,564)
Net loss and comprehensive loss	—	—	—	(54,098)	(54,098)
Common stock issued February through December upon exercise of stock options for cash at $1.40 to $4.00 per share	132,916	—	360	—	360
Common stock issued February upon exercise of warrants for cash at $2.6073 per share	4,375,000	—	11,407	—	11,407
Common stock issued May upon vesting of restricted stock units	160,000	—	—	—	—
Common stock issued December upon net exercise of stock options	27,575	—	—	—	—
Fair value of warrant liability transferred to equity upon warrant exercise	—	—	28,579	—	28,579
Stock-based compensation expense	—	—	4,723	—	4,723
Balance at December 31, 2016	42,851,477	$ 4	$ 299,641	$ (389,238)	$ (89,593)

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

1. Description of Business

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

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

In December 2010 we completed an initial public offering (the "IPO") of our common stock in Australia and registered with the U.S. Securities and Exchange Commission ("SEC") and, consequently, became an SEC filer. Our stock is traded in the form of CHESS Depositary Interests ("CDIs") on the Australian Securities Exchange ("ASX"); each share of our common stock is equivalent to ten CDIs. Our trading symbol is "RVA.AX." Under an agreement with the current holders of our convertible notes, we intend to pursue a listing of our common stock on NASDAQ or another exchange approved by our noteholders, with the intention to be accepted for listing by June 30, 2017.

2. Capital Resources and Basis of Presentation

***Capital Resources*:** As of December 31, 2016 we had cash of $6,674,000, all of which is available for operations and which reflects receipt of $11,407,000 cash proceeds from warrant exercises in February 2016. Based on our current operating plans and projections, we believe this cash balance will be sufficient to fund our operating and capital needs through the first quarter of 2017. We have generated losses and negative cash flows since our inception and, as of December 31, 2016, we had an accumulated deficit of $389,238,000 and current liabilities of $98,810,000 (including the Notes, $32,155,000 could become due and payable in 2017). The holders of our convertible notes have a one-time option to redeem the notes on June 30, 2017 for face value plus accrued interest, a total of approximately $30,286,000. If the noteholders were to collectively exercise the early redemption option, which management believes they will not do, and if the notes were not otherwise converted under either the automatic conversion feature of the notes or at the election of a noteholder, the Company would be unable to make the redemption payment.

We have been actively pursuing a financing to secure additional capital to continue our operations, with the intention to finalize the financing by March 31, 2017. There can be no assurance, however, that we will be successful in completing a financing on a timeframe that coincides with our cash needs, or completing it at all, or that it will be on terms that are acceptable to us.

While we believe we will receive CE Mark regulatory approval and initiate commercial operations by mid-2017, until we generate revenue, and at a level to support our cost structure, we expect to continue to incur substantial operating losses and net cash outflows. Even if we do attain revenue, we may never become profitable and even if we do attain profitable operations, we may not be able to sustain profitability or positive cash flows on a recurring basis.

Our current financial condition, pre-revenue stage of operations, and history of losses and cash outflows, as well as the magnitude of the redemption payment if the holders of our convertible notes exercise the early redemption option and the uncertainties surrounding the outcome of our current fundraising efforts, raise substantial doubt about our ability to continue as a going concern.

Additionally, even if we are successful in our current fundraising and commercialization efforts, we may need to raise further capital in the future to service our debt or fund our operations until the time we can sustain positive cash flows.

2. Capital Resources and Basis of Presentation (continued)

If we are unable to raise sufficient additional capital when needed, now or in the future, we may be compelled to reduce the scope of our operations and planned capital expenditures or sell certain assets, such as our intellectual property assets. 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, and, as such, the financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the company be unable to continue in existence.

***Basis of Presentation*:** We have prepared the accompanying consolidated financial statements in accordance with U.S. generally accepted accounting principles ("GAAP"). The consolidated financial statements include the accounts of REVA and our wholly owned subsidiary, REVA Germany GmbH. All intercompany transactions and balances, if any, have been eliminated in consolidation.

***Use of Estimates*:** In order to prepare our financial statements in conformity with accounting principles generally accepted in the United States, we are required to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Our most significant estimates relate to the fair value of our convertible notes payable, the fair value of our common stock warrant liability, our accrued expenses, including clinical study expenses, our stock-based compensation expense, and our deferred income taxes and the valuation allowance against those deferred taxes. Actual results could differ from our estimates.

3. Significant Accounting Policies

***Cash and Cash Equivalents*:** All highly liquid investments with original maturities of three months or less are classified as cash equivalents.

***Investments*:** Excess cash is invested in high-quality marketable securities. Investments are classified as either short- or long-term based on their maturity dates. Investments with a maturity of less than one year are classified as short-term; all others are classified as long-term. We categorized our investments as "held-to-maturity" based on our intent and ability to hold to maturity. Investments are stated at cost; their fair value is determined each reporting period through quoted market prices of similar instruments in active markets. During the reporting period there were no declines in fair value that were deemed to be other than temporary.

***Property and Equipment*:** Property and equipment is stated at cost, less accumulated depreciation and amortization. Depreciation is determined using the straight-line method over the estimated useful lives of the related assets, generally three to five years. Amortization of leasehold improvements is determined using the straight-line method over the lesser of the useful life of the asset or the term of the underlying lease. Upon disposition or retirement of an asset, its cost and related accumulated depreciation or amortization are removed from the accounts and any gain or loss is recognized in the consolidated statement of operations.

***Patents*:** Costs related to patent development, filing, and maintenance are expensed as incurred since the underlying technology associated with these assets is purchased or incurred in connection with our research and development efforts and the future realizable value cannot be determined.

***Impairment of Long-Lived Assets*:** We review our long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable and exceeds its undiscounted future cash flows. The amount of impairment, if any, is determined by comparing an asset's estimated fair value to the asset's respective carrying amount. During the years ended December 31, 2014, 2015, and 2016 we determined there were no indications of long-lived asset impairment.

