REVA MEDICAL, INC.

FORM 10-K
(Annual Report)

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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, 2015

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 for 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, 2015 totaled approximately $96,546,000 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, 2015. The identification of 10% or greater stockholders as of June 30, 2015 is based on Schedule 13G and amended Schedule 13G reports publicly filed before June 30, 2015. This calculation does not reflect a determination that such parties are affiliates for any other purposes.

As of March 1, 2016, there were 42,535,986 shares of the registrant's Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document Description
Portions of the registrant's definitive proxy statement for its 2016 annual meeting of stockholders to be filed pursuant to Regulation 14A within 120 days after the registrant's fiscal year end of December 31, 2015 are incorporated by reference into Part III (items 10, 11, 12, 13, and 14) of this report.

REV A MEDICAL, INC.

FORM 10-K — ANNUAL REPORT
For the Fiscal Year Ended December 31, 2015

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PAR T I

Forward-Looking Statements

This Annual Report on Form 10-K for the year ended December 31, 2015, 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:

- our history of net losses and our expectation of significant operating losses for the foreseeable future;
- our ability to repay our convertible notes when, and if, required or otherwise comply with the requirements under the convertible notes;
- changes in the fair value of our convertible notes and the gains or losses that may arise upon such change each reporting period;
- failure to raise additional financing to fund our operations when needed or on terms favorable to us;
- our ability to continue as a going concern;
- 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;
- increases in our projected expenditures on research and development and administrative activities;
- failure of our products to gain market acceptance domestically or internationally;
- our inability to attract or retain skilled personnel for our product development and commercialization efforts;
- 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;
- 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; and,
- refusal of third-party payors to reimburse our customers for use of our products.

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.

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 the treatment of conditions in the human body. Since our inception in 1998, our efforts have been concentrated on the development of a stent for use in coronary applications. We currently are in the later stages of clinically testing bioresorbable drug-eluting coronary stents. We refer to bioresorbable stents 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 from the stenting procedure, which is also called "restenosis."

Use of fully bioresorbable scaffolds, and the number of patients receiving them, has continued to increase since becoming commercially available outside the United States approximately three years ago. 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 and ease of clinical use, we believe our products will enable us to compete effectively in the broader stent market, which had approximately $3.8 billion in worldwide revenues in 2015, and, in particular, with other bioresorbable scaffolds, which had estimated annual revenues of approximately $125.0 million in 2015.

Our scaffolds have not yet been approved for sale; they are still in a clinical testing stage and will require successful clinical trial results and regulatory approval before they can be sold and generate any revenue. We have invested significant time and funds in development, having performed scientific research, engineering development, and testing in laboratory and preclinical studies. We have developed, tested, and selected the polymer formulation, tested and selected the anti-restenotic drug and coating process, created and iterated the device design, and identified and implemented methods and processes to produce and test the scaffold. We designed and performed extensive preclinical tests that ranged from bench and engineering studies to in vitro and in vivo laboratory studies. In 2007, we enrolled patients in a small clinical study that proved the viability of our technology while confirming the areas needing further development. We have been developing and advancing our technology in both its design and polymer composition since that study and have undertaken significant testing that has shown the technology to be safe and effective.

We have enrolled over 230 patients in a clinical trial of our *Fantom* scaffold. We enrolled 110 patients between March 2015 and September 2015, from which we will obtain follow-up data at a six-month time point. If this data has acceptable safety and efficacy results, we plan to apply for European regulatory approval. In October 2015, we began enrolling a second set of 110 patients to obtain additional data to facilitate regulatory and commercialization needs; we completed enrollment of this second set of patients in February 2016. Prior to developing *Fantom* , we had enrolled a total of 165 patients in three clinical trials between June 2007 and January 2014 with predecessor scaffolds that were developed utilizing our proprietary x-ray visible polymer in combination with our "slide and lock" stent design. While these predecessor scaffolds demonstrated viability of the technology, we believe the enhanced characteristics of *Fantom* , including its conventional design, better position it for commercial success.

Fantom's enhanced features include a unibody design, lo wer strut thickness, smaller crossing profile, optimized polymer properties, and streamlined manufacturing processes, while still maintaining all the beneficial features of our prior scaffolds. In March 2014 we announced *Fantom* as our sole focus for develo pment and testing and concurrently reduced headcount by approximately 45 percent and reduced other overhead costs to a lesser extent.

Our current plan is to apply for European CE Marking, the regulatory approval that would allow us to sell our scaffolds in Europe and other countries that recognize the CE Mark, in approximately the third quarter of 2016. When, and if, we receive CE Mark approval, we will evaluate how best to implement our sales and marketing strategies for commercialization. While our *Fantom* scaffold could be approved for sale in late 2016 or early 2017, our efforts to generate substantial revenue and achieve positive cash flows from our operations may take several years, even if our clinical results are favorable.

In order to produce quantities of our scaffold large enough to accommodate commercial needs, when that time arrives, we will need to scale-up our manufacturing processes and expand our capabilities to allow for such things as additional scaffold sizes. We have developed plans and have begun implementation of the methods and processes for such manufacturing scale-up, including work on additional product sizes. We will continue implementation of manufacturing preparedness throughout 2016 as we approach commercialization.

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, determine a course of development for additional products.

We perform all of our research and development activities from one location in San Diego, California. We have three clean rooms 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 57 employees as of December 31, 2015, a significant number of who are degreed professionals and six of whom are PhDs. We leverage our internal expertise with contract research and preclinical laboratories, catheter manufacturing, 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 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, cash proceeds of $9.5 million from the exercise of 50 percent of the warrants on October 1, 2015, and cash proceeds of $11.4 million from exercise of the other 50 percent of the warrants on February 12, 2016. Our cash balance at December 31, 2015 of approximately $16.9 million combined with the warrants proceeds in February 2016 provides over $28.0 million in available cash resources. We believe these cash resources are adequate to fund our operating and capital needs through 2016 and into 2017 as we approach the commercialization of *Fantom* .

We have incurred substantial losses since our inception; as of December 31, 2015, we had accumulated a deficit of approximately $335.1 million. We expect our losses to continue as we complete our development work, clinical studies, and preparations for commercialization during the remainder of 2016. If these efforts are successful and we are able to obtain regulatory approval, we expect to commence product sales thereafter. In order to successfully transition to profitable operations, we will need to achieve a level of revenues and product margins to support the Company's cost structure. Until such time as we generate positive cash flow, we plan to continue to fund our operations by utilizing our existing cash and, if needed, 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 throughout the body. Coronary arteries, which supply blood to heart muscle, are susceptible to the buildup of plaque and 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, heart ("cardiac") muscle may become starved of nutrients and oxygen, resulting in severe 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 life threatening condition that is commonly known as a heart attack, or "myocardial infarction."

Cardiovascular disease is a leading cause of death. In a January 2015 report published by the World Health Organization, CVD was 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 approximately 370,000 deaths in the United States during 2013, or approximately one in every seven deaths, and that coronary artery disease will cost an estimated $129.6 billion in direct and indirect costs in 2015. According to the AHA, nearly one million people in the United States will have a new or recurrent coronary heart attack annually.

The European Heart Network reported in 2012 that coronary artery disease is the most common cause of death in Europe, accounting for approximately 1.8 million deaths per year, or approximately 20 percent of all male and 22 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 the healthy lifestyle alternative is not being universally adopted. Medication therapy using cholesterol-lowering medications, beta blockers, diuretics, aspirin, nitroglycerin, calcium channel blockers, and others aim 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 also prolong survival, a large number of patients will require invasive treatments to improve cardiac health. Invasive treatments include bypass surgery and minimally invasive treatments including stenting.

Invasive procedures, developed and used over the past four decades, quickly and safely restore blood flow by either rerouting the flow around a plaque buildup with a surgical procedure or by reopening the artery with an interventional procedure. The procedures have evolved from invasive surgeries to minimally invasive catheter-based therapies. These advancements have generally resulted in less severe procedure-related complications, as well as reduced costs due to shorter procedure and recovery times. Physicians have rapidly adopted each new therapy. The main treatment options typically used by physicians and available to patients are:

- ***Coronary Artery Bypass Surgery*** **:** An extremely invasive technique whereby open heart surgery is required. 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. Surgeons can bypass multiple blocked coronary arteries during one surgery.
- ***Balloon Angioplasty*** **:** A minimally invasive therapy developed in the late 1970s that allows a physician to insert a slender balloon-tipped catheter into the femoral artery in the groin or the radial artery in the wrist to access a blockage in the heart. At the blockage site, the balloon is inflated to compress plaque and widen the narrowed artery to allow restoration of blood flow. This therapy was rapidly adopted because it is minimally invasive and results in shorter hospital and recovery times compared to bypass surgery. However, 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 and/or formation of scar tissue within the artery. Restenosis typically requires a repeat of the angioplasty procedure or bypass surgery. Additionally, some patients experience abrupt vessel closure after angioplasty, which leads to complications that include heart attack or death, and may require emergency bypass surgery.

- ***Bare Metal Stents*** **:** A minimally invasive therapy introduced in the 1990s t o address the iss ues of abrupt vessel closure and restenosis following balloon angioplasty . Stents are small tube-like devices that are inserted into an artery; they stabilize the artery by propping it open to facilitate blood flow. Bare metal stents are flexible metal wir e mesh tubes that are permanently implanted ; they are mounted on a balloon -tipped catheter, delivered to the lesion (similar to angioplasty) , and then stretch ed open ("expanded") by inflation of the balloon until the desired diameter is reached . The balloon is then deflated and removed with the catheter, leaving the stent permanently implanted in the vessel. While bare metal stent s 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 the treatment site to help minimize the buildup of scar tissue during healing. After bare metal stents were introduced, physicians determined that restenosis was caused by the body's inflammatory response to the trauma caused by the procedure and stent, rather than by the underlying coronary artery disease. The most common method to overcome restenosis is the use of pharmacological agents, delivered from a drug- eluting stent, that 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 lesion has healed. After drug-eluting metal stents were introduced, studies showed they successfully lowered the rates of restenosis; however, safety concerns arose when other studies suggested risks from late-stent thrombosis and the failure to restore 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 two are available for sale, and only in locations outside the United States. Since bioresorbable stents are temporary in nature, being designed to hold the artery open while it is healing, they are often described as bioresorbable scaffolds or "scaffolds."

Coronary Stent Market

In 2015, annual worldwide revenues from coronary stent sales approximated $3.8 billion, of which drug-eluting stents accounted for approximately $3.6 billion in revenues and 91 percent of units sold. We believe there are three companies with significant market share that have received approval for five drug-eluting metal stents. According to analyst reports, approximate 2015 annual coronary stent revenues were:

- $1.4 billion in the United States from approximately 1.1 million stent implants;
- $2.0 billion in Europe and Asia (excluding Japan) and other countries that rely on CE Mark approval from approximately 3.5 million stent implants; and,
- $0.4 billion in Japan from approximately 250,000 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 $111.0 million in 2014 and $125.0 million in 2015. Scaffold revenues are anticipated to continue to grow, and become a larger percentage of all stent sales, as adoption of the technology increases and as the scaffolds are approved for sale in additional countries, including the anticipated approval for sale in the United States by the end of 2016.

Sales of bioresorbable scaffolds in Europe represent a majority of all scaffold revenues. Our plan is to initially sell in Europe after, and if, we receive CE Marking, the European regulatory approval required for commercial sales. 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.

O ur Products

The product we have developed and are currently studying in clinical patients is a drug-eluting fully bioresorbable polymer stent. We refer to bioresorbable stents as "scaffolds" because they are temporary in nature and their purpose is to hold an artery open during healing following an implant procedure. After being implanted, our scaffolds are designed to 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. Following artery healing, our scaffolds are designed to gradually degrade and benignly clear from the body, a process called "resorption." As a scaffold resorbs, there is an integration of artery tissue into the space previously occupied by the scaffold and the artery returns to its natural state, allowing return of its natural "vasomotion," or the ability to contract and expand with blood flow and exertion.

We believe the features of bioresorbable scaffolds, combined with their temporary nature, provide advantages over permanent metal stents. We believe the primary advantage is the ability of the artery to return to its natural state, thereby allowing better quality of life in the near term and better retreatment options if future cardiovascular disease occurs in the long-term. We have designed our bioresorbable 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:

- ***Restoration of Vessel Movement*** **:** We believe there is significant benefit to allowing an artery's natural movement, which is not possible with a permanent metal stent. Our bioresorbable scaffolds dissolve after an artery has healed, allowing restoration of vasomotion. 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 late-stent thrombosis 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 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*** **:** Since our bioresorbable scaffolds dissolve, we believe that potential complications of subsequent medical treatments are reduced. Coronary artery disease is typically progressive and many patients will require additional treatments. A patient may undergo re-stenting, receive treatment for lesions located downstream from the original stent, or undergo surgical procedures to an artery. These treatments may be inhibited by a metal stent whereas the disappearance of a scaffold helps to ensure all treatment options remain available. In addition, we believe our products have potential to be used in the treatment and reduction of vulnerable plaque and as a delivery vehicle for agents such as drugs to treat a number of different indications. If our products are used for these purposes, we believe they will be able to 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 through the use of a bioresorbable stent implanted using minimally invasive techniques; resorbs leaving no permanent device;
- ***Efficacy*** **:** Restores and maintains blood flow and the artery's natural movement is restored as the scaffold begins to resorb;
- ***Drug Eluting*** **:** Delivers standard anti-restenotic drug to the stented artery;
- ***Standard Deployment*** **:** Catheter mounted scaffold that does not require presoaking and that deploys in a one-step continuous inflation the same as current clinical practice, including deliverability through the radial artery;
- ***Storage and Handling*** **:** Clinical handling and storage the same as current practice with no refrigeration required;
- ***Size*** **:** Treats arteries with diameters of 2.5 millimeters and larger, the diameters most commonly treated;
- ***Expansion Range*** **:** Allows expansion within a clinically relevant range of the sized artery, to allow 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*** **:** Manufactured with conventional repeatable processes in compliance with applicable standards.

We believe that due to risks associated with bare metal and drug-eluting metal stents, the coronary stent market will continue to convert from metal stents to fully bioresorbable polymer scaffolds. To help ensure our bioresorbable scaffolds are commercially competitive, we have 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 bioresorbable 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 bioresorbable scaffolds do not require any change to traditional storage or handling or to the method of deployment.
- ***Visible Using Standard Imaging Techniques*** **:** Our bioresorbable scaffolds are visible under x-ray, thereby allowing physicians to see the scaffold during implant and at early patient follow-up. It is also compatible with magnetic resonance imaging ("MRI") and computed tomography ("CT") imaging technologies, both of which may become more widely used in the diagnosis and treatment of coronary artery disease.
- ***Controlled Resorption Rate*** **:** Our polymer is designed to degrade and clear from the body in a predictable and safe manner. 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 bioresorbable 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 ten 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 10,000 scaffolds tested in various manners. Our preclinical tests generally comprise the following:

- ***Comparative Testing*** **:** We compared our technology to commercially available metal stents and, to a lesser extent, bioresorbable scaffolds. Our extensive tests show that our scaffolds maintain the opening of the artery in the 90 days following implant, and then as the lumen size (the inside area of the artery) increases during the time the scaffold begins and continues to resorb, our technology leaves a more normal lumen area. 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 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. 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 a substantial portion of the byproducts were cleared from the body.

- ***Toxicity Testing*** **:** Among other tests, we performed an ISO -10993-1 test for genotoxicity. O ur test showed that there is no change to the DNA or chrom osomes of cells tested and that our polymer is not genotoxic. W e 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 have 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, which is drug-eluting and made from our proprietary polymer, is implanted in a coronary artery using a balloon-mounted angioplasty catheter during a minimally invasive procedure. *Fantom's* features include full x-ray visibility both during and after implant, a unibody deformable design, low strut thickness, crossing profile to accommodate a 6-french delivery catheter, optimized polymer properties, and streamlined manufacturing processes. Our production process involves manufacture of the scaffold device, application of a drug coating, assembly onto the balloon catheter system, sterilization, and packaging. The handling and storage requirements of *Fantom* , as well as the clinical procedure for implant, do not vary from those commonly used in clinical practice with metal stents. Because of its unique full x-ray visibility and other polymer properties, it is currently the only bioresorbable scaffold that 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 smallest 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 a larger clinical study of *Fantom* . We enrolled 110 patients in this larger study between March 2015 and September 2015, from which we will obtain follow-up data at a six-month time point. If this data has acceptable safety and efficacy results, we intend to use it in an application for regulatory approval. In October 2015, we began enrolling a second set of 110 patients in the trial to obtain additional clinical data to facilitate regulatory needs and commercialization. We completed enrollment of the second set of patients in February 2016 and have implanted over 230 patients with *Fantom* . Our current plan is to apply for European CE Marking, the regulatory approval that would allow us to sell our scaffolds in Europe and other countries that recognize the CE Mark, in approximately the third quarter of 2016. We believe our scaffold could receive regulatory approval in late 2016 or early 2017. We plan to be in a position to commercially sell *Fantom* shortly after, and if, we receive CE Mark approval.

