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REVA MEDICAL, INC.

FORM 10-K
(Annual Report)

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Address	5751 COPLEY DRIVE SAN DIEGO, CA 92111
Telephone	(858) 966-3000
CIK	0001496268
SIC Code	3842 - Orthopedic, Prosthetic, and Surgical Appliances and Supplies
Fiscal Year	12/31

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2011

or

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

For the transition period from to

Commission file number: 000-54192

REVA MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware	**33-0810505**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
5751 Copley Drive, 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 ☐ (Do not check if a smaller reporting company) 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, 2011 totaled approximately $201,306,000 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, 2011. The identification of 10% or greater stockholders as of June 30, 2011 is based on Schedule 13G and amended Schedule 13G reports publicly filed before June 30, 2011. This calculation does not reflect a determination that such parties are affiliates for any other purposes.

As of February 15, 2012, there were 33,076,203 shares of the registrant's Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document Description
Portions of the registrant's notice of annual meeting of stockholders and proxy statement to be filed pursuant to Regulation 14A within 120 days after registrant's fiscal year end of December 31, 2011 are incorporated by reference into Part III of this report

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REVA MEDICAL, INC.

FORM 10-K — ANNUAL REPORT
For the Fiscal Year Ended December 31, 2011

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PART I

Forward-Looking Statements

This Annual Report on Form 10-K for the year ended December 31, 2011, 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 that are not 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," "goal," "intend," "may," "objective," "plan," "predict," "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 development and involve known and unknown risks, uncertainties, and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Form 10-K may turn out to be inaccurate. Factors that may cause such differences 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 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 *ReZolve* ™ scaffold to meet our required clinical specifications;
- failure of our products to gain market acceptance domestically or internationally;
- less than anticipated growth in the market for bioresorbable stents 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 attract or retain skilled personnel for our product development and commercialization efforts;
- our inability to protect our intellectual property and operate our business without infringing upon the intellectual rights of others, which could result in litigation and significant expenditures; and
- refusal of third-party payors to reimburse our customers for use of products.

Shareholders, 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.

Currency

Unless indicated otherwise in this Annual Report on Form 10-K, all references to "$" or "dollars" refer to United States dollars, the lawful currency of the United States of America. References to "A$" refer to Australian dollars, the lawful currency of the Commonwealth of Australia.

Corporate Information

Our company was founded in California in June 1998 and named 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. 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 name *ReZolve* ™ has received trademark approval in the United States, European Union, and Australia. 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.

Item 1. Business

Overview

We are a development stage medical device company located in San Diego, California, that is focused on the development and eventual commercialization of our proprietary bioresorbable stent products. Stents are minimally invasive, implantable medical devices that are used by interventional cardiologists for the treatment of coronary artery disease. Stents help stabilize diseased arteries by propping them open and restoring blood flow. Our stent products are designed to provide the same benefits as traditional metal stents, with the additional benefit of being dissolved by the body over time. Our principal stent product, the *ReZolve* ™ scaffold, combines our proprietary design with our proprietary bioresorbable polymer. We call *ReZolve* a scaffold because it is not a permanent device like a stent. *ReZolve* is designed to offer full x-ray visibility, clinically relevant sizing, and a controlled and safe resorption rate. In addition, by early encapsulation of the scaffold in the artery tissue, coupled with the loss of its structure over time, *ReZolve* may reduce the incidence of late forming blood clots, or thrombosis, a rare but serious problem associated with drug-eluting metal stents currently on the market. We believe that, due to the number of risks associated with commercially available metal stents, bioresorbable stents will be the next major advance in coronary stent technology, and, if approved for commercialization by the relevant regulatory authorities, we believe the *ReZolve* scaffold will enable us to compete effectively in the stent market, which had approximately $4.9 billion in worldwide revenues during 2011.

Our stent products have not yet been approved for sale by regulatory authorities and will require extensive clinical testing and regulatory approval before they can be sold and generate any revenue. We began clinical testing of the *ReZolve* scaffold in December 2011 with the initiation of a pilot study that is planned to enroll 50 patients in multiple clinical centers in Brazil and Europe through our second quarter 2012. The study is designed to evaluate the safety and performance of *ReZolve*, with primary evaluation of patients at one, six, and 12 months following implant and follow-up for five years. If acceptable results from this pilot study are achieved, we will initiate a larger clinical trial that will provide the data needed to apply for regulatory approval to commercialize in Europe. Our efforts to generate revenue from our stent products will take several years, even if our clinical results are favorable.