3. Significant Accounting Policies (continued)

***Concentrations of Credit Risk*:** Our financial instruments, which potentially subject us to concentration of credit risk, comprise cash, cash equivalents, and investments. We maintain our cash and cash equivalents in bank accounts, the balances of which generally exceed limits that are insured by the Federal Deposit Insurance Corporation ("FDIC"). Cash balances are insured by the FDIC up to $250,000 per bank. Our cash and cash equivalents at December 31, 2016 exceeded the balance insured by the FDIC by $6,424,000. Our investments, if any, are held in custody by a large financial asset manager in the United States. Management believes the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which the assets are held. Additionally, we maintain our cash and investments in accordance with our investment policy, which is designed to maintain safety and liquidity. We have not realized any losses in our investments and believe we are not exposed to significant credit risk related to our cash and cash equivalents.

***Convertible Notes Payable*:** Convertible notes payable 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 the consolidated statement of operations. We remeasure the fair value at each reporting date utilizing a complex fair value model 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, for the change in fair value. 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(s), to obtain future financings when and if needed, and to comply with the terms and conditions of any outstanding notes payable.

Following an analysis of their embedded and derivative features and a projection of the volatility of their effective interest rates under the cost method, we elected to utilize fair value accounting for the convertible notes payable we issued in November 2014 (the "Notes"). Management believes the fair value method of accounting provides a more appropriate presentation of these liabilities than would be provided under the cost method. Through September 30, 2015, the fair values of the Notes were determined using a binomial valuation model; we moved to a least squares Monte Carlo simulation model thereafter as it was considered better aligned with the inputs to, and features of, the Notes. This change in models did not have a material effect on the fair value of the Notes.

***Common Stock Warrants*:** The fair value of warrants issued for the purchase of common stock is recorded as a liability whenever warrants call for issuance of registered shares upon exercise, a condition that we may not be able to accommodate and which would then result in a net settlement of 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 payable.

The warrants we issued in November 2014 were exercised in full by February 2016 and none remain outstanding as of December 31, 2016. Through September 30, 2015, we determined the values of the warrants utilizing a binomial valuation model since two exercise prices were possible; we moved to a Black-Scholes valuation model beginning in October 2015 because Company milestones had been met that resulted in a fixed exercise price. This change in models did not have a material effect on the fair value of the warrants.

***Research and Development*:** 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.

***Segment Information*:** We operate in one business segment, which is the development and commercialization of medical devices.

3. Significant Accounting Policies (continued)

***Income Taxes*:** We account for income taxes using the asset and liability method, under which the current income tax expense or benefit is the amount of income tax expected to be payable or refundable in the current year. Deferred tax assets and liabilities are recorded for the estimated future tax consequences of temporary differences between the financial statement carrying amounts of assets and liabilities and their respective tax bases, and for operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which the temporary differences are expected to be recovered or settled.

We evaluate the realizability of our deferred tax assets and establish a valuation allowance when it is more likely than not that all or a portion of our deferred tax assets will not be realized. In making such a determination, we consider all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax planning strategies, and results of recent operations. If we determine that we would be able to realize our deferred tax assets in the future in excess of their net recorded amount, we would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

We account for the uncertainty in income tax components based on tax positions taken or expected to be taken in a tax return. To recognize a benefit, a tax position must be more likely than not to be sustained upon examination by taxing authorities. We do not recognize tax benefits that have a less than 50 percent likelihood of being sustained. Our policy is to recognize interest and tax penalties related to unrecognized tax benefits in income tax expense; no interest or tax penalties on uncertain tax benefits have been recorded through December 31, 2016.

We are subject to taxation in U.S. and California jurisdictions. As of December 31, 2016, we are no longer subject to U.S. federal or state examinations for years before 2012 and 2011, respectively. However, to the extent allowed by law, the tax authorities may have the right to examine prior periods where net operating losses were generated and carried forward and to make adjustments up to the amount of the net operating loss carryforward amount. We are not currently under Internal Revenue Service ("IRS"), state, or local tax examination.

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

For 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. We adjust stock-based compensation expense for estimated option forfeitures based on our five-year historical average of actual forfeitures. For restricted stock 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 general and administrative expense based on a recipient's work classification.

For stock options and RSUs that vest based on achievement of performance milestones, 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," recognize a 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, 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.

3. Significant Accounting Policies (continued)

***Net Loss Per Common Share*:** Basic and diluted net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents because they would be antidilutive.

The following equivalent shares were excluded from the computation of diluted net loss per share because including them would have been antidilutive:

	Year Ended December 31,		
	2014	2015	2016
Weighted Average Shares Excluded:			
Options to purchase common stock	4,355,536	4,812,372	6,355,093
Unvested restricted stock	91,750	61,623	31,528
Restricted stock units	—	768,908	882,779
Warrants to purchase common stock	1,150,685	7,647,260	502,049
Common share equivalents of convertible notes	1,513,138	11,506,156	11,506,156
	7,111,109	24,796,319	19,277,605

***Foreign Currency*:** The functional currency of our subsidiary REVA Germany GmbH is the Euro. Balance sheet accounts of our subsidiary are translated into United States dollars using the exchange rate in effect at the balance sheet date while expenses are translated using the average exchange rate in effect during the period. Gains and losses arising from translation of our subsidiary's financial statements are recorded to other comprehensive income (loss). These gains and losses, in the aggregate, were insignificant through December 31, 2016.