Concurrently, with developing and testing *Fantom* , we have been performing feasibility tests on additional technologies in our patent portfolio and are in the early stages of developing a follow-on product pipeline.

Our Product Strategy

Our goal is to become a world leader in the development and commercialization of bioresorbable stent 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*** **:** We intend to demonstrate the safety and efficacy of our products through human clinical trials and to develop a regulatory strategy covering the trials and the pathway to approval for commercial sales. We believe the data from our current clinical trial of *Fantom* will demonstrate the safety and efficacy of our technology. We plan to use the data and results from the *Fantom* study, if they are acceptable, to apply for European CE Marking during the third quarter of 2016. When, and if, we receive CE Mark approval we intend to implement our sales and marketing strategies for commercialization.
- ***Develop Follow-on Products*** **:** We intend to perform feasibility tests on additional technologies in our patent portfolio at the same time we are preparing for commercialization of our *Fantom* scaffold. If feasibility is proven, we will determine a course of product development and seek to provide follow-on products.

- ***Commercialize and Drive Adoption of our Products*** **:** Concurrent with our clinical studies, we are focusing on commercialization readiness. As part of our plan, and in order to meet supply demands for anticipated sales should we receive regulatory approval in the European Union and other markets , such as Au stralia, we intend to refine and expand our manufacturing capabilities to required levels. We have also granted BSC an option to negotiate for a worldwide, exclusive right 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 may pursue the use of our technology to treat peripheral artery disease, which is an expanding market. We believe current treatments for peripheral artery disease, particularly in the superficial femoral artery, have demonstrated only marginal benefit. We believe 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 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 other 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 proprietary polymer, a drug coating, and a unibody deformable stent design.

Our patented polymer is based on an iodinated, tyrosine-derived polycarbonate. We license the polymer technology and all improvements on the polymer technology 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*** **:** Between 2007 and 2014, we performed human clinical trials with earlier versions of our polymer; none of those earlier versions has shown any adverse biological reactions. The current polymer formulation has been designed to enhance mechanical properties and reduce scaffold profile and it demonstrates equal biocompatibility in preclinical testing to the prior formulation. A 12-month preclinical study of our desaminotyrosine polycarbonate polymer showed no indication of adverse biological reactions while the scaffold material was degrading, consistent with other testing of the polymer.

- ***Predictable Degradation and Resorption*** **:** Our polym er 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 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 so that they may help to inhibit restenosis of the artery in the location of the scaffold. For our commercial devices, we intend to use the drug sirolimus, an anti-restenotic drug that has been 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 this early and slow release characteristic optimizes the efficacy of the drug and that delivery of the drug within 90 days may help with the healing process.

The unibody 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 allow for taper of the artery and other implant procedure needs and variation. *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 10,000 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 submissions to the relevant regulatory bodies, for which we received approval to proceed with clinical trials.

Clinical Studies and Regulatory Strategy

We have targeted Europe as our initial commercial market. Accordingly, we have developed a regulatory strategy that concentrates on our clinical trials and pathway in Europe and other countries that recognize the European CE Mark regulatory approval for commercial sales. Our strategy contemplates additional markets, including the United States, after we have achieved initial sales in Europe.

The European Medical Devices Directive ("MDD") 93/42/EEC sets out the general requirements for clinical trials in the European Union (the "EU") and other essential requirements for approval and CE Marking; there are numerous other directives and standards regulating the design, manufacture, clinical trials, and labeling for medical devices. For our products to bear the CE Mark and be sold commercially throughout the EU, we will need human clinical trial data and to comply with the other requirements of the MDD.

In Australia, the Therapeutic Goods Administration ("TGA") is responsible for administering the Therapeutic Goods Act and maintaining the Australian Register of Therapeutic Goods. Unless exempt, all medical devices must be included on the register before they may be imported, supplied in, or exported from Australia. Any unapproved medical devices used in humans in Australia, even in pilot trials, require an exemption from the requirement for inclusion on the register. In addition to agreeing to trial protocols and obtaining ethics committee approvals at these centers, we have obtained an exemption from the Australian Register of Therapeutic Goods for human clinical trials of our scaffolds in Australia. In order to sell commercially in Australia, we will need TGA approval.

In the United States, medical devices are subject to approval by the Food and Drug Administration (“ FDA ”). The FDA has classified approximately 1,700 different generic types of devices, organized within 16 medical specialties. A device’s classification reflects the FDA’s determination of the level of regulatory control necessary to assure the safety and effectiveness of that type of device, and determines the process the manufacturer must complete in order to market the device. The two basic types of marketing authorizations are the 510(k) premarket notification and the premarket approval (“PMA”). The three general classes of medical devices are as follows:

- ***Class I (lowest risk)*** **: “** General controls” are sufficient to provide reasonable assurance of safety and effectiveness.
- ***Class II (moderate risk)*** **:** In conjunction with general controls, there is sufficient information to establish “special controls” to provide reasonable assurance of safety and effectiveness.
- ***Class III (highest risk)*** **:** I and II above are not sufficient to provide reasonable assurance of safety and effectiveness, the device is for use in supporting or sustaining life, or of substantial importance in preventing impairment to human life.

Devices such as our bioresorbable scaffolds are designated as Class III and require the FDA’s PMA prior to commercialization. PMA is the most stringent type of device marketing application and it requires sufficient valid scientific evidence, including clinical trial data, to assure the device is safe and effective for its intended use.

We enrolled a total of 165 patients in three clinical studies between 2007 and 2014 with our predecessor scaffolds, which combined our proprietary “slide and lock” designs with our proprietary polymer formulations. While these predecessor scaffolds demonstrated the viability of the technology, we believed enhanced characteristics were needed and, therefore, do not intend to commercialize any of the predecessor scaffolds.

We developed our *Fantom* scaffold and are currently studying it in clinical trials in eight countries, including Australia, Brazil, and Europe, to obtain patient data that we intend to use to apply for European CE Mark regulatory approval during the third quarter of 2016. We are additionally enrolling patients in the trial to provide data for marketing and other commercial purposes, including the BSC distribution option (see “— Distribution and License Agreements” below for additional information). Following our application for CE Marking, we intend to design and conduct additional trials of *Fantom* for regulatory and marketing purposes.

Our clinical trials utilize standard industry measures of safety, including patient monitoring on a prescribed and regular basis, and are designed to evaluate both safety and performance and provide the data necessary to apply for CE Marking. For our *Fantom* trial, we have set forth the following:

- ***Product Performance*** **:** The primary endpoints we will evaluate are late lumen loss (reduction of internal artery diameter) and MACE (death, heart attack, and target lesion revascularization) as compared to historical values for marketed drug-eluting metal stents and bioresorbable scaffolds.
- ***Patient Safety*** **:** Clinical follow-up will be performed with all patients on a regular basis between the date of implant and six months, at six months, and annually thereafter for a period of up to five years following implant.
- ***Product Performance, Patient Safety, and Study Data*** **:** Patients will return for an interventional follow-up at six months in order to evaluate the healing process and obtain images of the artery and scaffold.

While we have enrolled patients in our *Fantom* clinical trial and expect to be in a position to apply for CE Marking during the third quarter of 2016, no guarantee can be given that we will achieve our expected results from the clinical trials or that CE Marking will be attained in a timely fashion, or at all.

Based on the outcome of our *Fantom* trials, we plan to conduct a clinical trial in the United States, which is expected to be a randomized trial of 2,000 or more patients. Pursuant to our clinical and regulatory strategy, the timing of this trial will be determined after evaluating the CE Marking results, our capacity to manage multiple trials concurrently, and the availability of funding.

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 believe 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 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 San Diego facility has the capacity to produce quantities of *Fantom* that will be needed for clinical trials and initial commercial sales; the facility is currently certified to ISO 13485:2012, with such certification made by an independent third-party.

In order to produce commercial quantities of our scaffold, if and when that time arrives, we will need to scale-up our manufacturing processes and expand our capabilities to allow for such things as increased production volumes and additional scaffold sizes. We began implementing the methods and processes for scale-up in 2015, including work on the product's size offerings, and plan to continue manufacturing preparedness during 2016 as we approach commercialization. We may expand our manufacturing beyond our current facility to allow for continued sales growth when, and if, our sales volumes grow following our planned initial product introduction in Europe.

Although certain portions of our scaffold manufacturing process are completed by external parties, we have not entered into any material agreements with any third parties regarding our supply chain or manufacturing process. Currently, our suppliers have no contractual obligation to supply, and we are not obligated to purchase, any components used in our bioresorbable scaffolds, which may result in supply interruptions. We intend to assess the need for supplier contracts prior to commercialization and secure such contracts as necessary. The strategy of outsourcing selected manufacturing processes is intended to minimize capital and operating costs while at the same time maintaining required quality standards.

The process to manufacture our bioresorbable scaffolds involves seven main components, some of which currently involve a degree of manual intervention. We plan to continue to improve our manufacturing process with the objectives of improving capacity, yield, and automation. These seven manufacturing steps are as follows:

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

Currently, our catheter supply and lasing process are outsourced to third parties. We believe we have a number of qualified suppliers readily available; however, any interruption or delay in obtaining products from third-party suppliers, or our inability to obtain products from sources at acceptable prices in a timely manner, could impair our ability to meet the demand for our planned clinical trials or could delay commercialization of 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 testing, conducting clinical trials, obtaining regulatory approvals, and marketing 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, and Medtronic. Smaller or early-stage companies may also prove to be significant 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, 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 have historically 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, Boston Scientific, and Medtronic. Of the three, only Abbott currently offers a bioresorbable scaffold.

Abbott began selling its *Absorb* bioresorbable scaffold in 2012; it is currently available in approximately 100 countries outside the United States. Sales of *Absorb* during 2015 were estimated to be approximately $125.0 million. In January 2013, Abbott initiated a U.S. randomized clinical trial of *Absorb* , enrolling 2,250 patients. It is anticipated that *Absorb* may receive U.S. PMA approval during 2016.

Abbott is enrolling an additional 3,000 patients in a follow-on trial that compares rates of angina at one year and target lesion failure rates between one and five years; a finding of superiority in this trial would demonstrate added clinical benefits of bioresorbable scaffolds and potentially lead to differentiated product claims and perhaps further differentiated reimbursement rates from those of metal stents. 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; their first commercial implant was performed in January 2014. Additionally, during 2014, Elixir received CE Mark approval for a second, thinner strut bioresorbable scaffold; they are currently conducting a clinical trial of this thinner device prior to commercializing it. In addition to Abbott's activities, Elixir's ability or inability to obtain reimbursement for, and secure adoption of, its 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 Biotronik SE & Co. KG, Arterial Remodeling Technologies, and Amaranth Medical. Biotronik is developing an absorbable metal scaffold called *Dreams* , which is deformable, balloon-expandable, and manufactured from a magnesium alloy. Unlike polymer bioresorbable scaffolds that take multiple years to degrade, the magnesium scaffold is designed to absorb within the first year. In 2010, Biotronik initiated a 50-patient clinical trial of *Dreams* and reported six- and 12-month data. In February 2015, Biotronik completed a 120-patient clinical trial of a newer version of *Dreams* , which we believe will provide the data necessary to apply for a CE Mark. Arterial Remodeling Technologies and Amaranth Medical are also conducting clinical trials of their bioresorbable polymer scaffolds and have released 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 $19.2 million in 2013, $14.3 million in 2014, and $16.8 million in 2015. We expect our research and development expenditures to increase in 2016 as we continue to enroll and follow patients in the *Fantom* clinical trials, apply for CE Marking, test and prepare for commercialization, and assess feasibility of products in our contemplated product pipeline.

Sales and Marketing

We intend to be in a position to sell our products once we receive regulatory approval. As a pre-revenue company, we have a limited sales and marketing focus and currently have limited experience in the sale, marketing, or distribution of products. To achieve commercial success for an approved product, we will need to develop a sales and marketing organization or enter into arrangements with others to market and sell our products. During 2013, we developed a sales and marketing launch plan; we continue to revise and update that plan based on market changes, competitor activities, and our clinical progress. The plan contemplates initial European sales of our *Fantom* scaffold in 2017.

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. In the United States, payors such as Medicare, private health insurance plans, and health maintenance organizations reimburse all or part of the cost of medical devices and related surgical procedures; however, for a new device there will often be uncertainty as to reimbursement status and rates that will apply. 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. In the United States, third-party payor requirements and government regulations impose substantial program requirements, ongoing compliance requirements, and limits on the manner in which medical device companies may market products and interact with healthcare professionals.

Currently, coronary stents are sold directly or through distribution channels, primarily targeting interventional cardiologists who treat patients likely to require stenting. We believe the costs and barriers are large to develop a sales and distribution channel focused around one group of products. We may, therefore, consider partnering with an established distributor. For example, we have entered into a Distribution Option Agreement with BSC that would cover the sale and distribution of our scaffolds in markets in which the technology is approved for sale. The terms of this agreement are described under "— Distribution and License Agreements" below.

If BSC does not exercise its option to market and distribute our products, or if we are unable to reach an agreement on the terms of distribution, we may sell our products through a combination of independent distributors and direct sales. We plan to solidify our sales strategy in 2016, upon receipt of the necessary regulatory approvals and clearances for commercial sales. Generally, our planned targeted roll-out will occur as follows:

- ***Initial Market*** **:** The EU and other countries outside the United States that recognize the CE Mark will be our initial target commercial market since the CE Marking is our first targeted regulatory approval.
- ***Follow-on Markets*** **:** Australia, China, India, Japan, and the Middle East will comprise our follow-on commercial markets because we believe regulatory approval in these countries will require additional clinical trials and/or approvals beyond the CE Mark.
- ***United States*** **:** The United States will be a later commercial market since completion of U.S. FDA trials and PMA approval requires extensive, and expensive, clinical trial results.

Intellectual Property

We rely on a combination of patents, trade secrets, and copyright, 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 March 1, 201 6 , on a worldwide basis , our patent por tfolio comprises 31 5 issued and pending U.S. and foreign patents that we own directly or for w hich we are the licensee. Our latest patent expiration date with respect to these patents is 2035 . We have been issued 5 2 U.S. pa tents and have 1 0 U.S. patent applications that are pending examination or have been allowed in the United States Patent and Trademark Office. For these 62 technology patents and applications , we have sought intellectual property protection outside the United States and have been granted 209 foreign patents and have 4 4 pending foreign application s. 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. W e 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 distribution 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 angiog raphic follow-up of at least 100 of the i mplanted scaffolds; and , (iii) eight - to nine - month optical coherence tomography of at least 40 of the i mplanted scaffolds . 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 agreement s 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, or the License, with Rutgers, The State University of New Jersey, or "Rutgers," that superseded our 2004 Exclusive License Agreement with Rutgers. Under the 2010 License, Rutgers granted us 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. In order to maintain our rights under the Rutgers License, we have to satisfy certain development and commercialization obligations specified in the agreement. 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 2035. The License allows Rutgers to sublicense certain technology that Rutgers invented, we jointly invented with Rutgers, or that we solely invented, outside the field of use specified in the License. If Rutgers sublicenses inventions and improvements solely owned by us, Rutgers shall 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 $25 to a maximum of approximately $100 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, and payment of patent filing, maintenance, and defense fees.

Third-Party Reimbursement

In most countries throughout the world, 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, or the United States, we will need to obtain appropriate regulatory approvals for product sales.

The Center for Medicare and Medicaid Services ("CMS") is the U.S. government entity that administers the Medicare program, which is considered a reimbursement benchmark. CMS establishes, reviews, and updates Medicare coverage and reimbursement policies for medical products and procedures. Both CMS and commercial payors have established coverage and reimbursement policies for stents currently being sold; however, we have no assurances these existing reimbursement codes would apply to our bioresorbable scaffolds. We also have no assurance that existing payment rates under these reimbursement codes will continue.

Outside of the United State s , 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 r eimbursement for stents, a small 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 reimburseme nt approval in countries where it makes economic sense to do so.

In certain regions, such as Europe, innovative pricing and reimbursement agreements are being 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.

In Australia, the Department of Health and Ageing is the government department and Medicare is the government entity responsible for administering the Medicare Benefits Scheme and the Medicare Benefits Schedule ("MBS"). Medicare establishes coverage and reimbursement policies for medical products and procedures and such policies are periodically reviewed and updated. Medicare and MBS have established coverage and reimbursement policies for stents that are currently being sold. However, similar to the United States, there are no assurances that existing policies or reimbursement codes will be used for our bioresorbable scaffolds or that existing payment rates under the reimbursement codes will continue.