Over the last ten years, we have developed and advanced our technology in both its design and polymer composition and have undertaken significant laboratory and preclinical testing which has shown the technology, and the *ReZolve* scaffold, are safe and effective across various preclinical models. We have funded much of our research and development to date with the proceeds from our Initial Public Offering, or “IPO,” that was completed in December 2010 and, prior to the IPO, from investments from health care venture capital funds and global medical device manufacturers including Medtronic, Inc., or “Medtronic,” and Boston Scientific Corporation, or “BSC.” We had 62 employees as of December 31, 2011.

Market Opportunity

Coronary Artery Disease

Cardiovascular disease, or “CVD,” is a term used to describe all diseases and conditions that relate to the heart and blood vessels. Coronary arteries, which supply blood to heart muscle, are susceptible to the build up of plaque, which can block or inhibit blood flow, a condition known as coronary artery disease. If the coronary arteries become too narrow as a result of this plaque build up, cardiac tissue may become starved of nutrients and oxygen, and the result is 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.

Coronary artery disease is a leading cause of death. In a September 2011 report published by the World Health Organization, CVD was the number one cause of death globally with an estimated 17.3 million deaths in 2008, representing 30% of all global deaths. Of these, an estimated 7.3 million were due to coronary artery disease. The American Heart Association, or “AHA,” reported that coronary artery disease accounted for 425,425 deaths in the U.S. in 2006, or approximately one in every six deaths, and was estimated to cost the U.S. government, directly and indirectly, $177.1 billion in 2010. According to the AHA, in the U.S. more than 17 million people have a history of heart attack or angina and approximately 1.2 million people will have a new or recurrent coronary attack annually.

The European Heart Network reported that coronary artery disease is the most common cause of death in Europe, accounting for approximately 1.92 million deaths per year, or approximately 21% of all male and 22% of all female deaths. In addition, the Australia Institute of Health and Welfare has also reported that coronary artery disease kills more Australians that any other disease, accounting for 22,727 deaths in 2007, or 16.5% of all deaths in Australia.

Current Interventional Treatments for Coronary Artery Disease

The treatment options available to patients with coronary artery disease vary between invasive and non-invasive techniques and within these groups there are a variety of interventions that have varying degrees of benefits and side effects. Due to the lifestyle risk factors associated with coronary artery disease, interventions that can reverse these factors, such as living a healthy and active lifestyle, are used for the prevention and treatment of coronary artery disease. Lifestyle changes include regular exercise, smoking cessation, and healthy diet and nutrition. The evidence to date shows that the healthy lifestyle alternative is not being well adopted in developed or developing societies, likely due to technological advancements which are leading to more inactive lifestyles.

Medication therapy using cholesterol lowering medications, beta blockers, diuretics, aspirin, nitroglycerin, calcium channel blockers, and angiotensin-converting enzyme inhibitors aim to reduce blood pressure and blood cholesterol levels and aid in the treatment of coronary artery disease. Although drug therapy for coronary artery disease can improve quality of life and also prolong survival, many of these current therapies must be combined with stenting to achieve satisfactory long-term solutions for a large number of patients.

When lifestyle changes and medications fail to prevent the development of coronary artery disease, open heart and other surgical procedures are usually required to restore blood flow and functionality to the heart muscle. These procedures, developed 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 reopening the artery with an interventional procedure. The procedures have evolved from invasive surgical approaches to minimally-invasive catheter-based therapies. These procedural 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 these new therapies. The main treatment options typically prescribed by physicians and available to patients are:

- ***Coronary Artery Bypass Surgery*** **:** Bypass surgery, also called coronary artery bypass grafting, or “CABG,” creates a detour around a blocked or narrowed coronary artery with a new blood vessel. This is an extremely invasive technique whereby open heart surgery is required. During CABG, a surgeon takes a vein or an artery from somewhere else in the patient’s body and connects 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*** **:** Developed in the late 1970s, balloon angioplasty proved to be a significant advancement in the treatment of coronary artery disease. This minimally-invasive therapy allows a physician to insert a slender balloon-tipped catheter into the femoral artery in a patient’s groin to access a trouble spot in the heart. At the site of the blockage, the balloon is inflated to compress the plaque, which widens the narrowed coronary artery so that blood can flow more easily. This therapy was rapidly adopted by physicians because it was minimally invasive and resulted in shorter hospital and recovery times when compared to bypass surgery. However, the long-term effectiveness of balloon angioplasty is limited by restenosis, a renarrowing 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 balloon angioplasty procedure or bypass surgery to overcome. While angioplasty is successful in initially restoring blood flow, according to a study published in 1994 by *The New England Journal of Medicine* , restenosis occurred within six months in about 40% of cases. In addition, some patients experienced abrupt vessel closure after angioplasty, which led to major complications including death, heart attack, and emergency bypass surgery.
- ***Bare-Metal Stents*** **:** To address the issues of abrupt vessel closure and high rates of restenosis following balloon angioplasty, coronary stents were developed and introduced in the 1990s. Stents are small tube-like devices that are inserted into an artery following balloon angioplasty; they stabilize the artery by propping it open to facilitate blood flow. The stents currently being used in clinical practice are flexible metal wire mesh tubes that are permanently implanted. Coronary stents are typically mounted on a balloon and expanded, stretching open the stent to the desired diameter during implantation. While bare-metal stents minimized the issues and complications of abrupt vessel closure, restenosis continued to be a significant problem with as many as 30% of patients continuing to have restenosis following the coronary stent placement, according to a study published in 1994 by *The New England Journal of Medicine* .

- ***Drug-Eluting Metal Stents*** **:** After coronary stents were introduced, physicians determined that the cause of restenosis was not necessarily the recurrence of coronary artery disease, but the body's inflammatory response to the trauma caused by the angioplasty procedure and the coronary stent. This led to a number of methods designed to overcome restenosis, the most common being the use of pharmacological agents to treat restenosis at the site. The desire to introduce drug therapy at the site of the lesion resulted in the development of a combination device known as a drug-eluting stent, in which a thin polymer coating and therapeutic drug that minimizes the buildup of scar tissue during the healing process is combined with the metal stent. The drug-eluting metal stents currently on the market contain drugs that range from cytotoxic types (paclitaxel) to immunosuppressants (sirolimus, zotarolimus, and everolimus). Delivery of drugs locally to the artery wall, using lower dosages than would be required for systemic applications, has been shown to inhibit the events that might lead to restenosis. Patients usually also undergo treatment with aspirin and anti-clotting or antiplatelet drugs, such as clopidogrel (*Plavix*) or ticlopidine (*Ticlid*) after stenting, to reduce the incidence of blood clots, or thrombosis. Early indications were that drug-eluting metal stents succeeded in reducing the issue of restenosis with some clinical trials with drug-eluting metal stents demonstrating a restenosis rate under 10%, according to a study published in 2006 by *The New England Journal of Medicine* . In coronary stenting, we believe the key clinical measures of success or failure of the therapy are:
  - ***Target Lesion Revascularization*** , or "TLR," which measures the incidence of restenting or bypass surgery required due to a failure of the initial coronary angioplasty and stenting; and
  - ***Major Adverse Coronary Events*** , or "MACE," which are events of death, ischemia, TLR, or heart attack.
- ***Bioresorbable Stents*** **:** After studies showed that drug-eluting metal stents succeeded in lowering the rates of restenosis, safety concerns were raised when other studies suggested risks arose from late-stent thrombosis and the failure to restore natural movement of the artery. While coronary stents were originally conceived to be temporary devices and initial work was undertaken to develop them from biodegradable polymers so they would dissolve or resorb over time, all stents used currently are metal and remain in place permanently. More recently, the focus has been on producing a coronary stent that is safe and overcomes the potential for late-stent thrombosis. The first bioresorbable stent was developed by researchers at Duke University in the early 1980s. While there have been a number of researchers developing bioresorbable stents intended to be resorbed by the body over time, there are many technical challenges, and to date, no coronary bioresorbable stents are available for sale in Europe or the United States. Due to the temporary nature of these devices as compared to bare metal and drug eluting stents, and their intended design to hold the artery open while it is healing following angioplasty, bioresorbable stents are often described as bioresorbable scaffolds or scaffolds.