***Fair Value Measurements*:** We measure the fair value of our financial and non-financial assets and liabilities at each reporting date. Fair value is defined as the exchange price at which an asset or liability would be transferred in the principal or most advantageous market in an orderly transaction between market participants as of a measurement date. Accounting guidance provides an established hierarchy to be used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs; observable inputs are required to be used when available. Observable inputs are those used by market participants to value an asset or liability and are developed based on market data obtained from sources independent of us. Unobservable inputs are those that reflect our assumptions about factors that market participants would use to value an asset or liability. Fair value measurements are classified and disclosed in one of the following three categories:

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

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

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

We carry our convertible notes payable and, prior to the time the warrants were exercised, our common stock warrant liability at fair value. We carry our other financial instruments at amortized cost; these items include cash, investments, accounts payable, and accrued expenses. We held no investments and had no Level 1 or Level 2 financial instruments as of December 31, 2015 or December 31, 2016. The carrying amounts of our cash and cash equivalents, accounts payable, and accrued expenses are considered to be reasonable estimates of their respective fair values due to their short-term nature and, therefore, fair value information is not provided in the table on the next page.

3. Significant Accounting Policies (continued)

***Fair Value Measurements (continued)*:** Utilizing the lowest level inputs available under the measurement hierarchy, the fair values of our measured financial instruments comprise the following:

	Level 3 (in thousands)
Fair Value of Liabilities at December 31, 2015:	
Convertible notes payable	$ 75,365
Common stock warrant liability	19,622
	$ 94,987
Fair Value of Liabilities at December 31, 2016:	
Convertible notes payable	$ 91,655

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

	Year Ended December 31,	
	2015	2016
Weighted Average Assumptions:		
Market price per share of common stock	$5.14	$7.90
Risk-free interest rate	1.7%	2.0%
Expected volatility of common stock	81.7%	79.7%
Expected life (in years)	4.21	2.90
Bond yield of equivalent securities	29.0%	27.0%

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.

3. Significant Accounting Policies (continued)

***Fair Value Measurements (continued)*:** We recorded unrealized losses on changes in fair values of our Level 3 financial liabilities totaling $12,542,000, $56,788,000, and $25,247,000 for the period from November 14, 2014 to December 31, 2014 and for the years ended December 31, 2015 and 2016, respectively, in our consolidated statements of operations. Our Level 3 fair value activity is as follows:

	Level 3 (in thousands)
Balance at December 31, 2013	$ —
Fair value on Issuance Date:	
Convertible notes payable	29,689
Common stock warrant liability	10,938
Balance at November 14, 2014	40,627
Loss from Change in Fair Value:	
Convertible notes payable	8,091
Common stock warrant liability	4,451
Balance at December 31, 2014	53,169
Transfer to additional paid-in capital upon exercise of warrants	(14,970)
Loss from Change in Fair Value:	
Convertible notes payable	37,585
Common stock warrant liability	19,203
Balance at December 31, 2015	94,987
Transfer to additional paid-in capital upon exercise of warrants	(28,579)
Loss from Change in Fair Value:	
Convertible notes payable	16,290
Common stock warrant liability	8,957
Balance at December 31, 2016	$ 91,655

Recently Adopted Accounting Pronouncements: We adopted ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, effective January 1, 2016. ASU 2014-15 requires us to evaluate our ability to continue as a going concern and to provide related footnote disclosure in certain circumstances. Accordingly, we have included relevant disclosures in these Notes to Consolidated Financial Statements.

***Recent Accounting Pronouncements*:** In November 2015, ASU 2015-17, *Balance Sheet Classification of Deferred Taxes*, was issued. ASU 2015-17 requires all deferred taxes to be classified as either non-current assets or long-term liabilities; adoption is required the first quarter of 2017. We do not expect adoption to have a material impact on our consolidated financial statements as we have applied a valuation allowance to our deferred taxes due to the uncertainty surrounding our ability to generate future taxable income to realize those deferred taxes.

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

In March 2016, ASU 2016-09, *Stock Compensation: Improvements to Employee Share-Based Payment Accounting*, was issued. 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. We expect to adopt the actual forfeiture approach. We do not expect adoption to have a material impact on our consolidated financial statements as our pre-adoption forfeiture allowance is relatively immaterial and tax net operating loss carryforward is significant.

4. Convertible Notes Payable and Warrants to Purchase Common Stock

In November 2014, we issued 250 convertible notes payable (the "Notes"), split equally between two holders, for total cash proceeds of $25,000,000. Each Note has a face value of $100,000; in total, the Notes are convertible into 11,506,155 shares of common stock, which is a conversion rate of $2.17275 per share. The Notes are convertible at any time at the holders' election, except the Notes will automatically convert in the case where we have (i) received CE Mark approval of our *Fantom* product and (ii) our CDIs have sustained a market trading price of at least A$0.60 for 20 consecutive trading days and (iii) listed our securities for trading on NASDAQ or another stock exchange that is acceptable to the noteholders. The Notes contain a negative covenant that may limit our ability to pay dividends. The Notes mature on November 14, 2019, if not converted or redeemed earlier. Interest accrues on the Notes at the rate of 7.54 percent per annum, compounded annually, and is payable upon redemption or maturity; accrued interest is not payable or convertible upon conversion of the Notes. Total accrued interest was $2,152,000 and $4,204,000 as of December 31, 2015 and 2016, respectively. The Notes were amended March 22, 2016, as approved by our shareholders, adding the third milestone condition to automatic conversion and extending a right held by the noteholders for cash redemption of the Notes (face value plus accrued interest) from January 2017 to June 30, 2017, if they have not been converted or redeemed prior to that time. Noteholders are required to provide at least 30 days' written notice to elect the one-time early cash redemption. The Notes are classified as current liabilities as of December 31, 2016 as a result of the cash redemption option.

On the issue date, we evaluated the embedded conversion feature of the Notes and certain other rights provided to the noteholders and determined that they qualified as embedded derivatives that required bifurcation from the Notes and separate accounting. Following this evaluation, we made an irrevocable election to account for the Notes at fair value. The fair value of the Notes on the date of issue was calculated to be $29,689,000. This fair value exceeded the stated value of the Notes by $4,689,000; we recorded the excess as a loss on issuance. The fair value of the Notes as of December 31, 2015 and 2016 was calculated to be $75,365,000 and, $91,655,000, respectively, which was $50,365,000 and $66,655,000, respectively, more than the unpaid principal balance of the Notes. As of December 31, 2015 and 2016, the fair value of the 11,506,155 shares into which the Notes are convertible was calculated to be $72,293,000 and $90,749,000, respectively.