In addition, U.S. governmental and private sector payors have instituted initiatives to limit the growth of health care costs, using, for example, price regulation or controls and competitive pricing programs. Some third-party payors also require pre-approval of coverage for new or innovative devices or therapies before they will reimburse health care providers who use such devices or therapies. Providers also have sought ways to manage costs, such as through the use of group purchasing organizations. While we believe the clinical performance of our scaffolds will be sufficient to secure reimbursement, there remains uncertainty as to whether our products will be viewed as sufficiently cost-effective to warrant adequate coverage and reimbursement levels.

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 fro m the market. The FDA also has the authority to require repair, replace ment , 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 other parties 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 Car e 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 currently suspended. 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 t o 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 requi re 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 f inancial 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, 2015, we had 57 employees, 55 of whom were full-time. A total of 47 were in research and development and 10 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 March 1, 2016, are as follows:

Regina E. Groves , age 57, was appointed as our Chief Executive Officer on September 23, 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. She currently serves on the board of two private companies.

Robert K. Schultz, Ph.D. , age 59, 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 57, 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 49, 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 20 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 f rom 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.

Donald K. Brandom, Ph.D. , age 56, has served as our Senior Vice President of Product Development since December 2013, our Vice President of Product Development since December 2010, and our Vice President of Biomaterial Product Development since January 2008. He has directed all biomaterial development activities since 2003 and the scaffold development program since 2010. He has over 25 years of industry experience, including technical, senior, and executive management product development positions in the aerospace, microelectronics, and medical device industries. Dr. Brandom earned his Ph.D. in Materials Engineering Science at Virginia Tech and has a B.S. in Chemistry from the University of California, Davis.

Richard M. Kimes **,** age 54, has served as our Senior Vice President of Operations since January 18, 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.

Joan Ze ltinger, Ph.D. , age 53 , has served as our Vice President of Scientific Affairs since June 2004 and has directed our biological activities since 2000. Dr. Zeltinger has over 20 years of industry research and business experience that includes several publications and patents. Dr. Zeltinger previously directed the bioresorbable coronary graft and tissue engineered heart valve programs at Advanced Tissue Sciences and chaired the American Society for Testing and Materials, or ASTM , standard development fo r combination medical products. She received her Ph.D. in Biology from the University of South Carolina with post-doctoral work conducted at the University of Washington , School of Medicine , and has a B.S. in Biology from the University of North Dakota.

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 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

We 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 $27.9 million, $51.0 million, and $82.6 million for the fiscal years ended December 31, 2013, 2014, and 2015, respectively. As of December 31, 2015, our accumulated deficit was approximately $335.1 million. Currently, we have no products approved for sale in any jurisdiction. We expect to continue to incur significant operating losses and cash outflows for at least the next two years as we incur costs associated with:

- completing our CE clinical trials to obtain human data on our *Fantom* scaffold;
- seeking regulatory approvals in the EU, Australia, and possibly the 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 developing our 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 all of the activities listed above. We may not succeed in these activities and we may be unsuccessful in developing other alternatives; therefore, we may not ever generate revenues sufficient to achieve profitability. If we do achieve profitability, we may not be able to sustain it.

We may need additional funding to meet o ur future operating, capital , and debt service needs and may be unable to raise capital when needed .

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. We had cash totaling $16.9 million as of December 31, 2015. Additionally, we received $11.4 million cash proceeds upon the exercise of warrants on February 12, 2016, which, together with the cash balance at December 31, 2015, provides over $28.0 million in operating funds. We have no other existing sources of capital and we may need to raise additional capital to achieve net cash inflows.

Any 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 future 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 losses, the occurrence of these losses may make it more 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.

If the holders of our convertible notes elect to be repaid in cash in January 2017 when they have that right, we most likely will not have the cash resources to repay the notes. We would then be in default under the note terms, which would have 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 in January 2017, or at any time we become in default of the notes. The notes are convertible into common stock at any time. On February 11, 2016, we entered into an agreement with the noteholders to move the one-time election date from January 14, 2017 to June 30, 2017; such agreement is pending approval by stockholders. The conversion rate of the notes of $2.17275 per share is favorable for the noteholders, as it is below the $6.28 market price of our common stock as of December 31, 2015. However, in a decision to either convert or redeem the notes, many factors may influence the noteholders; some of these factors 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, and the results achieved in our human clinical trials.

If the noteholders collectively, or individually, elect redemption prior to maturity and prior to converting the notes into common stock, we most likely would not have the cash resources to repay the notes and would then be in default of the note provisions. If we were unable to cure the default 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.

Our ability to generate revenue depends upon our successfully completing our clinical trial, obtaining regulatory approval, and commercializing our scaffolds, which we may be unable to accomplish.

Our products will require clinical data, regulatory approval, and significant marketing and distribution efforts before they can be sold and generate any revenue. Our efforts to generate revenue may not succeed for a number of reasons including:

- we may experience delays in completing our clinical trials and submitting our planned CE application;
- our *Fantom* scaffold may not demonstrate safety and efficacy in our clinical trials or it may not be considered an effective alternative to other existing treatments;
- we may not receive regulatory approvals in the markets we seek, or the approved indications for *Fantom* may be narrower than we currently anticipate;
- 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 ma y not receive adequate coverage and reimbursement for procedures using our products ;
- new product introductions by our competitors or any rapid technological change may make our technology and product candidates obsolete;
- we may not be able to manufacture or distribute our products in commercial quantities or at an acceptable cost; 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 preclinical and clinical data regarding its potential long-term benefits;
- the strength of our sales and marketing initiatives;
- the success, or failure, of our competitors who bring bioresorbable scaffolds to market before we do; 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 prior to our sales launch prove unsuccessful or cause negative sentiments about bioresorbables, we may not be able to 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 95 percent of the $3.8 billion worldwide stent sales in 2015. 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 large and 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, we are aware of companies that are developing less-invasive technologies for treating cardiovascular disease, which 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 damage 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 significant damages and could seriously harm our business. We maintain clinical trial insurance and limited product liability insurance; we cannot be certain that such insurance will be sufficient to cover all claims that may be made against us. Our insurance policies generally must be renewed 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 or the surrounding area, for example, due to a natural disaster, we would have no means to manufacture scaffolds until we were able to restore our facility or procure alternative manufacturing facilities. Assuming we receive regulatory approval for our scaffolds, we currently have limited resources and facilities and no prior history of commercially manufacturing our products. In order to produce commercial quantities of our products, we will need to substantially enhance our production processes and the efficiency of our manufacturing operations. There are significant technical and regulatory challenges to increasing manufacturing capacity and efficiency, and developing commercial-scale manufacturing facilities will require additional capital investment and the addition of managing and technical personnel who have relevant manufacturing experience. We may not successfully complete increases in our manufacturing in a timely or economically viable manner, or at all. In addition, we may not be able to receive the necessary regulatory approvals for our manufacturing facilities on a timely basis, or at all. If we are unable to manufacture a sufficient or consistent supply of our scaffolds, if our manufacturing process yields 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 significantly upon our ability to attract, retain, and motivate highly skilled and qualified research, technical, clinical, regulatory, sales, marketing, 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, our President and Chief Operating Officer, our Chief Financial Officer, and our Senior Vice President of Clinical and Regulatory Affairs, we have not e ntered 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 b usiness.

BSC has an option to distribute our products. If we do not enter into distribution with BSC, we will need to develop our own sales network or distribution arrangement. Any delay or problems associated with a distribution partner or our own sales network could have a serious impact on our sales and our financial performance.

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.

We have developed a preliminary sales and marketing launch strategy, which focuses on selecting a distribution partner to assist in the marketing and sale of our products in jurisdictions where it is approved for sale.

Although BSC has an option to negotiate a distribution agreement, there is no guarantee they will exercise the option, or, if they do exercise the option, that we will reach a definitive distribution agreement. If we do not enter into a distribution arrangement with BSC, we will need to find a different distribution partner or develop our own sales and marketing network. There can be no assurance that we will be able to identify and enter into a distribution arrangement with a third party distributor on acceptable terms, or at all. The development of our own sales, distribution, and marketing network would require significant amounts of financial and management resources and we will face a number of risks, including:

- our ability to attract and build a significant, successful, or qualified marketing or sales force;
- the cost to train and provide regulatory oversight for a marketing or sales force may be substantial; and,
- any failure to comply with legal and regulatory requirements for sales, marketing, and distribution could result in enforcement actions, could jeopardize our ability to market our products, or could subject us to liability.

Any delay or problems associated with a distribution partner or our own sales and marketing network could have a material adverse impact on our sales and our financial performance.

If we commercialize outside the United States, we may be subject to the risks of operating in foreign markets.

Our research and development operations are located in the United States. We intend to seek regulatory approvals for our products in the EU, Australia, and elsewhere prior to seeking a PMA in the United States. If 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 produ cts 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 executi ve 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 the outcome of our human clinical trials. If our Fantom scaffold does not meet the intended clinical results or causes adverse or unexpected results or if we are not able to address issues arising from clinical trials, our Company will be significantly negatively impacted.

The outcome of human clinical trials cannot be predicted, even when preclinical results are favorable. Although our results to date are acceptable, if our *Fantom* scaffold should demonstrate adverse issues such as restenosis, stroke, thrombosis, and/or death, it is likely the clinical trial will need to be halted. In such case, we may need to modify our technology to address the issues. Our clinical trials may be suspended or terminated at any time by regulatory authorities, the U.S. Data Safety and Monitoring Board, or by us, including during the enrollment period or during the subsequent patient follow-up period.

There is no guarantee that we will be able to successfully address and overcome any adverse events arising in the clinical trials. If we are unable to address these issues, we will not be able to commercialize our technology, and it will likely have a nominal value, if any at all.

The completion of our clinical trials could also be substantially delayed or prevented by several factors, including:

- failure of patients to complete the clinical trial or our inability to monitor patients adequately after implant;
- 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.

There is no guarantee that, even with successful data from our clinical trials, we will be able to 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;
- 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 approval by the regulatory authorities will have a material adverse effect on our business, financial condition, and results of operations.

We must generate long-term human data on the safety and efficacy of our scaffolds. Any long-term data may not be consistent with our limited short-term data, which could affect the regulatory approval of our products or the rate at which our products are adopted.

An important factor in our clinical trials, upon which the safety and efficacy of our scaffolds may be measured, is the rate of restenosis, or the re-narrowing of the treated artery over time, and the rate of re-intervention, or retreatment, following scaffold implant. We believe that physicians and regulators will compare the rates of long-term restenosis and re-intervention for *Fantom* against other bioresorbable, bare metal, and drug-eluting metal stent procedures and other alternative procedures.

If we fail to demonstrate reasonable restenosis and re - intervention rates, as well as other clinical trial endpoints , and product performance comparable to other stents or scaffolds that have been approved by the FDA and other regulatory authorities, our ability to successfully market our *Fantom* s caffold may be significantly limite d. If *Fantom's* long-term rate s of restenosis and re - intervention do not meet regulators' or physicians' expectations , it may not receive regulatory approval or, if approved, it may not be widely adopted and physicians may recommend alternative trea tm ents f or patients . Another performance measurement of *Fantom* will be the incidence of late-ste nt thrombosis. We cannot assure that our long-term data, once obtained, will prove a low incidence of late-stent thrombosis. If the results obtained from our clinical t rials indicate that our scaffolds are not as safe or effective as other trea tm ent options or as effective as current short-term data would suggest, our products may not be approved, adoption of our products may suffer , and our business would be harmed.

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.

Our manufacturing facilities and those of our suppliers must comply with applicable regulatory requirements. If these facilities do not achieve regulatory approval, our business and our results of operations would be harmed.

Completion of our clinical trials and commercialization of our products require access to, or the development of, facilities that meet applicable regulatory standards to manufacture a sufficient supply of our products. Approvals are required to achieve CE Marking in Europe; similar facility approvals must be obtained from the FDA to manufacture products for U.S. purposes. Suppliers of components and products used to manufacture our products must also comply with applicable regulatory requirements, which often require significant time, money, resources, record-keeping, and quality assurance efforts and subject us and our suppliers to potential regulatory inspections and stoppages. If we or our suppliers fail to comply with the regulatory requirements for our manufacturing operations, our commercialization efforts could be delayed, which would harm our business and our results of operations.

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.

We have received a Certificate of Registration certifying that our Quality Management System complies with the requirements of ISO 13485:2012. In the future, if we fail to continue to comply with ISO regulations, or any other regulation that we may be subject to, the relevant regulatory authorities 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 comply with the requirements or 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 operations, 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 productio n 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 health care 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. For example, the American Recovery and Reinvestment Act of 2009 provided funding to study the comparative effectiveness of health care treatments and strategies. This funding is used, among other things, to conduct, support, or synthesize research that compares and evaluates the risks and benefits, clinical outcomes, effectiveness, and appropriateness of medical products; it remains unclear how the research will impact coverage, reimbursement, or other third-party payor policies. 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. In addition, recent U.S. legislation and proposed bills provide funding to assess the comparative effectiveness of medical devices. It is unclear what impact the comparative effectiveness analysis would have on our products or our financial results. 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”). 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. 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. We expect compliance with the ACA 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 A nti- K ickback S tatute 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 pr ivate 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, that are for services not provided as claimed, or for 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 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. Such a challenge 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 and security of patient information, we could be subject to civil suits and civil or criminal penalties, which could increase our liabilities and harm our reputation or our 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 2035; 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 no t 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 commercial success depends in part on obtaining, maintaining, and enforcing intellectual property rights, including patents, covering our scaffolds and future product candidates. If we are unable to obtain, maintain, or enforce intellectual property protection covering our products, others may be able to 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 is comprised, on a worldwide basis, of 315 issued and pending U.S. and foreign patents that we own directly or for which we are the licensee and that expire as late as 2035. Pending patent applications could further extend our patent portfolio life. However, we might not receive approval of our pending applications or future patent applications owned by or licensed to us and, moreover, issued patents owned or licensed to us now or in the future may be found by a court to be invalid or otherwise unenforceable. Even if our patents are determined by a court 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.

We have licensed certain intellectual property from third parties related to our products, and we rely on them to file and prosecute patent applications, maintain patents, and otherwise protect that intellectual property. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or 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 prioritize their or our enforcement of such patents or defense of such claims 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 of our proprietary know-how and for 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, contractors, outside 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, including patent 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 our management's time and resources. 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 applicat ions 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 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, including:

- announcements of our development progress, including delays or advancements in our timelines;
- announcements regarding the regulatory status of our scaffolds and future product candidates;
- any reported adverse events in our human clinical trials;
- announcements of technological innovations, new products, contracts, acquisitions, or strategic alliances by us or our competitors;
- 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;
- failure to service our debt or raise additional financing to fund our operations when needed or on terms favorable to us or on terms that are not overly dilutive to our current securityholders;
- 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,
- changes in general economic, industry, and market conditions.

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 ready liquid market for them, particularly since a small number of securityholders own a majority of our outstanding capital. 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 the New York Stock Exchange, the NASDAQ Stock Market, or any other exchange.

We may not retain our ASX listing and we may not qualify for listing on a nother 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 consider in 2016. 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 March 1, 2016, officers, directors, and stockholders holding more than five percent of our outstanding shares collectively controlled approximately 72 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. 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.

Additionally, we are required, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404") to furnish reports by management and by our independent auditors to the SEC on, among other things, the effectiveness of our internal controls over financial reporting. The controls and other procedures are designed to ensure that information required to be disclosed by us in reports that we file with the SEC is accurate and recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms. Although we have developed effective controls, these controls may become inadequate because of changes in conditions, our degree of compliance may deteriorate, or weaknesses in our internal controls 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 the accuracy and completeness of 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, including transactions involving a premium over market price for our CDIs. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove members of our board of directors. 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 of directors ("Board");
- 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 application to CE Marking and initial commercial sales. 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, 2015 and December 31, 2015, the sales price of our CDIs ranged from a low sales price of A$0.40 to a high sales price of A$0.94, or a low sales price per share of common stock of $2.92 and a high sales price of $6.84 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.