Coronary Stent Market

The global market for coronary stents comprises three main sub-markets: the U.S., Europe, and Asia, which principally comprises Japan and includes Australia. Europe represents a large market and will be the first market targeted by REVA, if we achieve the CE Mark approval required to authorize the sale of our *ReZolve* scaffold in the European Union.

In 2011, total annual revenues from coronary stent sales approximated $4.9 billion, of which drug-eluting stents accounted for approximately $4.2 billion. Approximate 2011 annual coronary stent revenues by submarket were:

- $1.9 billion in the U.S. from approximately 1.4 million stent implants, constituting approximately 88% of all interventional cardiology procedures in the U.S.;
- $2.3 billion in Europe from approximately 1.8 million stent implants, constituting approximately 90% of all interventional cardiology procedures in Europe; and
- $0.7 billion in Japan from approximately 0.4 million stent implants, constituting approximately 98% of all interventional cardiology procedures in Japan.

Drug-eluting stents account for approximately 74% of stent usage worldwide. From 2006 to 2007, there was a reduction in market size and sales of drug-eluting stents by over $1 billion, which we believe was due in part to the concerns regarding increased risk of late-stent thrombosis. We believe there are three companies with significant market share which have received both FDA and CE Mark approval for four drug-eluting stents.

Our Products

We have developed and are currently testing our initial product, the *ReZolve* scaffold, which is a drug-eluting fully bioresorbable polymer stent. After implantation, the scaffold is intended to become fully captured within the artery wall. As the vessel remodels and heals, the scaffold is designed to gradually degrade and benignly clear from the body. We expect these features to overcome a number of the issues caused by permanent metal stents. As the stent degrades and is resorbed, there is an integration of artery tissue into the space previously occupied by the stent. We initiated the human clinical trial of the *ReZolve* scaffold in December 2011; the trial is a 50-patient safety study at multiple centers in Brazil and Europe.

We developed an early version of our bioresorbable stent that was not drug-coated. After extensive preclinical testing of the early version stent, we performed a small human clinical trial in 2007 with 25 patients in Brazil and Germany. We were successful in deploying the stent and demonstrated its ability to dilate and hold open the artery, as anticipated and consistent with the results of our preclinical data. However, at approximately four months, we saw adverse device performance resulting in a higher than anticipated number of patients requiring retreatment with another metal stent. At approximately the three-year time point, we performed follow-up imaging on a subset of patients that were both retreated and not retreated. This imaging showed that the artery remained open and stable, which we believe supports our claims as to the safety of the polymer as it degrades.

After extensive investigative analysis, we concluded that embrittlement of the polymer was one of the primary underlying causes for the retreatments in the first clinical study. In addition to planned advancements to the stent's design, we modified the polymer formulation, developed more predictive bench testing, and incorporated the results of our analysis into the design of a revised stent, which is named the *ReZolve* scaffold.

The *ReZolve* scaffold is implanted using a balloon-mounted angioplasty catheter. Our production of the scaffold involves manufacture of the stent device, assembly on the balloon catheter system, sterilization, and packaging. While the handling and storage requirements of *ReZolve* do not vary from those commonly used in clinical practice with metal stents, we currently include a sheath over the scaffold to protect it during the implantation procedure; the sheath is removed once the stent is positioned in the coronary artery. We believe that use of standard clinical practice is important, and since *ReZolve* uses standard clinical procedures other than a small step related to retraction of the sheath, we believe *ReZolve* is positioned for rapid adoption by physicians once we receive regulatory approval for commercialization. The intended key features of the *ReZolve* scaffold include:

- ***Intended Use*** **:** Implants use minimally invasive techniques; the stent resorbs leaving no permanent device;
- ***Efficacy*** **:** Restores blood flow through the artery; natural movement to the artery is restored following resorption;
- ***Drug Eluting*** **:** Delivers standard restenotic drug to the stented artery;
- ***Size*** **:** Treats arteries with diameters of 2.75mm and above, which is standard size;
- ***Standard Deployment*** **:** Catheter mounted with handling and storage the same as current clinical practice;
- ***Expansion Range*** **:** Provides a range of diameter sizing; "slide &lock" mechanism allows the physician to ratchet open the scaffold to a desired diameter during the implant procedure;
- ***Recoil*** **:** Limited stent recoil, which we believe decreases the risk of restenosis; and,
- ***Radiopaque*** : Visible by X-ray during and after implant, allowing verification of placement in the artery.