We recorded the following as other expense in our consolidated statements of operations:

	Year Ended December 31,		
	2014	2015	2016
		(in thousands)	
Arising from Convertible Notes Payable:			
Interest expense	$ 986	$ 1,904	$ 2,053
Loss on change in fair value	$ 8,091	$ 37,585	$ 16,290

In connection with issuing the Notes, we issued warrants to the noteholders to purchase up to 8,750,000 shares of common stock. In October 2015, a total of 4,375,000 warrants were exercised for $9,506,000 cash proceeds and on February 12, 2016, the remaining 4,375,000 warrants were exercised for $11,407,000 cash proceeds to the Company. The fair value of the warrants on the November 14, 2014 issue date of $10,938,000 was recorded as a loss on issuance since we elected fair value accounting for the Notes. The fair value of the warrants as of December 31, 2015 and February 12, 2016 was calculated to be $19,622,000 and $28,579,000, respectively. The changes in fair value of the warrant liability between November 14, 2014 and December 31, 2014, for the year ended December 31, 2015, and for the period January 1, 2016 to February 12, 2016 of $4,451,000, $19,203,000, and $8,957,000, respectively, were recorded as losses in the consolidated statement of operations.

Following exercise of the warrants, the two noteholders own 10.2 percent and 13.5 percent of our outstanding common stock, for total ownership of 23.7 percent. If the Notes, which represent a 21.2 percent dilution to our outstanding common stock as of December 31, 2016, were to be converted in full, and absent any other equity issuances, the holders would own 18.6 percent and 21.2 percent, for a total of 39.8 percent, of our then outstanding common stock. Acting together, or individually, the noteholders would be in a position to exert control or significant influence over the Company. The noteholders are not related to each other, do not hold management or board positions with the Company, and have had no other transactions with the Company through December 31, 2016.

5. Balance Sheet Details

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

	December 31,	
	2015	2016
	(in thousands)	
Property and Equipment:		
Furniture, office equipment, and software	$ 650	$ 655
Laboratory equipment	5,952	6,604
Leasehold improvements	2,386	2,412
	8,988	9,671
Accumulated depreciation and amortization	(6,269)	(7,394)
	$ 2,719	$ 2,277
Accrued Expenses and Other Current Liabilities:		
Accrued salaries and other employee costs	$ 1,311	$ 1,456
Accrued operating expenses	745	519
Accrued use taxes and other	186	198
	$ 2,242	$ 2,173

6. Income Taxes

We have reported net losses for all periods through December 31, 2016; therefore, no provision for income taxes has been recorded. The following table provides the reconciliation between income taxes computed at the federal statutory rate and our provision for income taxes:

	Year Ended December 31,		
	2014	2015	2016
		(in thousands)	
Provision for Income Taxes:			
Federal income taxes at 34%	$ (17,352)	$ (28,082)	$ (18,393)
State income taxes, net of federal benefit	(1,243)	(1,513)	(1,484)
Research and development tax credits	(660)	(650)	(889)
Changes in fair value of convertible notes payable and common stock warrant liability	9,577	19,308	8,584
Increase in valuation allowance	8,716	8,789	10,583
Accrued interest on convertible notes payable	152	944	698
Expiration of state net operating losses	450	692	641
Stock-based compensation expense	358	287	223
Other	2	225	37
	$ —	$ —	$ —

6. Income Taxes (continued)

Our deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets and liabilities are as follows:

	December 31,	
	2015	2016
	(in thousands)	
Net Deferred Tax Assets:		
Net operating loss carryforwards	$ 71,057	$ 80,382
Research and development credits	7,541	8,422
Amortization	5,020	4,302
Stock-based compensation expense	5,654	6,766
Depreciation	398	416
Accrued operating expenses	66	22
Other	395	404
	90,131	100,714
Valuation Allowance	(90,131)	(100,714)
	$ —	$ —

As of December 31, 2016 we had aggregate federal and California state net operating loss carryforwards of approximately $210,602,000 and $152,629,000, respectively, which may be available to offset future taxable income for income tax purposes. The federal net operating loss carryforwards begin to expire in 2019 and the California carryforwards begin to expire in 2027.

As of December 31, 2016, we also had federal and California state research tax credit carryforwards of approximately $7,054,000 and $6,325,000, respectively. The federal carryforwards begin to expire in 2020 and the California carryforwards have no expiration.

A total of $326,000 of the federal and California net operating loss relates to excess tax benefits generated from stock compensation that will be recorded as an increase to additional paid-in capital if, and when, realized.

Under Internal Revenue Code ("IRC") Sections 382 and 383, annual use of our net operating loss and research tax credit carryforwards to offset taxable income may be limited based on cumulative changes in ownership. An analysis of the impact of this provision from December 1, 1999 through December 31, 2016 has been performed and it was determined that, although ownership changes have occurred, the carryovers should be available for utilization by the Company before they expire, provided we generate sufficient future taxable income. Future ownership changes could result in limitations and may impact the realizability of these loss and credit carryforwards in future periods.

As of December 31, 2016, we had deferred tax assets of $100,714,000 and have established a valuation allowance against those deferred tax assets due to the uncertainty surrounding the Company's ability to generate future taxable income to realize those assets. The change in the valuation allowance for the years ended December 31, 2015 and 2016 was $8,791,000 and $10,583,000, respectively.

We recognize a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. Income tax positions must meet a more-likely-than-not recognition at the effective date to be recognized. As of December 31, 2016, the unrecognized tax benefits recorded were approximately $3,345,000. We do not anticipate a significant change in the unrecognized tax benefits within the next 12 months.