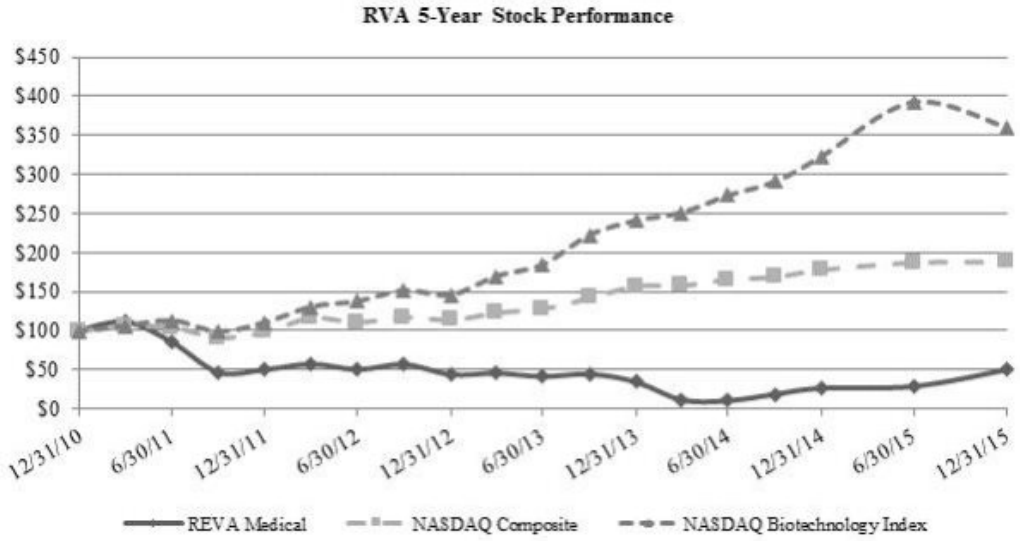
The high and low sales prices for our CDIs during each quarter, and on an equivalent basis as converted to common stock and U.S. dollars, were as follows:

	CDI Price Range		Stock Price Range	
	Low	High	Low	High
Year Ended December 31, 2014:				
First quarter	$0.14	$0.48	$1.29	$4.31
Second quarter	0.12	0.21	1.13	1.97
Third quarter	0.11	0.33	0.98	2.83
Fourth quarter	0.17	0.57	1.48	4.74
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

As of March 1, 2016 we had 42,535,986 shares of common stock issued and outstanding with 837 holders of record. The holders included CHESS Depositary Nominee Pty Limited, which held 26,379,803 shares of our common stock, or approximately 62% of the outstanding shares, in the form of CDIs on behalf of the CDI holders; there were 780 registered owners of our CDIs on March 1, 2016.

Stock Price Performance Graph

The following graph compares our total common stock return, after giving effect to the ten-for-one CDI-to-common stock exchange ratio and after converting to U.S. dollars using the spot rate applicable on the relevant date, with the total return for (i) the NASDAQ Composite Index and (ii) the NASDAQ Biotechnology Index for the period from December 23, 2010 (the date our common stock commenced trading on the ASX) through December 31, 2015. The figures represented below assume an investment of $100 in our common stock at the closing price of $12.52 per share of common stock on December 23, 2010, and in the NASDAQ Composite Index and the NASDAQ Biotechnology Index on December 23, 2010, and the reinvestment of dividends, if any, into shares of common stock. 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. This 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. 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.

Use of Proceeds from Public Offering of Common Stock

In December 2010, we completed an initial public offering (the "IPO") of our common stock with aggregate proceeds from the offering of approximately $84.3 million. The securities issued in the IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-168852), which was declared effective by the SEC on November 15, 2010. Our net IPO proceeds, after deducting placement agent fees and other offering expenses, were approximately $76.2 million. We had used approximately 96 percent of the proceeds through December 31, 2014 and used the remainder in early 2015 in a manner generally consistent with our projections at the time of the IPO, as follows:

- $40.0 million was projected to be used for research and development activities, including advancement of our scaffolds and development of pipeline products, if any. Approximately $40.0 million was used for R&D.
- $10.0 million was projected for clinical trials and approximately $6.0 million was used for that purpose.
- $4.0 million was projected for commercial infrastructure, including manufacturing capacity. Approximately $4.0 million was used for R&D equipment, laboratory improvements, and related infrastructure.
- The balance of the IPO proceeds was expected to be used for working capital and other general corporate purposes and they have been used for those purposes.

Item 6. Selected Financial Data

We have derived our statements of operations data for the years ended December 31, 2011 and 2012 and our balance sheet data as of December 31, 2011, 2012, and 2013 from our audited financial statements, which are not included in this Form 10-K. We have derived our statements of operations data for the years ended December 31, 2013, 2014, and 2015 and our balance sheet data as of December 31, 2014 and 2015 from our audited financial statements appearing elsewhere in this Form 10-K. Our audited financial information is prepared and presented in accordance with generally accepted accounting principles in the United States, or U.S. GAAP. Our selected consolidated 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 ending December 31, 2015.

	Year Ended December 31,				
	2011	2012	2013	2014	2015
	(in thousands, except per share data)				
Statements of Operations Data:					
Operating Expense:					
Research and development	$ 13,401	$ 15,822	$ 19,212	$ 14,318	$ 16,760
General and administrative	7,695	8,043	8,731	7,645	7,210
Loss from operations	(21,096)	(23,865)	(27,943)	(21,963)	(23,970)
Other Income (Expense):					
Interest income	188	92	30	8	9
Interest expense	—	—	—	(986)	(1,904)
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)
Other income (expense)	—	(3)	(9)	73	59
Net Loss	$ (20,908)	$ (23,776)	$ (27,922)	$ (51,037)	$ (82,594)
Net Loss Per Share: (1)					
Net loss per share, basic and diluted	$ (0.64)	$ (0.72)	$ (0.84)	$ (1.53)	$ (2.38)
Shares used to compute net loss per share, basic and diluted	32,777,509	33,072,058	33,124,655	33,382,381	34,680,634

(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,				
	2011	2012	2013	2014	2015
	(in thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$ 59,161	$ 38,876	$ 19,229	$ 25,814	$ 16,895
Short- and long-term investments	5,226	5,223	1,492	995	—
Working capital	59,847	42,323	17,656	24,351	13,996
Total assets	67,320	47,397	24,785	30,195	20,071
Convertible notes payable	—	—	—	37,780	75,365
Common stock warrant liability	—	—	—	15,389	19,622
Total liabilities	2,737	2,771	3,960	56,644	100,635
Accumulated deficit	(149,811)	(173,587)	(201,509)	(252,546)	(335,140)
Total stockholders' equity (deficit)	64,583	44,626	20,825	(26,449)	(80,564)

Item 7. Management's Discussion and Ana lysis 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 Consolidated Financial Data" and our consolidated financial statements and the related notes thereto that appear elsewhere in this Form 10-K. In addition to historical information, the following discussion and analysis includes forward-looking information that involves 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. See also "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 the treatment of conditions in the human body. We are in the later stages of developing and clinically testing bioresorbable drug-eluting coronary stents. We refer to bioresorbable stents as "scaffolds" because they are not permanent devices like metal stents that are commonly used today. In clinical use, a scaffold is implanted by an interventional cardiologist during a minimally invasive surgery. It is delivered to a coronary artery location with a balloon catheter system, whereupon it is deployed to restore blood flow through the artery and medicate the artery to prevent further blocking, or "restenosis."

Use of fully bioresorbable scaffolds, and the number of patients receiving them, has continued to increase since becoming commercially available outside the United States approximately three years ago. 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 and ease of clinical use, we believe our products would enable us to compete effectively in the stent market, which had approximately $3.8 billion in worldwide revenues during 2015, and, in particular, with other bioresorbable scaffolds, which had estimated annual revenues of approximately $125.0 million in 2015.

Our scaffolds have not yet been approved for sale; they are still in a clinical testing stage and will require successful clinical trial results and regulatory approval before they can be sold and generate any revenue. We have invested significant time and funds in development, having performed scientific research, engineering development, and testing in laboratory and preclinical studies. We have developed, tested, and selected the polymer formulation, tested and selected the anti-restenotic drug and coating process, created and iterated the device design, and identified and implemented methods and processes to produce and test the scaffold. We designed and performed extensive preclinical tests that ranged from bench and engineering studies to in vitro and in vivo laboratory studies. In 2007, we enrolled patients in a small clinical study that proved the viability of our technology while confirming the areas needing further development. We have been developing and advancing our technology in both its design and polymer composition since that study and have undertaken significant testing that has shown the technology to be safe and effective across various models.

We have enrolled over 230 patients in a clinical trial of our *Fantom* scaffold. We enrolled 110 patients in this trial between March 2015 and September 2015, from which we will obtain follow-up data at a six-month time point. If this data has acceptable safety and efficacy results, we plan to apply for European regulatory approval. In October 2015, we began enrolling a second set of 110 patients in the trial to obtain additional clinical data to facilitate regulatory and commercialization needs; we completed enrollment of this second set of patients in February 2016. Prior to developing *Fantom* , we had enrolled a total of 165 patients in three clinical trials between June 2007 and January 2014 with predecessor scaffolds that were developed utilizing our proprietary x-ray visible polymer in combination with our "slide and lock" stent design. While these predecessor scaffolds demonstrated viability of the technology, we believe the enhanced characteristics of *Fantom* , including its conventional design, better position it for commercial success.

Our current plan is to apply for European CE Marking, the regulatory approval that would allow us to sell our scaffolds in Europe and other countries that recognize the CE Mark, in approximately the third quarter of 2016. When, and if, we receive CE Mark approval, we will evaluate how best to implement our sales and marketing strategies for commercialization. While our *Fantom* scaffold could be approved for sale in late 2016 or early 2017, our efforts to generate substantial revenue and achieve positive cash flows from our operations may take several years, even if our clinical results are favorable.

In order to produce quantities of our scaffold large enough to accommodate commercial needs, when that time arrives, we will need to scale up our manufacturing processes and expand our capabilities to allow for such things as additional scaffold sizes. We hav e developed plans and have begun implementation of the methods and processes for such manufacturing scale-up, including work on additional product sizes. We will continue implementation of manufacturing preparedness throughout 2016 as we approach commercia lization.

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

During our development efforts, we have also pursued, tested, and abandoned development programs that we determined would not lead to feasible products or for which a product could not be developed in a timeframe that would allow for reasonable commercialization. The largest of these abandoned programs centered on development of a thin metal stent technology for use in small blood vessels. Although abandoned in 2002 after approximately $13.0 million had been invested and used, this technology became the basis for the “slide and lock” mechanism we maintain in our patent portfolio and the knowledge base for our current scaffolds. Additionally, we licensed a potential anti-restenotic drug in 2001 with the intent to develop it for use as a stand-alone drug or as a complement to our scaffold. Although the drug’s development was abandoned in 2004 after we had invested approximately $6.0 million, the knowledge we gained from that program was used in our development of the drug coating for our current scaffolds.

We perform all of our research and development activities from one location in San Diego, California. We have three clean rooms 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 57 employees as of December 31, 2015, a significant number of who are degreed professionals and six of whom are PhDs. We leverage our internal expertise with contract research and preclinical laboratories, catheter manufacturing, 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 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, cash proceeds of $9.5 million from the exercise of 50 percent of the warrants on October 1, 2015, and cash proceeds of $11.4 million from exercise of the other 50 percent of the warrants on February 12, 2016. Our cash balance at December 31, 2015 of approximately $16.9 million combined with the warrants proceeds in February 2016 provides over $28.0 million in available cash resources. We believe these cash resources are adequate to fund our operating and capital needs through 2016 and into 2017 as we approach the commercialization of *Fantom* .

We have incurred substantial losses since our inception; as of December 31, 2015, we had accumulated a deficit of approximately $335.1 million. We expect our losses to continue as we complete our development work, clinical studies, and preparations for commercialization during the remainder of 2016. If these efforts are successful and we are able to obtain regulatory approval, we expect to commence product sales thereafter. In order to successfully transition to profitable operations, we will need to achieve a level of revenues and product margins to support the Company’s cost structure. Until such time as we generate positive cash flow, we plan to continue to fund our operations by utilizing our existing cash and, if needed, by raising additional capital through equity or debt financings or strategic or other transactions.

Key Components of our Results of Operations

We are still in a pre-revenue stage and our activities are focused on further refining, testing, and obtaining clinical data on our bioresorbable coronary scaffold with the goal of commercially selling it, as well as performing minimal research and tests to determine the feasibility of other product possibilities. Consequently, our operating results primarily consist of research and development expenses, including costs to perform clinical trials, general and administrative expenses, and other expenses that are primarily the costs of the convertible notes and warrants that we issued in November 2014 to provide the funds to continue our developments efforts.

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 producing our scaffolds and other product possibilities. 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, 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. In March 2014 we announced a change in scaffold programs, moving to our *Fantom* scaffold as our sole focus. This change resulted in a decrease in research and development expenses in 2014, primarily due to a concurrent reduction in headcount by approximately 46 percent and a reduction of other development and clinical trial expenses due to the earlier stage of development for *Fantom* compared to the predecessor program. In 2015 as we continued refining *Fantom* , we began enrolling patients in a non-U.S. clinical trial. We enrolled 110 patients in the trial between March 2015 and September 2015 . We plan to obtain data at a six-month time point on these patients, and, if this data has acceptable safety and efficacy results, apply for European regulatory approval of *Fantom* in the third quarter of 2016. We began enrolling a second set of 110 patients in the trial in October 2015 to obtain additional data for regulatory and commercialization purposes; we completed enrollment of this second set of patients in February 2016.

Research and development expenses as a percentage of our total operating expenses were 70 percent for the year ended December 31, 2015 compared to 65 percent for the year ended December 31, 2014. We expect our research and development expense to continue to increase during 2016 as we continue enrolling and following patients in our clinical trials and preparing *Fantom* for commercialization, including development of final manufacturing processes and equipment. We also plan to research the feasibility of developing additional products from technology in our intellectual property portfolio.

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

Historically, our general and administrative expenses have represented between 25 and 30 percent of our total operating expenses; they represented 30 percent of total operating expenses for the year ended December 31, 2015 and 35 percent for the year ended December 31, 2014. In March 2014, upon the change to the *Fantom* scaffold program, we made a concurrent reduction in general and administrative personnel by approximately 44 percent and we took additional steps to reduce other overhead expenses. During 2015, we continued our cost-efficient approach to general and administrative activities, while ensuring adequate support for the progress of *Fantom* and our corporate compliance and other requirements. Also during 2015, we appointed a new Chief Executive Officer in anticipation of commercializing *Fantom* ; this addition resulted in a higher executive compensation expense and $210,000 in non-recurring severance expense that arose upon termination of the former Chief Executive Officer. We anticipate that we will expand our corporate infrastructure in 2016 to continue to support the needs of being a public company and to prepare for commercial sales of our products, which will increase our general and administrative expenses accordingly. We also expect to begin to incur sales and marketing expenses by mid-2016 as we prepare for product sales in the event we receive CE Marking. We anticipate that we will continue to invest in patents at similar levels as we have in the past.

Other Income and Expense **:** Since our IPO in 2010 and prior to November 2014, our other income and expense was relatively immaterial and primarily comprised interest income on investments and gains and losses from foreign currency fluctuations. Following our issuance of convertible notes and warrants in November 2014, the components of other income and expense also include interest expense on the notes and losses related to t he changes in fair values of the notes and warrants.

We recorded the notes and warrants at fair value upon issuance, which resulted in a non-recurring loss because their values exceeded the cash proceeds from issuance. We remeasure the fair values of the notes and warrants at each reporting date, and if those fair values change, we record a corresponding gain (upon decrease in fair value) or loss (upon an increase in fair value). During 2015, due to a variety of factors including our progress with *Fantom* , enrollment of over 175 patients in the clinical trial, addition of a new Chief Executive Officer, and an increase in the market trading price of our common stock of more than 85 percent, the value of the notes and warrants increased significantly and we recorded a $56.8 million loss on the increase in value during 2015. In October 2015, half of the warrants were exercised for cash; the remaining half was exercised in February 2016 for cash.

Since we account for the convertible notes and warrants at fair value, we expect our other income and expense to fluctuate, and possibly fluctuate by a significant amount, in future periods by the gains or losses on changes in fair value until such time as the notes are either converted into common stock or repaid; we do not expect fair value fluctuations from the warrants since none remain outstanding after February 2016. Also, we will accrue and record interest expense on the notes at the rate of 7.54 percent per annum until they are either converted or repaid. We do not expect any material changes in interest income or foreign currency gains or losses during 2016.

Critical Accounting Policies and Significant Estimates

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States. The preparation of our financial statements and related disclosures requires us to make 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 longer than a year. We record costs incurred under these contracts as the work occurs and make payments according to contractual terms. Until a contract is completed, we estimate the amount of work performed and accrue for estimated costs that have been incurred but not paid. As actual costs become known, we adjust our accruals. We expect our clinical expense accruals to 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 five years or longer. As these costs increase, if our estimates are inaccurate, possible material changes to our accruals could be required, which could materially affect our results of operations within any fiscal period. To date, there have been no material changes in our research and development expense estimates, including our estimates for accrued clinical costs.

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

For awards to employees and directors, we determine the amount of compensation expense by estimating the fair value of the option, stock or RSU on the date of award, with the resulting stock-based compensation recorded over the vesting period, which ranges from one to four years, on a straight-line basis. For stock options and RSUs that vest upon performance achievements, we record only the compensation expense for the performance targets that are probable of being achieved and we record such expense on a s traight-line basis over the vesting period. During the year ended December 31, 2015, we determined that two of the three performance targets for our performance-based awards were probable of being achieved and, therefore, recorded expense for those awards only. All stock-based compensation expense is recorded as either research and development or general and administrative expense based on a recipient's work classification. For stock options, we estimate the fair value by using the Black-Scholes option pric ing 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 5.5 0 and 6.25 years, and an estimate of volatility based on the market trading prices of comparative peer companies. The fair value of restricted stock and RSUs awarded is equal to the closing market price of our common stock on the date of award. Additionally, we reduce the amount of recorded compensati on expense to allow for potential forfeitures of the options; the forfeiture rate is based on our actual historical forfeitures and has ranged from approximately 2. 1 percent to 3.4 percent.

We have not granted any consultant options since January 2014; since March 31, 2015, no consultant options remained subject to vesting. When we do have unvested consultant options, we estimate the fair value at date of grant and at each subsequent accounting date 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 expect to increase the level of awards for options, restricted stock, and/or RSUs in 2016 as we expand our workforce and prepare for commercialization, which could result in an increase of our stock-based compensation in the future.

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

We elected to account for the convertible notes we issued in November 2014 at fair value, which does not require separate accounting for derivative features. On the issue date, 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) 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 for the December 31, 2015 valuation 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. Our 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 **:** We record the fair value of the warrants we have issued for the purchase of common stock as a liability since they call for issuance of registered shares upon exercise, a condition that we may not be able to accommodate and which would then result in a net settlement of the warrants. Until the time the warrants are exercised or expire, the fair value is assessed at each reporting date . Through September 30, 2015, the values were determined utilizing a binomial valuation model since two exercise prices we re possible; we moved to a Black-Scholes valuation model to deter m in e the value at December 31, 2015 because Company conditions had been met th a t re sul ted in a fixed exercise pri ce. This change in models did not have a material effect on the fair value of the warrants. Inputs to the valuation models are of the same nature as those used for our notes payable. A ny change in fair value is recorded as a gain (upon a decrease in fair value) or loss (upon an increase in fair value) in the consolidated statement of operations. Since the determination of fair value of the warrants is complex and involves the use of subjective assumptions, if our assumptions, estimates, or modeling approaches c hange and we use different assumptions or methods, our fair values could be materially different in the future.

Results of Operations

During the first quarter of 2014, our operating activities focused on testing and commercial preparation of a predecessor version scaffold. In March 2014 we announced that our *Fantom* scaffold would be our sole focus for development and testing and we concurrently reduced headcount by approximately 45 percent and reduced other overhead costs to a lesser extent. In addition to the development and testing of *Fantom* in 2014, we began the initial human clinical trial of *Fantom* in December of 2014. During 2015, our operating activities have consisted of further refinement of *Fantom* and clinical trial activities to support increasing enrollments of patients with *Fantom* .

In November 2014, we issued 250 senior unsecured convertible notes, each with a face value of $100,000, and warrants to purchase 8,750,000 shares of our common stock. We received cash proceeds of $25.0 million from the notes at that time. We account for the notes and warrant liability at their fair values and have recognized non-cash losses in the consolidated statement of operations for the increases in fair values since the issuance date. On October 1, 2015, we received cash proceeds of $9.5 million from the exercise of 50 percent of the warrants and on February 12, 2016, we received cash proceeds of $11.4 million from exercise of the remaining warrants.

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, the related reduction in headcount at that time, and the initiation of *Fantom* clinical trials 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 a one-time licensing fee 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 dec reased 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, including benefits and stock-based compensation expense, de creased $ 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 the headcount reduction; we recorded $210,000 in severance benefits in 2015 upon our transition to a new Chief Executive Officer. T he remainder of the decrease in personnel costs was due to an 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 trave l 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 convertible 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.

Comparison of the Years Ended December 31, 2013 and 2014

	Year Ended December 31,		Change	
	2013	2014	$	%
	(dollars in thousands)			
Research and development expense	$19,212	$14,318	$(4,894)	(25)%
General and administrative expense	$8,731	$7,645	$(1,086)	(12)%
Interest expense	$—	$986	$986	100%
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	$12,542	100%
Interest and other income	$21	$81	$60	>100%

Research and development expense decreased $4,894,000, or 25 percent, for the year ended December 31, 2014 compared to the year ended December 31, 2013. This decrease was primarily a result of our change in product development and testing focus to *Fantom* in late March 2014, the related reduction in headcount on March 26, 2014, and the completion of patient enrollment in a predecessor scaffold clinical study in January 2014. Direct materials, including purchased catheters and polymer lasing costs, decreased $1,708,000 and preclinical and consulting costs decreased $1,446,000 because of the type and timing of *Fantom* development work in 2014 compared to the predecessor scaffold testing and scale-up work performed in 2013. Personnel costs, including benefits, bonuses, and stock-based compensation, decreased $1,227,000 primarily due to the approximate 46 percent decrease in headcount during March 2014; these reductions were offset by $237,000 in severance benefits and payroll taxes recorded as a result of the headcount reduction. Clinical costs decreased $726,000 between years due to the timing of patient enrollments in our clinical trials; 111 patients were enrolled during 2013 compared to 5 patients in 2014. We paid a one-time licensing fee of $100,000 for certain polymer technology in 2013 for which we had no corresponding expense in 2014. Offsetting these decreases, depreciation increased $143,000 in 2014 primarily due to the addition of lab space, production equipment, and a back-up generator in 2013. The remainder of the change in research and development expenses between years resulted from individually immaterial changes in lab supplies, quality control, and facilities expenses.

General and administrative expense de creased $ 1,086,000 , or 12 percent, for th e year ended December 31, 2014 compared to the year ended December 31, 2013 . A combination of items contributed to this decrease. Personnel costs, including benefits, bonuses, and s tock-based compensation expense , de creased $872,000 primarily due to a decr ease of $707,000 in stock compensation upon final vesting of stock option grants made in 2010 for which there were no corresponding grants in 2014. Other personnel costs decreased $165,000 due to an approximate 44 percent decrease in headcount during March 2014; these reductions were offset by $178,000 in severance benefits and payroll taxes recorded as a result of the headcount reduction. Travel and entertainment costs decreased $334,000 in 2014 compared to 2013 as a result of the headcount reduction combi ned with reduced clinical travel following completion of patient enrollments in the predecessor scaffold clinical study. The remainder of the change in general and administrative expenses between periods was due to individually immaterial changes in invest or relations costs, office supplies, depreciation, insurance, franchise taxes, and other overhead expenses.

Our other non-operating expenses during 2014 primarily arose from the issuance on November 14, 2014 of convertible notes payable ("Notes") and warrants to purchase common stock. Interest expense of $986,000 related to the Notes and comprised $248,000 in interest accruing on the notes during the period from the issuance date through December 31, 2014 and $738,000 in costs to complete the financing. The $15,627,000 loss on issuance of convertible notes payable and warrants was a non-recurring charge that resulted because the fair value of the Notes and warrants on the issuance date exceeded the cash proceeds received. We additionally recorded a $12,542,000 loss on the change in fair value of the Notes and warrants for the period from November 14, 2014 through December 31, 2014.

Interest income was $8,000 and other income was $73,000 for the year ended December 31, 2014, each of which are considered immaterial.

Liquidity and Capital Resources

Sources of Liquidity

We are in the clinical testing phase of product development, but have not commercialized or generated revenue from the sale of any products and have incurred losses 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 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. We do not anticipate having a product available for sale and being able to generate revenue unless, and until, we successfully receive CE Marking or other regulatory approval for, and begin selling, or licensing, one of our products, which we do not anticipate will occur until late 2016 at the earliest. We anticipate that we will continue to incur substantial net losses and cash outflows through at least 2016 as we continue our development work, conduct and complete preclinical and clinical trials, expand our corporate infrastructure, and prepare for the potential commercial launch of our products.

The losses we have incurred since our inception are substantial; as of December 31, 2015, we had accumulated a deficit of approximately $335.1 million. We expect our losses to continue as we complete our clinical studies and prepare for commercialization during the remainder of 2016. If these efforts are successful and we are able to obtain regulatory approval, we expect to commence product sales thereafter. In order to successfully transition to profitable operations, we will need to achieve a level of revenues and product margins to support the Company's cost structure. Until such time as we generate positive cash flow, we plan to continue to fund our operations by utilizing our existing cash and, if needed, by raising additional capital through equity or debt financings or strategic or other transactions. Any future equity or debt financing, if available at all, may be on terms that are not favorable to us. We currently have no set plans for raising additional capital.

Our development efforts have been funded with a variety of capital received from angel investors, venture capitalists, strategic partners, hedge funds, the proceeds from our IPO in 2010, and the issuance of convertible notes and warrants in November 2014. We received cash proceeds of $25.0 million from the convertible notes in November 2014, cash proceeds of $9.5 million from the exercise of 50 percent of the warrants on October 1, 2015, and cash proceeds of $11.4 million from exercise of the remaining 50 percent of the warrants on February 12, 2016. Our cash balance at December 31, 2015 of approximately $16.9 million combined with the warrants proceeds in February 2016 provides over $28.0 million in available cash resources. We believe these cash resources are adequate to fund our operating and capital needs through 2016 and into 2017 as we approach the commercialization of *Fantom* .

The holders of the convertible notes have a one-time option in January 2017 to redeem the notes for face value plus accrued interest. Based on the Company's cash balances, if the noteholders wer e to collectively exercise this option, which management believes they will not do, the Company would be unable to make the redempti on payment of approximately $29.3 million . On February 11, 2016, t he Company and the noteholders entered into an agreement t o extend the optional redemption date to June 30, 2017, subject to stockholder approval . A special meeting of stockholders is scheduled for March 22, 2016; we believe it is probable our stockholders will approve the agreement.

Cash Flows

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

	Year Ended December 31,		
	2013	2014	2015
		(in thousands)	
Net cash used for operating activities	$(21,943)	$(17,930)	$(19,082)
Net cash provided by (used for) investing activities	$2,265	$(44)	$138
Net cash provided by financing activities	$31	$24,559	$10,025
Net increase (decrease) in cash and cash equivalents	$(19,647)	$6,585	$(8,919)

Net Cash Flow from Operating Activities

Net cash used for operating activities during 2013 primarily reflects the net loss of $27,922,000, offset by non-cash expenses of $4,090,000 for stock-based compensation, $978,000 from changes in operating assets and liabilities, $892,000 of depreciation and amortization, and $19,000 of other non-cash expense.

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 Flow from Investing Activities

Net cash was provided by investing activities during 2013, which consisted of $3,731,000 in net maturities of investments offset by $1,466,000 in purchases of property and equipment.

Net cash used for investing activities during 2014 consisted of property and equipment 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 Flow from Financing Activities

Net cash provided by financing activities in 2013 consists of proceeds from the issuance of common stock upon exercise of employee stock options.

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 that were 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.

Operating Capital and Capital Expenditure Requirements

We are in the clinical testing phase of product development, but have not commercialized or generated revenue from the sale of any products. We do not anticipate having a product available for sale unless, and until, we successfully receive CE Marking or other regulatory approval, which we do not anticipate will occur until late 2016 at the earliest. We have incurred substantial losses since our inception and we anticipate that we will continue to incur substantial net losses and cash outflows through at least 2016 and into 2017 as we continue our development work, conduct and complete preclinical and clinical trials, expand our corporate infrastructure, and prepare for the potential commercial launch of our products.

As of December 31, 2015, we had approximately $16.9 million in cash available for operations. Subsequent to year end, on February 12, 2016, we received cash proceeds of $11.4 million from the issuance of common stock upon the exercise of 4,375,000 of the warrants, which, combined with the cash balance at December 31, 2015, provided over $28.0 million in cash available for operations. We believe this amount will be sufficient to fund our operating and capital needs through the first fiscal quarter of 2017.

In order to successfully transition to profitable operations, we will need to achieve a level of revenues and product margins to support the Company's cost structure. If our available cash resources are insufficient to satisfy our liquidity requirements before we are able to maintain our operations from our cash inflows, or if we develop additional products or pursue new uses for our products, we may need to raise additional capital through equity or debt financings, strategic, or other transactions. We currently have no set plans for raising additional capital. Any such needed additional capital may not be available on reasonable terms, if at all. Additionally, we may be limited under the terms of the convertible notes as to the type, quantity, timing, or other aspects of a financing, unless the noteholders agree. Any financing, even one to which the noteholders agree, may result in additional dilution to our current securityholders, could have rights senior to those of our common stock, and/or could contain provisions that would restrict our operations. If we are unable to raise additional capital, if needed, we may be compelled to sell certain assets, including intellectual property assets. Even if we are able to commercialize our products and raise additional capital if and when needed, 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 the development and testing of medical devices, such as our bioresorbable scaffolds, we are unable to estimate the exact amounts of, or timing of, capital outlays and operating expenditures necessary to complete our ongoing preclinical studies and human clinical trials, successfully deliver a commercial product to market, and collect on our trade receivables. Our future funding requirements will depend on many factors, including, but not limited to:

- the time and cost it will take to successfully complete enrollment and follow-up of patients in our human clinical trials;
- the requirements, cost, and timing of regulatory approvals;
- the time and effort it will take to develop and scale-up our manufacturing processes;
- 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;
- the cost of filing and prosecuting patentable technologies and defending and enforcing our patent and other intellectual property rights;
- the terms and timing of any collaborative, licensing, or other arrangements that we may establish; and,
- the effect of competing technological and market developments.

Future 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. Additionally, 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.

Cont ractual Obligations, Commitments, and Contingencies

The following table summarizes our outstanding contractual obligations as of December 31, 2015:

	Payments Due by Period		
	Less than 1 Year	1-3 Years	Total
		(in thousands)	
Operating lease obligations	$690	$771	$1,461
Purchase obligations	84	2	86
Total contractual obligations	$774	$773	$1,547

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Recent Accounting Pronouncements

None

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Sensitivity

Our cash and cash equivalents of $16.9 million at December 31, 2015 consisted of cash and money market funds that will be used for working capital purposes. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates in the United States. Because of the short-term nature of our cash and cash equivalents, we do not believe that we have any material exposure to changes in their fair values as a result of changes in interest rates.

Foreign Currency Risk

To date, our purchases from foreign suppliers and consultants have been minimal and have been denominated primarily in the currencies of Australia and the European Union. Although minimal, we have had and will continue to have exposure to foreign currency exchange rate fluctuations. We do not enter into foreign currency hedging transactions. Although our German subsidiary is non-operational, its functional currency is the Euro; accordingly, the effects of exchange rate fluctuations on the net assets of the subsidiary are accounted for as translation gains or losses, a component of Comprehensive Loss; these translations adjustments have been immaterial to our financial statements through December 31, 2015. A change of ten percent or more in foreign currency exchange rates of the Australian dollar or the Euro would have a material impact on our financial position and results of operations if we continue or increase our purchases denominated in these currencies.

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements, and accompanying notes, and the Reports of Grant Thornton LLP and Ernst & Young LLP, our Independent Registered Public Accounting Firms, 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. Contro ls 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, 2015, 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.

Changes in Internal Control Over Financial Reporting

There was no change 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, 2015 that has 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 Shareholders
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, 2015, 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, 2015, 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, 2015, and our report dated March 10, 2016 expressed an unqualified opinion on those financial statements.

/s/ GRANT THORNTON LLP

San Diego, California
March 10, 2016

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 2016 Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission within 120 days of December 31, 2015 (the " 2016 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* .