6. Income Taxes (continued)

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits for 2015 and 2016, excluding interest and penalties, is as follows:

	December 31, 2015	December 31, 2016
	(in thousands)	
Gross Unrecognized Tax Benefits:		
Balance at beginning of year	$ 2,734	$ 4,298
Additions (reductions) for prior year tax positions	138	(1,297)
Additions for current year tax positions	1,426	344
	$ 4,298	$ 3,345

Due to our valuation allowance position, none of the unrecognized tax benefits, if recognized, will impact the Company's effective tax rate.

7. Stock-Based Compensation

***The Plan*:** Our 2010 Equity Incentive Plan, as amended (the "Plan"), provides for grants of incentive and non-qualified stock options for purchase of our common stock at a price per share equal to the closing market price on the date of grant, and for awards of restricted stock units ("RSUs") and restricted stock, for which there is no consideration payable by a 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 under the Plan may be increased annually by up to three percent of the outstanding stock of the Company. On January 1, 2016, an additional 550,000 shares were added, resulting in a total of 8,028,446 shares reserved for issuance under the Plan as of December 31, 2016. Option activity under the Plan is as follows:

	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at December 31, 2013	4,046,650	$7.15		
Granted	637,000	$3.53		
Cancelled	(180,500)	$6.61		
Exercised	(259,725)	$0.95		
Balance at December 31, 2014	4,243,425	$7.01		
Granted	2,152,500	$4.50		
Cancelled	(232,292)	$2.85		
Exercised	(251,208)	$2.27		
Balance at December 31, 2015	5,912,425	$6.46	6.50	$7,873,000
Granted	570,100	$8.22		
Cancelled	(106,834)	$10.81		
Exercised	(247,499)	$4.04		
Balance at December 31, 2016	6,128,192	$6.65	5.94	$13,857,000
Exercisable at December 31, 2016	4,803,171	$7.22	5.46	$9,445,000
Vested at December 31, 2016	4,129,491	$7.21	5.30	$8,871,000
Vested and Expected to Vest at December 31, 2016	6,094,650	$6.54	6.39	$13,774,000

7. Stock-Based Compensation (continued)

The Plan (continued): Employees, non-employee directors, and consultants are eligible to participate in the Plan. For purposes of determining stock-based compensation expense, we include non-employee directors with employees; we account for consultant compensation expense separately.

The term of awards granted under the Plan may not exceed ten years. Vesting periods of stock and unit awards and option grants are determined by the Company's board of directors and a majority of the vesting periods have been set at 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 the 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 December 31, 2015 and December 31, 2016, no unvested options had been exercised and, therefore, no shares were subject to repurchase.

During March 2015, we granted a total of 316,000 options that vest based on certain performance milestones of the Company. We estimated the vesting term for each performance 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 18.3 months as of December 31, 2015 and to be 12 months as of December 31, 2016. Through December 31, 2015 none of these options had vested or been cancelled. During the year ended December 31, 2016, a total of 65 percent of the options vested and 12,250 unvested options were cancelled.

As of December 31, 2016, our unvested stock options have vesting dates scheduled through 2020. Following is the vesting activity under the Plan for the year ended December 31, 2016:

	Options Outstanding	Weighted Average Grant Date Fair Value
Unvested Options at December 31, 2015	2,592,231	$2.44
Granted	570,100	$4.49
Vested	(1,131,796)	$2.56
Forfeited	(31,834)	$2.19
Unvested Options at December 31, 2016	1,998,701	$2.96

We awarded 33,000 and 87,500 shares of restricted stock during the years ended December 31, 2012 and 2013, respectively, all of which vest at the rate of 25 percent annually on each award anniversary date. Unvested restricted stock is subject to cancellation if a recipient terminates service prior to becoming fully vested. No restricted stock has been awarded since 2013 and, through December 31, 2016, no restricted stock has been cancelled.

During March 2015, we awarded 824,200 RSUs to employees that vest based on certain performance milestones of the Company. 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 21 months to 30 months at the grant date in March 2015. We estimated the remaining weighted average vesting term to be 22.9 months as of December 31, 2015 and to be 8.1 months as of December 31, 2016. Through December 31, 2016, none of these RSUs vested; during the year ended December 31, 2016, a total of 118,000 unvested RSUs were cancelled.

During May 2015, May 2016, and July 2016, we awarded 160,000, 35,200, and 12,600 RSUs, respectively, to members of our board of directors. Such RSUs vest at a single point in time, generally one year from the award date. As of December 31, 2015, none of the RSUs had vested and none had been cancelled. During the year ended December 31, 2016, a total of 160,000 of the RSUs vested and none were cancelled.

During 2016, a total of 114,583 stock options were exercised utilizing the "net" exercise feature available under the Plan, whereby 27,575 shares of common stock were issued and the remaining 87,008 options, representing the exercise value, were surrendered to the Company and retired from the Plan. The exercising employee paid related income taxes in cash upon the exercise of the stock options.

No tax benefits arising from stock-based compensation have been recognized in the consolidated statements of operations through December 31, 2016.

7. Stock-Based Compensation (continued)

Grants and Awards to Employees: We account for option grants, restricted stock awards, and RSU awards to employees based on their estimated fair values on the date of grant or award, with the resulting stock-based compensation recorded over the requisite service period on a straight-line basis. The fair value of restricted stock and RSU awards is equal to the closing market price of our common stock on the date of award. The fair value of option grants was estimated on the date of grant using the following weighted-average assumptions:

	Year Ended December 31,		
	2014	2015	2016
Risk-free interest rate	2.2%	1.8%	1.6%
Expected volatility of common stock	59.3%	55.6%	57.6%
Expected life in years	6.14	6.16	6.13
Dividend yield	0.0%	0.0%	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 from the historical market prices of a selected group of publicly traded companies considered to be our peers; we use peer group data due to the fact that we have limited historical trading data but adjusted the 2016 volatility upward by approximately ten percent to allow us to move toward using our trading history, which is more volatile than our peer group. For options that vest based on passage of time, the expected option life was calculated using the simplified method under the accounting standard for stock compensation and a ten-year option expiration; we use the simplified method because we do not yet have adequate history as a public company traded on a U.S. stock exchange to establish a reasonable expected life. For options that vest based on performance milestones, the expected life was calculated based on the requisite service periods estimated by management and a ten-year option expiration. The expected dividend yield of zero reflects that we have not paid cash dividends since inception and do not intend to pay cash dividends in the foreseeable future.

For the options and RSUs that vest upon performance milestones, we record compensation expense for only those milestones that are probable of being achieved. Through December 31, 2015, we determined that two of the three milestones for the performance-based awards were probable of being achieved and, therefore, recorded expense for those two milestones only. During the year ended December 31, 2016, we determined that all three performance milestones were probable of being achieved and, therefore, recorded approximately $367,000 in cumulative expense for the third milestone, as well as straight line expense for all three performance milestones during the year. Upon the cancellation of unvested performance based awards during the year ended December 31, 2016, we reversed a total of $163,000 in compensation expense that had been recorded during the year ended December 31, 2015.

Stock-based compensation arising from employee options and awards under the Plan is as follows:

	Year Ended December 31,		
	2014	2015	2016
		(in thousands)	
Employee Stock-Based Compensation:			
Research and development expense	$ 1,142	$ 1,502	$ 1,260
General and administrative expense	2,284	1,905	3,423
	$ 3,426	$ 3,407	$ 4,683

As of December 31, 2016, we had approximately $5,820,000 of total unrecognized compensation costs related to unvested employee options that are expected to be recognized over a weighted average period of 1.77 years.

7. Stock-Based Compensation (continued)

Grants and Awards to Employees (continued): Following is a summary of grant date fair and intrinsic values:

	Year Ended December 31,		
	2014	2015	2016
	(in thousands, except per share data)		
Weighted-average grant date fair value per share	$1.98	$2.40	$4.48
Intrinsic value of options exercised	$553	$511	$976
Total fair value of options vested during the year	$3,546	$1,429	$2,853

***Stock Options to Consultants*:** We account for stock options granted to consultants at their fair value. Under this method, the fair value is estimated at each reporting date during the vesting period using the Black-Scholes option valuation model. The resulting stock-based compensation expense, or income if the fair value declines in a reporting period, is recorded over the consultant's service period.

Fully vested options to purchase 7,500 shares of common stock were granted to consultants during the year ended December 31, 2016. No options were issued to consultants during 2015. Options to purchase 110,000 shares of common stock were granted to consultants during the year ended December 31, 2014, all of which were either vested or cancelled by the first quarter of 2015. There were no unvested consultant options outstanding as of December 31, 2015 or December 31, 2016. The fair values of the 2016 and 2014 grants were determined using the following assumptions: Assumed risk-free interest rate of 1.7 to 2.8 percent; assumed volatility of 56 to 59 percent; expected option life of 5.0 to 10.0 years; and, expected dividend yield of zero percent. The total fair value of consultant options that vested during the years ended Decembers 31, 2014, 2015, and 2016 was $116,000, $27,000, and $40,000, respectively.

For the assumptions, the assumed risk-free interest rate was based on the implied yield on a U.S. Treasury zero-coupon issue with a remaining term equal to the expected life of the option. The assumed volatility was calculated from the historical market prices of a selected group of publicly traded companies considered to be our peers; we used peer group data due to our limited historical trading but adjusted the 2016 volatility upward by approximately five percent to allow us to move toward using our trading history, which is more volatile than our peer group. The expected option life is the remaining term of the option. The expected dividend yield of zero reflects that we have not paid cash dividends since inception and do not intend to pay cash dividends in the foreseeable future.

Consultant stock-based compensation expense is recorded to the financial statement line item for which the consultant's services are rendered. Stock-based compensation expense arising from consultant options is as follows:

	Year Ended December 31,		
	2014	2015	2016
	(in thousands)		
Consultant Stock-Based Compensation:			
Research and development expense	$ 69	$ —	$ —
General and administrative expense	21	27	40
	$ 90	$ 27	$ 40

8. Retirement Plan

In 2003 we adopted a qualified 401(k) profit sharing plan (the "401(k) Plan") for the benefit of our employees. Employees are eligible to participate in the 401(k) Plan the month following hire and may defer up to the maximum allowed under IRS regulations, on an annual basis. We match 25 percent of an employee's deferral amount, up to a maximum of four percent of qualified compensation. We may, at our discretion, make additional contributions. Employees are immediately vested in the employer matching contributions. Our contributions to the 401(k) Plan were $46,000, $42,000, and $49,000 for the years ended December 31, 2014, 2015, and 2016, respectively.

9. Commitments and Contingencies

We license certain patents and other intellectual property rights related to the composition and coating of our bioresorbable stent and our other biomaterial products. Terms of these licenses include provisions for royalty payments on future sales of products, if any, utilizing this technology, with provisions for minimum royalties once product sales begin. The amount of royalties varies depending upon type of product, use of product, stage of product, location of sale, and ultimate sales volume, and ranges from a minimum of approximately $15 per unit to a maximum of approximately $50 per unit sold, with license provisions for escalating minimum royalties that could be as high as $2,200,000 per year. Additionally, in the event we sublicense the technology and receive certain milestone payments, the licenses require that up to 40 percent of the milestone amount be paid to the licensors. Additional terms of the technology licenses include annual licensing payments of $175,000 until the underlying technology has been commercialized.