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 March 1, 2016

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 March 1, 2016 are as follows:

	Number of Common Shares	% of Total Common Shares	Number of CDIs	% of Total CDIs	Total Holdings	
Security Holder	Held	Outstanding	Held	Outstanding	Equivalent Number of CDIs Held	% of Total Securities Outstanding
Brookside Capital and affiliates	—	—	29,650,222	11.2%	29,650,222	7.0%
Cerberus and affiliates	—	—	28,844,260	10.9%	28,844,260	6.8%
Citicorp Nominees Pty Limited	—	—	13,203,196	5.0%	13,203,196	3.1%
DNU Nominees Pty Limited	—	—	15,918,126	6.0%	15,918,126	3.7%
Domain Partners and affiliates	3,691,188	22.8%	—	—	36,911,880	8.7%
Elliott Associates, L.P.	3,227,031	20.0%	—	—	32,270,310	7.6%
Goldman Sachs International	4,375,000	27.1%	—	—	43,750,000	10.3%
Group Outcome Investors/Robert B. Stockman	1,694,906	10.5%	933,000	0.4%	17,882,060	4.2%
Kenneth Rainin Trust and affiliates	—	—	13,470,695	5.1%	13,470,695	3.1%
Medtronic, Inc.	379,651	2.3%	22,558,280	8.6%	26,354,790	6.2%
Gordon E. Nye	823,531	5.1%	96,000	0.0%	8,331,310	1.9%
Saints Capital Everest, L.P.	—	—	32,235,131	12.2%	32,235,131	7.6%
Senrigan Capital and affiliates	—	—	57,652,300	21.9%	57,652,300	13.6%
Total securities held by ≥ 5% holders	14,191,307	87.8%	214,561,210	81.3%	356,474,280	83.8%
Total securities held by all other holders	1,964,876	12.2%	49,236,820	18.7%	68,885,580	16.2%

Distribution of Security Holders as of March 1, 201 6

As of March 1, 2016, we had a total of 42,535,986 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 and warrants 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	10	3,614	108	47,542	2	2,000	—	—	—	—
1,001 – 5,000	10	30,000	198	618,248	3	9,500	—	—	—	—
5,001 – 10,000	5	36,963	125	1,057,377	—	—	—	—	—	—
10,001 – 100,000	18	655,374	290	9,856,067	19	806,000	—	—	15	438,000
100,001 and over	14	15,430,232	59	252,218,796	13	5,577,425	2	11,506,155	4	546,200
Total holders and securities	57	16,156,183	780	263,798,030	37	6,394,925	2	11,506,155	19	984,200

The number of shareholders holding less than a marketable parcel of CDIs (being a parcel of securities not less than A$500) as of March 1, 2016 was 55.

Top 20 CDI Holders as of March 1, 2016

Following are the top 20 holders of our CDIs as of March 1, 2016 (does not include holdings in common stock):

	Number of CDIs Held	**% of CDIs Outstanding**
1. HSBC Custody Nominees (Australia) Limited – GSCO ECA	59,560,483	22.6%
2. Merrill Lynch (Australia) Nominees Pty Limited	57,422,064	21.8%
3. Citicorp Nominees Pty Limited	42,047,456	15.9%
4. Brookside Capital Partners Fund LP	27,832,040	10.6%
5. JP Morgan Nominees Australia Limited	16,213,973	6.2%
6. DNU Nominees Pty Limited	15,918,126	6.0%
7. Mr Timothy J Barberich	4,600,930	1.7%
8. Frederic H Moll	3,345,610	1.3%
9. Trienos Group LLC	3,000,000	1.1%
10. UBS Nominees Pty Ltd	2,368,401	0.9%
11. Mr Jon Benjamin Platt	2,000,000	0.8%
12. Warman Investments Pty Ltd	1,451,771	0.6%
13. Viking Management Services Pty Ltd <VHK Superannuation Fund A/C>	1,159,121	0.4%
14. Lightstorm Pty Ltd <Hotspice A/C>	1,082,000	0.4%
15. Mrs Danielle Susan Borgas	1,006,000	0.4%
16. HSBC Custody Nominees (Australia) Limited	964,863	0.4%
17. Mr Antony Richard Kerr + Mr Peter Michael Clerk <AR Kerr Family A/C>	900,000	0.3%
18. Mr Robert Thomas + Mrs Kyrenia Thomas <Rob Thomas Super Fund A/C>	750,000	0.3%
19. BT Portfolio Services Limited <Wade Family Super Fund A/C>	646,394	0.2%
20. National Nominees Limited	601,219	0.2%
Total CDIs held by top 20 CDI holders	242,870,451	92.1%
Total CDIs held by all other CDI holders	20,927,579	7.9%
Total CDIs outstanding	263,798,030	100%

The table at the top of the next page provides a list of the top 20 holders of our securities as of March 1, 2016, 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	—	5,765,230	5,765,230	13.6%
2. Goldman Sachs International	4,375,000	—	4,375,000	10.3%
3. Domain Partners V, L.P.	3,606,002	—	3,606,002	8.5%
4. Elliott Associates, L.P.	3,227,031	—	3,227,031	7.6%
5. Saints Capital Everest, L.P.	—	3,223,513	3,223,513	7.6%
6. Brookside Capital Partners Fund, LP	—	2,783,204	2,783,204	6.5%
7. Medtronic, Inc.	379,651	2,255,828	2,635,479	6.2%
8. DNU Nominees Pty Limited	—	1,591,813	1,591,813	3.7%
9. Group Outcome Investors I, LLC	1,341,175	—	1,341,175	3.1%
10. Citicorp Nominees Pty Limited	—	1,320,320	1,320,320	3.1%
11. Cerberus Series Four Holdings, LLC	—	1,046,486	1,046,486	2.5%
12. Cerberus International, Ltd	—	995,553	995,553	2.3%
13. Gordon E. Nye	823,531	9,600	833,131	2.0%
14. Cerberus Partners, L.P.	—	520,641	520,641	1.2%
15. Timothy J. Barberich	—	460,093	460,093	1.1%
16. C. Raymond Larkin Jr.	351,749	—	351,749	0.8%
17. Frederic H. Moll	—	334,561	334,561	0.8%
18. Robert K. Schultz	311,500	—	311,500	0.7%
19. Trienos Group LLC	—	300,000	300,000	0.7%
20. UBS Nominees Pty Ltd	—	236,840	236,840	0.6%
Total securities held by top 20 holders (stated as common stock)	14,415,639	20,843,682	35,259,321	82.9%
Total securities held by all other holders (stated as common stock)	1,740,544	5,536,121	7,276,665	17.1%

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

As of March 1, 2016, we had 6,394,925 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 37 individuals. With the exception of our Chief Executive Officer, Regina E. Groves, who holds 2,000,000 options representing 31.3 percent of the outstanding options, no other single person holds 20 percent or more of the outstanding options.

As of March 1, 2016, we had issued 250 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 March 1, 2016, we had issued 984,200 restricted stock units; each restricted stock unit entitles the holder to one share of common stock upon vesting. These restricted stock units are held by 19 individuals, with no single person holding 20 percent or more.

Restricted Stock

As of March 1, 2016, we had 42,000 shares of restricted stock on issue under our 2010 Equity Incentive Plan, held by three individuals.

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 t he 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 by-laws, or by an agreement signed with the holders of the shares at issue. Our amended and restated certificate of incorporation and by-laws 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 other exchange.

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 3 rd Edition ("ASX Recommendations") in force for the Company's financial year ended December 31, 2015 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, 2015, 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 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. Qualified candidates are recommended for Board appointment or candidacy. The backgrounds and any other relevant information of candidates who are recommended for election or re-election to the Board 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 in the Corporate Governance section on the Company's website at *www.revamedical.com* . The background of each Board member 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 March 1, 2016 are set forth below:

Ross Breckenridge, MD, MRCP, PhD , age 46, was appointed as a director in January 2015. Dr. Breckenridge is a senior clinical lecturer and Programme Director for the Masters Programme in Clinical and Experimental Medicine at University College London, a Fellow of the Royal College of Physicians (London), and a Consultant Physician at University College London Hospital. His research focuses on the heart's response to low levels of oxygen, with an overall aim to identify novel therapeutic targets for cardiac disease. Dr. Breckenridge provides consultation services to investors in the biotech and healthcare sector. He is a board member of Senrigan Capital, Empower India, and the Cornelia de Lange Society of Great Britain. 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 74, has served as a director since June 2001. 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 and 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 five.

Mr. Dovey currently sits on the board of two public companies: REVA and Orexigen Therapeutics. Prior to joining Domain, Mr. Dovey spent six years at Rorer Group, Inc. (now part of Sanofi-Aventis), a pharmaceutical and medical device company l isted 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. He also held management positions with Howmedica, Inc., Howmet Corporation, and New York Telephone Company. Mr. Dovey has served as both President and Chairman of the National Venture Capital Association. He is former Chair and currently serves on the Board of Trustee s of the Wistar Institute, a non-profit preclinical biomedical research company. Mr. Dovey serves on the board of directors and is also Chairman at the Center for Venture Education (Kauffman Fellows Program) and on the La Jolla Playhouse Board of Trustees. He was also a former board member of the industry association representing the medical device industry, as well as the association representing consumer pharmaceuticals. His is a trustee emeritus of Germantown Academy and is a former trustee of the Univer sity of Pennsylvania School of Nursing and the Burnham Institute for Medical Research. Mr. Dovey received his B.A. in mathematics from Colgate University and his MBA from the Harvard Business School. We believe Mr. Dovey is qualified to sit on our Board du e to his strong financial expertise, 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 a t a health care venture capital firm.

Scott Huennekens , age 51, was appointed as a director in March 2015. He is currently 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 boards of EndoChoice and the Medical Device Manufacturers Association ("MDMA"). He received his B.S. in Business Administration from the University of Southern California and an MBA from Harvard Business School. We believe 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, and his experience serving on multiple other boards of directors.

Anne Keating , age 62, 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, and Goodman Group Limited, a global property development and management company. Ms. Keating is Chairman of Houlihan Lokey Australia, investment bank. Ms. Keating is also a Director of the Garvan Institute of Medical Research and an Inaugural Governor for the Cerebral Palsy Foundation. 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. We believe 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 61, has served as a director since 1999. He is currently 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. We believe 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 of R2 Dermatology, ZELTIQ Aesthetics, Inc., and two former Johnson & Johnson divisions, his extensive consumer marketing background, and his other board service.

Robert B. Stockman , age 62, our co-founder, has served as Chairman of the Board and a director since 1999 ; he was our Chief Executive Officer from August 2010 to Septem b er 18, 2015. He is a director of HeartWare Limited/HeartWare International, Inc., a NASDAQ - listed medical device company (formerly also ASX-listed) , since December 2006. Mr. Stockman also serves as a board member for MuseAmi, Inc., a privately held advanced music software company that he co-founded. He previously served on the board of ZELTIQ Aesthetics, Inc., a medical technology company listed on NASDAQ, from July 2010 until April 2012. S ince 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 tec hnology 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 divest itures, "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 fo cused 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. We believe Mr. Sto ckman 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 medical device companies, and his experience as an executive in the investmen t banking industry. Mr. Stockman's qualifications also include his strong financial background, including his work early in his career at Price Waterhouse and his ability to provide financial expertise to the Board.

Robert Thomas , age 70, has served as a director since July 2010. He has also been 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), since November 2004. 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 Securities. He also is a member of the advisory board of Inteq Limited. 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. We believe 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, 2015, there were no material variations to any of the Company's employment letters.

Recommendation 1.4 — T he 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 2015 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, 2015, the Company reports that women represented 14 percent of its Board members, 50 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, 2015 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, 2015.

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. Dr. Breckenridge was appointed to the committee on July 23, 2015. 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, 2015; 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 looks 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.

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 Board as of December 31, 2015, as well as each member's independence status during 2015, was as follows:

				Committees		
Director	**Director Position**	**Year Appointed**	**Independent**	**Audit**	**Compensation**	**Nominating and Corp. Governance**
Robert B. Stockman	Chairman	1999	No (1)	–	–	–
Dr. Ross A. Breckenridge	Non-Executive	2015	Yes	–	–	X
Brian H. Dovey	Non-Executive	2001	(2)	X	X	–
R. Scott Huennekens	Non-Executive	2015	Yes	Chair	–	–
Anne J. Keating	Non-Executive	2010	Yes	–	–	Chair
Gordon E. Nye	Non-Executive	1999	Yes (3)	–	Chair	X
Robert B. Thomas	Non-Executive	2010	Yes	X	X	–

(1) Mr. Stockman's employment as our Chief Executive Officer terminated 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.

(2) Independent Director under the rules of NASDAQ and the SEC, but not considered independent under the ASX.

(3) Our Board approved a one-time cash payment to Gordon Nye in January 2015 in the amount of $87,500 as compensation for consulting services provided to the Company during the period August 2014 through January 2015. Although the compensation Mr. Nye received was in excess of his director fees for 2014, the Board does not believe the compensation was material in amount or created a material relationship with the Company, and as such, the Board continues to believe that Mr. Nye qualifies as an independent director.

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, 2015. Effective January 28, 2015, Dr. Breckenridge, an independent member, was appointed to the Board to fill a vacant seat. Additionally, on March 25, 2015, the Board expanded the number of director seats to seven and appointed Mr. Huennekens, an independent member. For the period from January 1, 2015 through September 18, 2015, Mr. Stockman was our Chairman and our Chief Executive Officer and he is not considered independent. Additionally, 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. 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

As previously disclosed, our Chairman served as our Chief Executive Officer during the period from January 1, 2015 to September 18, 2015, and, as a result, will not be considered independent for ASX purposes until three years following his termination as an executive. The Board appointed a new Chief Executive Officer effective September 23, 2015, who is not a Board member. We believe that Mr. Stockman is not able to exert undue influence on the decision-making process of governance functions of the Board, although he is not independent. The Company has separated the Chairman and Chief Executive Officer roles and ensures that the day-to-day operations are addressed by management, excluding Mr. Stockman, while the oversight and governance functions of the Company are addressed by the Board, including Mr. Stockman.

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.

During the year ended December 31, 2015, members of the Audit Committee were Mr. Thomas (Chair until May 12, 2015), Mr. Huennekens (appointed to committee on April 29, 2015; appointed Chair on May 12, 2015), Mr. Dovey, and Ms. Keating (member until April 29, 2015). All committee members are non-executive directors and a majority are independent. Mr. Thomas, Mr. Huennekens, and Ms. Keating are all 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 six meetings during 2015; with the exception of one member at one meeting only, all committee members attended all 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. Brian Dovey 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, 2015, there were no exceptions contained in the certifications.

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, 2015 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. 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 in the Corporate Governance section on its website at *www.revamedical.com* . 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 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 security holders. 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, 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 four formal and numerous informal meetings during 2015, of which 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 non-executive and executive directors, as well as senior executives, are defined and disclosed. The Company has adopted a non-executive director compensation policy pursuant to which non-executive directors are compensated for their services to the Board. Non-executive director compensation comprises a base salary as well as 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 and 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 2015 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. This policy operates to help limit the economic risk to REVA's securities.

Item 11. Executi ve Compensation

The information required by this item is incorporated by reference to our 2016 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 2016 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, 2015 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 upon Exercise or Vesting of Outstanding Awards	Weighted Average Exercise Price of Outstanding Options	Number of Shares Remaining Available for Future Issuance (1)
Equity compensation plans approved by stockholders (2)	6,948,625	$ 6.46	7,885,945

(1) Our 2010 Equity Incentive Plan, as amended, contains a provision for an automatic increase each January 1 st 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 1 st 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 5,912,425 outstanding options to purchase common stock, 52,000 shares of restricted stock subject to future vesting, and 984,200 restricted stock units that each entitle 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 2016 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 2016 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:

   Reports of Independent Registered Public Accounting Firm (current and predecessor)

   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.

SIGNAT URES

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: March 10, 2016

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)	March 10, 2016
/s/ Katrina L. Thompson Katrina L. Thompson	Chief Financial Officer (principal financial and accounting officer)	March 10, 2016
/s/ Robert B. Stockman Robert B. Stockman	Chairman of the Board	March 10, 2016
/s/ Ross A. Breckenridge Dr. Ross A. Breckenridge	Director	March 10, 2016
/s/ Brian H. Dovey Brian H. Dovey	Director	March 10, 2016
/s/ R. Scott Huennekens R. Scott Huennekens	Director	March 10, 2016
/s/ Anne J. Keating Anne J. Keating	Director	March 10, 2016
/s/ Gordon E. Nye Gordon E. Nye	Director	March 10, 2016
/s/ Robert B. Thomas Robert B. Thomas	Director	March 10, 2016

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REPORT OF INDEPENDENT REGIST ERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
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 2014, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2015. 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 2014, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America.

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, 2015, 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 March 10, 2016 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ GRANT THORNTON LLP

San Diego, California
March 10, 2016

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
REVA Medical, Inc.

We have audited the consolidated statements of operations and comprehensive loss, cash flows, and stockholders' equity (deficit) of REVA Medical, Inc. (the Company) for the year ended December 31, 2013. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with 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 audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated results of its operations and its cash flows for the year ended December 31, 2013, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company has recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

San Diego, California
March 17, 2014

REVA Medic al, Inc.
Consolidated Ba lance Sheets
(in thousands, except share and per share amounts)

Assets	December 31, 2014	December 31, 2015
Current Assets:		
Cash and cash equivalents	$ 25,814	$ 16,895
Short-term investments	995	—
Prepaid expenses and other current assets	406	397
Total current assets	27,215	17,292
Non-Current Assets:		
Property and equipment, net	2,920	2,719
Other non-current assets	60	60
Total non-current assets	2,980	2,779
Total Assets	$ 30,195	$ 20,071
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable	$ 651	$ 1,054
Accrued expenses and other current liabilities	2,213	2,242
Total current liabilities	2,864	3,296
Long-Term Liabilities:		
Convertible notes payable	37,780	75,365
Common stock warrant liability	15,389	19,622
Other long-term liabilities	611	2,352
Total long-term liabilities	53,780	97,339
Total Liabilities	56,644	100,635
Commitments and contingencies (Note 9)		
Stockholders' Deficit:		
Common stock — $0.0001 par value; 100,000,000 shares authorized; 33,529,778 and 38,155,986 shares issued and outstanding at December 31, 2014 and December 31, 2015, respectively	3	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	226,094	254,572
Accumulated deficit	(252,546)	(335,140)
Total Stockholders' Deficit	(26,449)	(80,564)
Total Liabilities and Stockholders' Deficit	$ 30,195	$ 20,071

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,		
	2013	**2014**	**2015**
Operating Expense:			
Research and development	$ 19,212	$ 14,318	$ 16,760
General and administrative	8,731	7,645	7,210
Loss from operations	(27,943)	(21,963)	(23,970)
Other Income (Expense):			
Interest income	30	8	9
Interest expense	—	(986)	(1,904)
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)
Other income (expense)	(9)	73	59
Other income (expense)	21	(29,074)	(58,624)
Net Loss and Comprehensive Loss	$ (27,922)	$ (51,037)	$ (82,594)
Net Loss Per Common Share:			
Net loss per share, basic and diluted	$ (0.84)	$ (1.53)	$ (2.38)
Shares used to compute net loss per share, basic and diluted	33,124,655	33,382,381	34,680,634

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,		
	2013	**2014**	**2015**
Cash Flows from Operating Activities:			
Net loss	$ (27,922)	$ (51,037)	$ (82,594)
Non-cash adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	892	1,027	1,096
Loss on property and equipment disposal	1	—	—
Stock-based compensation	4,090	3,516	3,434
Interest on convertible notes payable	—	986	1,904
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
Other non-cash expenses	18	19	46
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	2	9	9
Accounts payable	549	(566)	365
Accrued expenses and other current liabilities	525	64	33
Other long-term liabilities	(98)	(117)	(163)
Net cash used for operating activities	(21,943)	(17,930)	(19,082)
Cash Flows from Investing Activities:			
Purchases of property and equipment	(1,466)	(541)	(857)
Purchases of investments	(1,492)	(995)	—
Maturities of investments	5,223	1,492	995
Net cash provided by (used for) investing activities	2,265	(44)	138
Cash Flows from Financing Activities:			
Proceeds from issuances of common stock	31	247	10,075
Proceeds from (costs of) issuance of convertible notes payable and warrants, net	—	24,312	(50)
Net cash provided by financing activities	31	24,559	10,025
Net increase (decrease) in cash and cash equivalents	(19,647)	6,585	(8,919)
Cash and cash equivalents at beginning of period	38,876	19,229	25,814
Cash and Cash Equivalents at End of Period	$ 19,229	$ 25,814	$ 16,895
Supplemental Non-Cash Information:			
Property and equipment in accounts payable	$ 195	$ 12	$ 50
Warrant liability transferred to equity upon exercise	$ —	$ —	$ 14,970

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		Additional	Accumulated	Total Stockholders'
	Shares	Amount	Paid-In Capital	Deficit	Equity (Deficit)
Balance at December 31, 2012	33,132,203	$ 3	$ 218,210	$ (173,587)	$ 44,626
Net loss and comprehensive loss	—	—	—	(27,922)	(27,922)
Common stock issued May and November upon exercise of stock options for cash at $0.61 per share	50,350	—	31	—	31
Restricted common stock issued January and May under equity incentive plan	87,500	—	—	—	—
Stock-based compensation expense	—	—	4,090	—	4,090
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 upon exercise of warrants	—	—	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)

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

1. Description o f 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; our product(s) will become available following completion of required clinical studies with acceptable data and when, and if, we receive regulatory approval. We are currently developing and testing a drug-eluting bioresorbable stent to treat vascular disease in humans. This stent, which we have named *Fantom* ®, was introduced in humans during December 2014 and has been implanted subsequently in over 230 patients in eight countries outside the United States. We intend to use the data from 100 of these patients at a six-month time point, if the data has acceptable safety and efficacy results, to apply for a European CE Marking by approximately the third quarter of 2016. The CE Mark is the regulatory approval that would allow us to commercialize *Fantom* in Europe.

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 registrant. 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."

2. Capital Resources and Basis of Presentation

Capital Resources **:** We had cash of $16,895,000 at December 31, 2015, which reflects the receipt of $9,506,000 cash proceeds from warrant exercises in October 2015 and the remaining funds from the issuance of $25,000,000 in convertible notes in November 2014. We additionally received $11,407,000 cash proceeds from warrant exercises on February 12, 2016. We believe the cash balance at December 31, 2015, combined with the proceeds received in February 2016, is sufficient to meet our operating and capital needs through the first quarter of 2017. The holders of the convertible notes have a one-time option in January 2017 to redeem the notes for face value plus accrued interest. Based on the Company's cash balances, if the noteholders were to collectively exercise this option, which management believes they will not do, the Company would be unable to make the redemption payment of approximately $29,282,000. On February 11, 2016, the Company and the noteholders entered into an agreement to extend the optional redemption date to June 30, 2017, subject to stockholder approval. A special meeting of stockholders is scheduled for March 22, 2016 to approve the agreement; we believe it is probable that our stockholders will approve the agreement.

We have experienced recurring losses and negative cash flows from operating activities since our inception and, as of December 31, 2015, we had an accumulated deficit of $335,140,000. 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 that profitability or positive cash flows on a recurring basis.

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, 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.

Basis of Presentation **:** We have prepared the accompanying consolidated financial statements in accordance with U.S. generally accepted accounting principles ("GAAP") and the rules and regulations of the SEC. 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 warrant liability, our expense accruals, including clinical study expenses, and our stock-based compensation expense. 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. Our 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 have categorized the investments as "held-to-maturity" based on our intent and ability to hold to maturity. Our 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, 2013, 2014, and 2015 we determined there were no indications of asset impairment.

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, 2015 exceeded the balance insured by the FDIC by $16,645,000. 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 and record a gain (upon a decrease in fair value) or loss (upon an increase in fair value) for the 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 for the December 31, 2015 valuation 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. 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. 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 the notes. 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. Management believes the fair value method of accounting provides a more appropriate presentation of these liabilities than would be provided under the cost method.

3. Significant Acc ounting Policies (continued)

Common Stock Warrants **:** We record the fair value of warrants issued for the purchase of common stock as a liability since the warrants call for issuance of registered shares upon exercise, a condition that we may not be able to accommodate and which would then result in a net settlement of the warrants. Until the time the warrants are exercised or expire, the fair value is assessed at each reporting date. Through September 30, 2015, the values were determined utilizing a binomial valuation model since two exercise prices were possible; we moved to a Black-Scholes valuation model to determine the value at December 31, 2015 because Company conditions had been met that resulted in a fixed exercise price per share of $2.6073. This change in models did not have a material effect on the fair value of the warrants. 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 model are of the same nature as those used for our convertible notes payable.

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.

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, 2015.

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, 2015.

We are subject to taxation in U.S. and California jurisdictions. As of December 31, 2015, we are no longer subject to U.S. federal or state examinations for years before 2011 and 2010, 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.

3. Significant Accounting Policies (continued)

Stock-Based Compensation **:** We recognize stock-based compensation expense in connection with stock option grants, restricted stock awards, and restricted stock unit ("RSU") awards to employees, directors, and consultants.

For options granted to employees and directors, we determine the 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 to a recipient based on achievement of performance milestones, we only record compensation expense for the performance milestones that are probable of being achieved, with such expense recorded on a straight-line basis over the expected vesting period. During the year ended December 31, 2015, we determined that two of the three performance targets for our performance-based awards were probable of being achieved and, therefore, recorded expense for those awards only. 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.

For options granted to consultants, we estimate fair values at the date of grant and at each subsequent reporting period and record compensation expense based on the fair value during the service period of the consultant. 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.

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

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

	Year Ended December 31,		
	2013	2014	2015
Weighted Average Shares Excluded:			
Options to purchase common stock	3,901,316	4,355,536	4,812,372
Unvested restricted stock	96,347	91,750	61,623
Restricted stock units	—	—	768,908
Warrants to purchase common stock	—	1,150,685	7,647,260
Common share equivalents of convertible notes	—	1,513,138	11,506,156
	3,997,663	7,111,109	24,796,319

3. Significant Accounting Policies (continued)

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 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. 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 following table.

Utilizing the lowest level inputs available under the measurement hierarchy, the fair values of our measured financial instruments comprise the following (we had no Level 1 financial instruments):

	Level 2	Level 3
	(in thousands)	
Fair Value at December 31, 2014:		
Assets:		
Certificates of deposit due in one year or less	$ 991	$ —
Liabilities:		
Convertible notes payable	—	37,780
Common stock warrant liability	—	15,389
	$ —	$ 53,169
Fair Value at December 31, 2015:		
Liabilities:		
Convertible notes payable	—	75,365
Common stock warrant liability	—	19,622
	$ —	$ 94,987

Our Level 2 financial assets consist of certificates of deposit ("CDs") that are held to maturity and carried at cost; their fair value is determined each reporting period through quoted market prices of similar instruments in active markets. We had $4,000 in unrealized losses on our CDs as of December 31, 2014. We held no CDs as of December 31, 2015.

3. Significant Accounting Policies (continued)

Fair Value Measurements (continued) **:** Our Level 3 financial liabilities, which are recurring, consist of convertible notes payable (the "Notes") and warrants for the purchase of common stock, all of which were issued on November 14, 2014. The fair values of these liabilities as of their issuance date and subsequent measurement dates through September 30, 2015 were determined utilizing a binomial model. Valuation of the Notes at December 31, 2015 was determined utilizing a least squares Monte Carlo simulation model and valuation of the warrants at December 31, 2015 was determined utilizing a Black-Scholes valuation model. This change in models did not have a material effect on the fair values of the securities. All of 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,	
	2014	2015
Weighted Average Assumptions:		
Market price per share of common stock	$3.03	$5.14
Risk-free interest rate	2.6%	1.7%
Expected volatility of common stock	87.7%	81.7%
Expected life (in years)	4.94	4.21
Bond yield of equivalent securities	29.2%	29.0%

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.

A total of $56,788,000 in unrealized losses arising from the change in fair value of our Level 3 financial liabilities was recorded during the year ended December 31, 2015. 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
Warrants to purchase common stock	10,938
Balance at November 14, 2014	40,627
Losses from Change in Fair Value:	
Convertible notes payable	8,091
Warrants to purchase common stock	4,451
Balance at December 31, 2014	53,169
Transfer to additional paid-in capital upon exercise of warrants	(14,970)
Losses from Change in Fair Value:	
Convertible notes payable	37,585
Warrants to purchase common stock	19,203
Balance at December 31, 2015	$ 94,987

3. Significant Accounting Policies (continued)

Recent Accounting Pronouncements **:** In April 2014, ASU 2014-08, *Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity* , was issued. ASU 2014-08 raises the threshold for a disposal to qualify as a discontinued operation and requires new disclosures for certain other disposals that do not meet the definition of a discontinued operation. We adopted this ASU January 1, 2015; its adoption did not have an effect on our financial position or results of operations.

In August 2014, ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* , was issued. ASU 2014-15 requires management to assess an entity's ability to continue as a going concern and to provide related footnote disclosure in certain circumstances. This ASU is effective for annual and interim periods ending after December 15, 2016. We are currently evaluating the provisions of ASU 2014-15 and assessing the impact, if any, it may have on our financial disclosures.

4. Convertible Notes Payable and Warrants to Purchase Common Stock

On November 14, 2014, we issued 250 convertible notes payable (the "Notes"), each with a face value of $100,000, for total cash proceeds of $25,000,000. The Notes are convertible into 11,506,155 shares of common stock, which is a conversion rate of $2.17275 per share. The Notes are convertible at any time at the holders' election, except the Notes will automatically convert in the case where the Company has received a CE Mark approval for its *Fantom* product and has sustained a market trading price of A$0.60 per CDI for 20 consecutive trading days. 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. Interest expense of $986,000 and $1,904,000 was recorded in the consolidated statement of operations for the years ended December 31, 2014 and 2015, respectively. The Notes provide the holders a one-time option for cash redemption in January 2017, if not previously converted or redeemed, for the face value plus accrued interest. See Note 12 regarding the proposal to extend this date to June 30, 2017.

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, 2014 and 2015 was calculated to be $37,780,000 and $75,365,000, respectively, which was $12,780,000 and $50,365,000, respectively, more than the unpaid principal balance of the Notes. The change in fair value of the Notes between November 14, 2014 and December 31, 2014 and for the year ended December 31, 2015 of $8,091,000 and $37,585,000, respectively, was recorded as a loss in the consolidated statement of operations. As of December 31, 2014 and 2015, the fair value of the 11,506,155 shares into which the Notes are convertible was calculated to be $38,200,000 and $72,293,000, respectively.

In connection with issuing the Notes, we issued warrants to the noteholders to purchase up to 8,750,000 shares of common stock at $2.17275 per share. The warrants are exercisable immediately and expire in November 2019. A total of 4,375,000 warrants were exercised October 1, 2015 with $9,506,000 cash proceeds to the Company. The exercise price of the warrants increased to $2.6073 in October 2015 when we achieved full enrollment in our *Fantom* clinical trial with the number of patients that will provide data for our CE Mark application. The fair value of the warrants on the date of issue 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, 2014 and 2015 was calculated to be $15,389,000 and $19,622,000, respectively; the change in fair value of the warrant liability between November 14, 2014 and December 31, 2014 and for the year ended December 31, 2015 of $4,451,000 and $19,203,000, respectively, was recorded as a loss in the consolidated statement of operations.

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,	
	2014	2015
	(in thousands)	
Property and Equipment:		
Furniture, office equipment, and software	$ 648	$ 650
Laboratory equipment	5,187	5,952
Leasehold improvements	2,361	2,386
	8,196	8,988
Accumulated depreciation and amortization	(5,276)	(6,269)
	$ 2,920	$ 2,719
Accrued Expenses and Other Current Liabilities:		
Accrued salaries and other employee costs	$ 1,315	$ 1,311
Accrued operating expenses	769	745
Accrued use taxes and other	129	186
	$ 2,213	$ 2,242

6. Income Taxes

We have reported net losses for all periods through December 31, 2015; 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,		
	2013	2014	2015
		(in thousands)	
Provision for Income Taxes:			
Federal income taxes at 34%	$ (9,493)	$ (17,352)	$ (28,082)
State income taxes, net of federal benefit	(1,553)	(1,243)	(1,513)
Research and development tax credits	(1,425)	(660)	(650)
Changes in fair value of convertible notes payable and common stock warrant liability	—	9,577	19,308
Accrued interest on convertible notes payable	—	152	944
Stock-based compensation expense	191	358	287
Increase in valuation allowance	11,622	8,716	8,789
Expiration of state net operating losses	677	450	692
Other	(19)	2	225
	$ —	$ —	$ —

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,	
	2014	2015
	(in thousands)	
Net Deferred Tax Assets:		
Net operating loss carryforwards	$ 62,738	$ 71,057
Research and development credits	6,891	7,541
Amortization	5,737	5,020
Stock-based compensation expense	5,085	5,654
Depreciation	366	398
Accrued operating expenses	64	66
Other	459	395
	81,340	90,131
Valuation Allowance	(81,340)	(90,131)
	$ —	$ —

As of December 31, 2015 we had aggregate federal and California state net operating loss carryforwards of approximately $188,399,000 and $142,660,000, 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 2016, with $10,990,000 expiring in 2016.

As of December 31, 2015, we also had federal and California state research tax credit carryforwards of approximately $6,367,000 and $5,586,000, respectively. The federal carryforwards begin to expire in 2020 and the California carryforwards have no expiration.

A total of $267,000 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, 2015 has been performed and it was determined that, although ownership changes had 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 further limitations and may impact the realizability of these loss and credit carryforwards in future periods.

As of December 31, 2015, we had deferred tax assets of $90,131,000 primarily comprising net operating loss and research tax credit carryforwards. We have established a valuation allowance against our 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, 2014 and 2015 was $8,717,000 and $8,791,000, 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, 2015, the unrecognized tax benefits recorded were approximately $4,298,000. 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 2014 and 2015, excluding interest and penalties, is as follows:

	December 31,	
	2014	2015
	(in thousands)	
Gross Unrecognized Tax Benefits:		
Balance at beginning of year	$ 2,490	$ 2,734
Additions (reductions) for prior year tax positions	(15)	138
Additions for current year tax positions	259	1,426
	$ 2,734	$ 4,298

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 and restricted stock for no consideration payable by the recipient. 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, 2015, an additional 1,005,893 shares were added, resulting in a total of 7,885,945 shares reserved under the Plan as of December 31, 2015.