Terms of the licenses also include other payments to occur during commercialization that could total $950,000, payment of $350,000 upon a change in control of ownership, payments of up to $300,000 annually to extend filing periods related to certain technology (of which, payments totaling up to $250,000 per year during the years 2016, 2017, and 2018 are being deferred to January 1, 2019; accordingly, $250,000 was accrued as a long-term liability at December 31, 2016), and payment of patent filing, maintenance, and defense fees. The license terms remain in effect until the last patent expires.

In connection with our operating and business activities, we periodically enter into contracts with consultants and suppliers. These contracts are generally cancelable with 30 days' written notice. As of December 31, 2016, the minimum future payments on these contracts totaled approximately $161,000.

We currently lease our office and lab facilities under a non-cancelable operating lease that expires in January 2018. The lease contains fixed annual escalations, an option for a five-year extension, leasehold improvement allowances and credits of $523,000, and rent abatements of $136,000. 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 liability. As of December 31, 2016, our deferred rent totaled $200,000, of which $184,000 was classified as a current liability. We recorded rent expense of $683,000, $794,000, and $770,000 for the years ended December 31, 2014, 2015, and 2016, respectively.

Future minimum payments under the lease are as follows:

	Minimum Payment (in thousands)
Minimum Lease Payments:	
Year ending December 31, 2017	$ 711
Year ending December 31, 2018	60
	$ 771

10. Related Parties

Our related parties include the members of our board of directors, investors with five percent or more of our outstanding securities, and holders of our convertible notes payable. Other than approved board compensation and the amendment to the Notes and exercise of warrants to purchase common stock (discussed above), we had no related party transactions during the year ended December 31, 2016. In addition to approved board compensation, the issuance of our convertible notes, and the exercise of warrants to purchase common stock, our related party transactions during the years ended December 31, 2014 and 2015 consisted of expenses totaling $73,000 and $15,000, respectively, recorded as compensation to a board member for board services provided to the Company in excess of normal director responsibilities. As of December 31, 2014, the $73,000 was reflected as an accrued expense; we paid the total $88,000 to the director during the first quarter of 2015.

11. Selected Quarterly Financial Information

The following table presents selected quarterly financial information that has been derived from our unaudited quarterly consolidated financial statements, which, in the opinion of management, include all adjustments (consisting only of normal recurring items) necessary for a fair presentation. The quarterly per share data presented below was calculated separately and may not sum to the annual figures presented in the consolidated financial statements. These operating results are also not necessarily indicative of results for any future period.

	Quarter Ended				Year Ended
	March 31,	June 30,	September 30,	December 31,	December 31,
	(in thousands, except per share data)				
Selected Financial Information for 2015:					
Loss from operations	$ (4,853)	$ (5,633)	$ (6,222)	$ (7,262)	$ (23,970)
Gain (loss) on change in fair values	(18,101)	11,970	(28,180)	(22,477)	(56,788)
Net income (loss)	(23,357)	5,854	(34,868)	(30,223)	(82,594)
Net income (loss) per common share, basic	$ (0.70)	$ 0.17	$ (1.04)	$ (0.81)	$ (2.38)
Net loss per common share, diluted	$ (0.70)	$ (0.12)	$ (1.04)	$ (0.81)	$ (2.38)
Selected Financial Information for 2016:					
Loss from operations	$ (7,481)	$ (7,031)	$ (6,149)	$ (6,119)	$ (26,780)
Gain (loss) on change in fair values	(32,764)	2,966	(17,269)	21,820	(25,247)
Net income (loss)	(40,798)	(4,555)	(23,943)	15,198	(54,098)
Net income (loss) per common share, basic	$ (1.01)	$ (0.11)	$ (0.56)	$ 0.36	$ (1.28)
Net loss per common share, diluted	$ (1.01)	$ (0.11)	$ (0.56)	$ (0.11)	$ (1.28)

For the quarterly periods provided above, when the Company recognized net income, diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method and the if-converted method, as applicable. For purpose of this calculation, common stock options and restricted stock subject to forfeiture are considered to be common stock equivalents; common share equivalents are included in the calculation of diluted net loss per share only when their effect is dilutive.

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

	Quarter Ended	
	June 30, 2015	December 31, 2016
Diluted Net Loss:		
Net income used for basic net income per share	$ 5,854	$ 15,198
Interest expense	470	531
Gain on change in fair value of convertible notes payable and warrant liability	(11,970)	(21,820)
	$ (5,646)	$ (6,091)
Weighted Average Shares used to Compute Diluted Net Loss per Share:		
Shares used for basic net loss per share	33,561,959	42,747,769
Common share equivalents	15,494,933	11,506,156
	49,056,892	54,253,925