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, 2012	3,550,000	$7.30		
Granted	589,500	$5.36		
Cancelled	(42,500)	$2.00		
Exercised	(50,350)	$0.61		
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
Exercisable at December 31, 2015	3,796,425	$7.55	5.45	$4,341,000
Vested at December 31, 2015	3,320,194	$7.98	5.33	$3,574,000
Vested and Expected to Vest at December 31, 2015	5,857,193	$6.34	7.04	$7,782,000

7. Stock-Based Compensation (continue d)

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 the options granted under the Plan may not exceed ten years. Vesting periods of stock awards and option grants are determined by the Company's board of directors and are generally four-year periods. All options granted prior to 2015 are immediately exercisable upon grant and are subject to repurchase by us at the exercise price in the event an optionee terminates service prior to being fully vested. Options granted in 2015 are exercisable upon vesting.

The majority of options granted by the Company vest over four years, with 25 percent vesting on the one-year anniversary of the vesting commencement date and 75 percent vesting in equal monthly installments thereafter. During March 2015, we granted a total of 316,000 options that vest based on certain performance milestones of the Company; through December 31, 2015 none of these options had vested or been cancelled. We estimated the vesting term for each performance objective on the date of grant, and on each reporting date thereafter, based on our internal timelines and operating projections. Our estimates of vesting ranged from approximately nine to 30 months, with a weighted average vesting term of 18.3 months as of December 31, 2015.

The unvested portion of outstanding options as of December 31, 2015 has vesting dates scheduled through 2019. Following is the vesting activity under the Plan for the year ended December 31, 2015:

	Options Outstanding	Weighted Average Grant Date Fair Value
Unvested Options at December 31, 2014	1,078,679	$2.64
Granted	2,152,500	$2.40
Vested	(531,656)	$2.79
Forfeited	(107,292)	$1.90
Unvested Options at December 31, 2015	2,592,231	$2.44

We awarded 87,500 shares of restricted stock during the year ended December 31, 2013, all of which vest at the rate of 25 percent annually on each award anniversary date. No restricted stock was awarded during the years ended December 31, 2014 and 2015.

During March 2015, we awarded 824,200 RSUs to employees. These RSUs vest based on certain performance milestones of the Company; we estimated the vesting term, which ranges from approximately 21 months to 30 months with a weighted average vesting term of 23 months, on the date of award based on our internal timelines and operating projections. During May 2015, we awarded 160,000 RSUs to employee and non-employee directors; such RSUs vest on the earlier of May 26, 2016 or one day prior to our 2016 annual stockholder meeting. Each RSU entitles the recipient to one share of our common stock upon vesting. Through December 31, 2015, none of the RSUs had vested and none had been cancelled.

No tax benefits arising from stock-based compensation have been recognized in the consolidated statements of operations through December 31, 2015.

7. Stock-Based Compensation (continue d)

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 vesting period on a straight-line basis. For the options and RSUs that vest upon performance milestones, we estimate the probability that the performance milestones will be met and record the related stock-based compensation expense. During the year ended December 31, 2015, we determined that two of the three performance targets for our performance-based awards were probable of being achieved and, therefore, recorded expense for those awards only. Stock-based compensation arising from employee options and awards under the Plan is as follows:

	Year Ended December 31,		
	2013	2014	2015
	(in thousands)		
Employee Stock-Based Compensation:			
Research and development expense	$ 1,069	$ 1,142	$ 1,502
General and administrative expense	2,965	2,284	1,905
	$ 4,034	$ 3,426	$ 3,407

As of December 31, 2015, we had approximately $7,910,000 of total unrecognized compensation costs related to unvested employee options that are expected to be recognized over a weighted average period of 1.93 years.

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,		
	2013	2014	2015
Risk-free interest rate	1.4%	2.2%	1.8%
Expected volatility of common stock	60.1%	59.3%	55.6%
Expected life in years	6.25	6.14	6.16
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 used peer group data due to the fact that we have limited historical trading data. For options that vest based on passage of time, the expected option life was calculated using the simplified method under the accounting standard for stock compensation and a ten-year option expiration; we use the simplified method because we do not yet have adequate history as a public company to establish a reasonable expected life. For options that vest based on performance 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.

A summary of grant date fair value and intrinsic value for options granted to employees is as follows:

	Year Ended December 31,		
	2013	2014	2015
	(in thousands, except per share data)		
Weighted-average grant date fair value per share	$2.95	$1.98	$2.40
Intrinsic value of options exercised	$231	$553	$511
Total fair value of options vested during the year	$3,809	$3,546	$1,429

7. Stock-Based Compensation (continued)

Stock Options to Consultants **:** We account for stock options granted to consultants at their fair value. Under this method, the fair value is estimated at each reporting date during the vesting period using the Black-Scholes option 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.

No options were issued to consultants during 2015 and all stock options granted to consultants had either vested or been cancelled as of March 31, 2015. Options to purchase 100,000 and 110,000 shares of common stock were granted to consultants during the years ended December 31, 2013 and 2014, respectively. The fair value of these awards was determined with 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 year ended Decembers 31, 2013, 2014, and 2015 was $40,000, $116,000, and $27,000, respectively.

The assumed risk-free interest rate was based on the implied yield on a U.S. Treasury zero-coupon issue with a remaining term equal to the expected life of the option. The assumed volatility was calculated from the historical market prices of a selected group of publicly traded companies considered to be our peers; we use peer group data due to the fact that we have limited historical trading data. The expected option life is the remaining term of the option. The expected dividend yield of zero reflects that we have not paid cash dividends since inception and do not intend to pay cash dividends in the foreseeable future.

There were no unvested consultant options outstanding as of December 31, 2015. The weighted average fair value of unvested consultant options at December 31, 2013 and 2014 was estimated to be $2.84 and $1.92 per share, respectively, based on the following assumptions:

	Year Ended December 31,	
	2013	2014
Risk-free interest rate	3.0%	2.2%
Expected volatility of common stock	59.4%	57.2%
Expected life in years	9.45	8.94
Dividend yield	0.0%	0.0%

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

	Year Ended December 31,		
	2013	2014	2015
	(in thousands)		
Consultant Stock-Based Compensation:			
Research and development expense	$ 9	$ 69	$ —
General and administrative expense	47	21	27
	$ 56	$ 90	$ 27

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 $52,000, $46,000, and $42,000 for the years ended December 31, 2013, 2014, and 2015, 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 $25 per unit to a maximum of approximately $100 per unit sold, with license provisions for escalating minimum royalties that could be as high as $2,200,000 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, and payment of patent filing, maintenance, and defense fees. The license terms remain in effect until the last patent expires.

In connection with our development activities, we periodically enter into contracts with consultants and vendors. These contracts are generally cancelable with 30 days' written notice. As of December 31, 2015, the minimum future payments on these contracts totaled approximately $86,000.

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, 2015, our deferred rent totaled $363,000, of which $163,000 was classified as a current liability. We recorded rent expense of $666,000, $683,000, and $794,000 for the years ended December 31, 2013, 2014, and 2015, respectively.

Future minimum payments under the lease are as follows:

	Minimum Payment (in thousands)
Minimum Lease Payments:	
Year ending December 31, 2016	$ 690
Year ending December 31, 2017	711
Year ending December 31, 2018	60
	$ 1,461

10. Related Parties

Our related parties include the members of our board of directors and investors with five percent or more of our outstanding securities. We had no related party transactions during the year ended December 31, 2013. During the years ended December 31, 2014 and 2015, we recorded expense of $73,000 and $15,000, respectively, as compensation to a board member for board services provided to the Company in excess of his normal director responsibilities. As of December 31, 2014, the $73,000 was reflected as an accrued expense; we paid the total amount of $88,000 to the director during the first quarter of 2015.

11. Selected Quarterly F inancial 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 2014:					
Loss from operations	$ (7,272)	$ (4,832)	$ (4,446)	$ (5,413)	$ (21,963)
Loss on issuance of convertible notes and warrants	—	—	—	(15,627)	(15,627)
Loss on change in fair values	—	—	—	(12,542)	(12,542)
Net loss	(7,276)	(4,833)	(4,397)	(34,531)	(51,037)
Net loss per common share, basic and diluted	$ (0.22)	$ (0.14)	$ (0.13)	$ (1.03)	$ (1.53)
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)

12. Subsequent Event

On February 12, 2016, the Company received cash proceeds of $11,407,000 and issued 4,375,000 shares of common stock from the exercise of warrants. Following the exercise, a total of 42,530,986 shares of common stock were outstanding and no warrants remained outstanding.

On February 11, 2016, the Company and the holders of the Notes entered into an amendment to the Convertible Note Deed dated September 25, 2014 (the “Note Deed”), which is the governing document of the Notes. The amendment provides for two modifications of the Note Deed. The first modification extends the date of an optional redemption right of the noteholders to June 30, 2017; the current optional redemption date is January 14, 2017. The second modification adds a third condition, being that the Company list its common stock on the NASDAQ stock exchange (or another exchange approved by the noteholders), for the Notes to automatically convert into common stock. The current conditions to an automatic conversion of the Notes are 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. The amendment to the Note Deed is subject to stockholder approval. The Company has scheduled a special meeting of Stockholders on March 22, 2016 to approve the amendment.

INDEX TO EXHIBITS

Exhibit Number	Description of Exhibits	Filed with this Form 10-K	Incorporated by Reference		
			Form	File No.	Date I
3.1	Amended and Restated Certificate of Incorporation		S-1/A	333-168852	10/22/
3.2	Amended and Restated Bylaws		S-1/A	333-168852	10/22/
3.3	Amendment No. 1 to the Amended and Restated Bylaws		8-K	000-54192	9/12/2
4.1	Form of Stock Certificate		S-1/A	333-168852	11/12/
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/
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	8/13/2
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	8/13/2
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	8/13/2
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	8/13/2
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	8/13/2
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/
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/
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	3/17/2
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	11/9/2
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	11/6/2
10.11	Royalty and License Agreement between Integra/LifeSciences Corporation and REVA Medical, Inc. dated February 2, 2004**		S-1/A	333-168852	9/21/2
10.12	2001 Stock Option/Stock Issuance Plan*		S-1	333-168852	8/13/2
10.13	Form of Stock Option Agreement*		S-1	333-168852	8/13/2
10.14	Form of Addendum to Stock Option Agreement*		S-1	333-168852	8/13/2
10.15	2010 Equity Incentive Plan*		S-1/A	333-168852	10/22/
10.16	Form of Stock Option Agreement*		S-1/A	333-168852	11/12/
10.17	Form of Stock Option Agreement entered into with Robert Thomas and Anne Keating*		S-1/A	333-168852	11/12/
10.18	Form of Director and Officer Indemnification Agreement*		S-1	333-168852	8/13/2

INDEX TO EXHIBITS

Exhibit Number	Description of Exhibits	Filed with this Form 10-K	Incorporated by Reference		
			Form	File No.	Date I
10.19	Director Compensation policy		10-K	000-54192	3/17/2
10.20	Employment Agreement, dated July 1, 2010, by and between REVA Medical, Inc. and Robert B. Stockman*		S-1/A	333-168852	10/22/
10.21	Employment Agreement, dated October 21, 2010, by and between REVA Medical, Inc. and Robert Schultz*		S-1/A	333-168852	11/12/
10.22	Employment Agreement, dated October 21, 2010, by and between REVA Medical, Inc. and Katrina Thompson*		S-1/A	333-168852	11/12/
10.23	Employment Agreement, dated February 22, 2011, by and between REVA Medical, Inc. and Jeffrey Anderson*		10-K	000-54192	3/17/2
10.24	Employment Agreement, dated September 21, 2015, by and between REVA Medical, Inc. and Regina E. Groves*		8-K	000-54192	8/21/2
10.25	Employment Agreement, dated January 18, 2016 by and between REVA Medical, Inc. and Richard M. Kimes*	X			
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/
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	3/9/2
21.1	List of Subsidiaries		S-1	333-168852	8/13/2
23.1	Consent of Grant Thornton LLP, Independent Registered Public Accounting Firm	X			
23.2	Consent of Ernst & Young 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/
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 10.25

January 4, 2016

Richard Kimes
2400 5 th Avenue, Unit 436
San Diego, CA 92101

Dear Rick,

I am delighted to confirm the offer of employment that we made and you verbally accepted. REVA Medical has offered and you have accepted the position of Sr. VP, Operations. In this position you will be a valuable member of the REVA team and will report directly to Reggie Groves.

Starting Date: Your employment will begin Monday, January 18, 2016. Please plan to arrive at 8:00 a.m. on that day. **Please be prepared to present documentation that can verify your eligibility to work in the United States on your first day of employment.** If you have questions about which documents are acceptable, please feel free to call me at (858) 966-3045.

Salary: Your bi-weekly salary will be $9,615.38, exempt classification, which equates to an annual salary of $250,000.

Bonus Program: To provide incentive and reward for excellent performance, REVA is working with its Compensation Committee of its Board of Directors to establish a Bonus Program for senior executives. The Bonus Program will likely be based on a combination of individual and Company-wide objectives, with measurement against the objectives to occur at or near December 31 year end and payment of bonuses, if any, to occur by March 15 th of the following. Your proposed target bonus in this program, if approved by the Compensation Committee, would be 35% on an annual basis.

Stock Options: In order for you to share in the success of the Company, and to incentivize you to help achieve that success, you will be granted an option to purchase 100,000 shares of REVA Medical common stock. Additionally, you will be eligible for future stock option grants based on performance. This option is subject to approval by the Board of Directors at a meeting held following your employment, at which time the exercise price and vesting periods will be determined.

In your position of Sr. VP, Operations, you will be a Section 16 officer (as defined by the SEC) and an "insider" with respect to REVA. You will be provided a copy of the Company's Insider Trading Policy; any securities transactions entered into by you (or controlled by you, or from your advice, or resulting from, etc.) will be bound by the policy.

Benefits: REVA provides medical, dental, life, ADD, and short- and long-term disability insurance, all with premier carriers and at minimal cost to employees. Additionally, the Company offers a 401(k) Plan with a fully vested matching feature. You will receive 120 hours of Personal Time Off per year, which accrues ratably throughout the year based on hours worked. Your effective date for group benefits will be February 1, 2016.

You will have an opportunity to ask questions before enrolling in any of the Company's benefit plans. General information regarding insurance benefits is available from Human Resources and may change from time to time.

Confidentiality Agreement and Confidential Information Belonging to Others: The success of REVA Medical is partly due to its competitive edge. To maintain that edge, we require employees to sign an Employee Proprietary Information and Inventions Agreement. REVA Medical believes that its employees are talented individuals who are hired based upon their qualifications and experience. Therefore, we do not permit employees to possess or to disseminate any confidential or proprietary information belonging to their former employers while on REVA Medical property.

Other Terms and Conditions: We at REVA Medical believe that the relationship between the Company and its employees can only be fruitful if both parties agree that it is desirable to continue the relationship. For this reason, your employment will be considered employment at-will. This means that employment is for no fixed term and that either party has the freedom to terminate the relationship at any time, for any reason.

This letter and the Employee Proprietary Information and Inventions Agreement contain the complete understanding we have about the terms of your employment. No other writing or understanding exists that contains different terms.

This agreement can be modified only in writing signed by the current President of this company or his successor(s).

Please sign one copy of this letter and return it to the Company indicating your acceptance and agreement. The other copy is for your records.

Sincerely,

/s/ *Cheryl Liberatore*

Cheryl Liberatore
Director, Communications

ACCEPTED AND AGREED TO:

/s/ *Richard Kimes* January 18, 2016
Richard Kimes, Signature Date

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our reports dated March 10, 2016, 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, 2015. 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 and 333-203103).

/s/ GRANT THORNTON LLP

San Diego, California
March 10, 2016

Exhibit 23.2

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements (Form S-8 Nos. 333-173371, 333-179845, 333-186966, 333-194619, and 333-203103) pertaining to the 2010 Equity Incentive Plan and 2001 Stock Option/Stock Issuance Plan of REVA Medical, Inc. of our report dated March 17, 2014, with respect to the consolidated financial statements of REVA Medical, Inc., for the year ended December 31, 2013, included in this Annual Report (Form 10-K) for the year ended December 31, 2015.

/s/ Ernst & Young LLP

San Diego, California
March 10, 2016

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: March 10, 2016

/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: March 10, 2016

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

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of REVA Medical, Inc. (the "Company") for the year ended December 31, 2015, 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: March 10, 2016

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

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