INDEX TO EXHIBITS

Exhibit Number	Description of Exhibits	Filed with this Form 10-K	Incorporated by Reference		
			Form	File No.	Date Filed
3.1	Amended and Restated Certificate of Incorporation		S-1/A	333-168852	10/22/2010
3.2	Amended and Restated Bylaws		S-1/A	333-168852	10/22/2010
3.3	Amendment No. 1 to the Amended and Restated Bylaws		8-K	000-54192	9/12/2014
4.1	Form of Stock Certificate		S-1/A	333-168852	11/12/2010
4.2	Form of Amended and Restated Investors' Rights Agreement, by and among REVA Medical, Inc. and holders of our common stock and convertible notes payable set forth therein		DEF14A	000-54192	10/14/2014
10.1	Telecom Business Center Business Lease between FSP Telecom Business Center Limited Partnership and REVA Medical, Inc. dated December 18, 2001		S-1	333-168852	8/13/2010
10.2	First Amendment to Telecom Business Center Business Lease between FSP Telecom Business Center Limited Partnership and REVA Medical, Inc. dated January 3, 2005		S-1	333-168852	8/13/2010
10.3	Second Amendment to Telecom Business Center Business Lease between ARI Commercial Properties, Inc. and REVA Medical, Inc. dated February 18, 2006		S-1	333-168852	8/13/2010
10.4	Third Amendment to Telecom Business Center Business Lease between ARI Commercial Properties, Inc. and REVA Medical, Inc. dated December 14, 2006		S-1	333-168852	8/13/2010
10.5	Fourth Amendment to Telecom Business Center Business Lease between ARI Commercial Properties, Inc. and REVA Medical, Inc. dated May 7, 2008		S-1	333-168852	8/13/2010
10.6	Fifth Amendment to Telecom Business Center Business Lease between ARI Commercial Properties, Inc. and REVA Medical, Inc. dated for reference purposes only as of August 28, 2011, executed and delivered on November 21, 2011		8-K	000-54192	11/23/2011
10.7	Distribution Option Agreement, dated December 7, 2007, by and between REVA Medical, Inc. and Boston Scientific Corporation		S-1/A	333-168852	10/22/2010
10.8	First Amendment to Distribution Option Agreement, dated February 12, 2014, by and between REVA Medical, Inc. and Boston Scientific Corporation		10-K	000-54192	3/17/2014
10.9	Exclusive License Agreement Number 2 between Rutgers, The State University of New Jersey and REVA Medical, Inc. dated July 1, 2010**		10-Q	000-54192	11/9/2015
10.10	Amendment #2 to Exclusive License Agreement Number 2 between Rutgers, The State University of New Jersey and REVA Medical, Inc. effective July 1, 2010**		10-Q	000-54192	11/6/2014
10.11	Amendment #3 to Exclusive License Agreement #2 between Rutgers, The State University of New Jersey and REVA medical, Inc. dated July 1, 2010**		10-Q	000-54192	11/9/2016
10.12	Royalty and License Agreement between Integra/LifeSciences Corporation and REVA Medical, Inc. dated February 2, 2004**		S-1/A	333-168852	9/21/2010
10.13	2001 Stock Option/Stock Issuance Plan*		S-1	333-168852	8/13/2010
10.14	Form of Stock Option Agreement*		S-1	333-168852	8/13/2010
10.15	Form of Addendum to Stock Option Agreement*		S-1	333-168852	8/13/2010
10.16	2010 Equity Incentive Plan*		S-1/A	333-168852	10/22/2010
10.17	Form of Stock Option Agreement*		S-1/A	333-168852	11/12/2010

INDEX TO EXHIBITS

Exhibit Number	Description of Exhibits	Filed with this Form 10-K	Incorporated by Reference		
			Form	File No.	Date Filed
10.18	Form of Stock Option Agreement entered into with Robert Thomas and Anne Keating*		S-1/A	333-168852	11/12/2010
10.19	Form of Director and Officer Indemnification Agreement*		S-1	333-168852	8/13/2010
10.20	Director Compensation policy		10-K	000-54192	3/17/2014
10.21	Employment Agreement, dated October 21, 2010, by and between REVA Medical, Inc. and Robert Schultz*		S-1/A	333-168852	11/12/2010
10.22	Employment Agreement, dated October 21, 2010, by and between REVA Medical, Inc. and Katrina Thompson*		S-1/A	333-168852	11/12/2010
10.23	Employment Agreement, dated February 22, 2011, by and between REVA Medical, Inc. and Jeffrey Anderson*		10-K	000-54192	3/17/2014
10.24	Employment Agreement, dated September 21, 2015, by and between REVA Medical, Inc. and Regina E. Groves*		8-K	000-54192	8/21/2015
10.25	Employment Agreement, dated January 18, 2016 by and between REVA Medical, Inc. and Richard M. Kimes*		10-K	000-54192	3/10/2016
10.26	Convertible Note Deed dated September 25, 2014 by and between REVA Medical, Inc., Goldman Sachs International, and Senrigan Master Fund		DEF14A	000-54192	10/14/2014
10.27	First Amendment to Convertible Note Deed, dated February 11, 2016, by and among REVA Medical, Inc., Goldman Sachs International, and Senrigan Master Fund		DEF14A	000-54192	3/9/2016
21.1	List of Subsidiaries		S-1	333-168852	8/13/2010
23.1	Consent of Grant Thornton LLP, Independent Registered Public Accounting Firm	X			
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended	X			
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended	X			
32.1 (1)	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350	X			
99.1	Section 13 of the ASX Settlement Rules		S-1/A	333-168852	10/22/2010
101.INS	XBRL Instance Document	X			
101.SCH	XBRL Taxonomy Extension Schema Document	X			
101.CAL	XBRL Calculation Linkbase Document	X			
101.DEF	XBRL Taxonomy Definition Linkbase Document	X			
101.LAB	XBRL Taxonomy Label Linkbase Document	X			
101.PRE	XBRL Taxonomy Presentation Linkbase Document	X			

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* Management Compensatory Plan or Arrangement

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

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

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our reports dated February 27, 2017, with respect to the consolidated financial statements and internal control over financial reporting included in the Annual Report of REVA Medical, Inc. on Form 10-K for the year ended December 31, 2016. We consent to the incorporation by reference of said reports in the Registration Statements of REVA Medical, Inc. on Forms S-8 (File Nos. 333-173371, 333-179845, 333-186966, 333-194619, 333-203103, and 333-210084).

/s/ GRANT THORNTON LLP

San Diego, California
February 27, 2017

Exhibit 31.1

CERTIFICATION

I, Regina E. Groves, certify that:

1. I have reviewed this Annual Report on Form 10-K 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: February 27, 2017

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

Exhibit 31.2

CERTIFICATION

I, Katrina L. Thompson, certify that:

1. I have reviewed this Annual Report on Form 10-K 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: February 27, 2017

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

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of REVA Medical, Inc. (the "Company") for the year ended December 31, 2016, as filed with the Securities and Exchange Commission (the "Report"), Regina E. Groves, Chief Executive Officer of the Company, and Katrina L. Thompson, Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: February 27, 2017

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

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