To address clinical requirements, we will develop several sizes and lengths of the *ReZolve* scaffold for treatment of the most common lesions found in coronary arteries. We may also eliminate the sheath feature in future iterations.

Our *ReZolve* scaffold, which consists of our "slide & lock" design and licensed polymer technology, has been extensively tested during development over the past ten years and has passed the following preclinical tests:

- ***Comparative Testing*** **:** We have performed tests comparing our technology to commercially available metal stents. This testing shows that our technology is safe and effective in animals, with more than 1,000 stents tested across various animal models. In the 90 days following implant, our tests show that our technology maintains the opening of the artery and that the lumen size, or the inside area of the artery, increases as the stent begins and continues to resorb, leaving a more normal lumen area. Comparatively, the lumen size was almost unchanged in arteries supported by metal stents in our preclinical tests.
- ***Strength, Embrittlement, and Fatigue Testing*** **:** We have conducted engineering and life cycle testing with machines that are designed to replicate both the physiological conditions in the coronary artery as well as measure the maximum stress levels that our technology can withstand. To date, these preclinical tests have demonstrated satisfactory design and polymer strength, low levels of embrittlement of the polymer, and resistance to fatigue prior to significant degradation of the stent.
- ***Biocompatibility Testing*** **:** The biological response to our stent technology has been evaluated by assessing healing in animal coronary arteries using standard microscopy for stented arteries. To date, these studies have demonstrated the polymer is safe and no adverse response occurs in the artery even while the polymer degrades.

- ***Rate of Degradation Testing*** **:** We have tested degradation of the polymer, as the stent needs to maintain its structural integrity for approximately a 90-day period following implant to allow sufficient time for the artery to heal. To date, these studies have demonstrated that our technology maintains its structural integrity and strength during that critical 90-day period. By design, at 12 months the stent no longer has significant mechanical strength and the polymer continues to resorb and be eliminated from the body, which continues for approximately four years, after which only tiny particles of the original polymer remain. A study of the byproducts resulting from the resorption of our stent 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*** **:** Our polymer material has been tested for toxicity and has been shown to date to be safe. As required by ISO-10993-1 regulations, our technology has undergone testing for genotoxicity. To date, our studies have shown that there is no change to the DNA or chromosomes of cells tested and no other genetic effect showing our polymer is genotoxic. We have conducted tests for several other types of toxicity that have demonstrated the polymer is safe. In addition to these laboratory tests, we have conducted follow-up tests on the human patients who were implanted with an early generation of the stent in 2007, and after three years of exposure to the polymer and breakdown of products in these patients, the vessels remain open and no long-term adverse clinical events related to the stent have been reported.
- ***Testing of Drug Coating*** **:** The implant of a stent in an artery can injure the diseased vessel and the body's wound-healing process can cause excessive scar tissue to form inside the stent, or in-stent restenosis. The drug sirolimus has been shown to minimize the overgrowth of tissue thereby minimizing the incidence of in-stent restenosis. In animal studies, we have tested the effects of the drug sirolimus, which is applied to the surface of *ReZolve* as a coating. This drug is already used in other drug-eluting stents due to a recognized safety profile and efficacy at reducing restenosis. Our studies demonstrated no major drug toxicity.

We have designed the *ReZolve* scaffold to overcome many of the limitations associated with currently marketed bare metal and drug-eluting stents. Our extensive preclinical testing, including bench and animal testing, provides data and results that indicate our stent could include the following benefits:

- ***Restoration of Vessel Movement and Decreased Risk of Adverse Effect*** **:** We believe adverse long-term reactions will be reduced due to the ability of our stent to be resorbed by the body over time. As *ReZolve* dissolves, and the lesion has healed, the expansion and contraction of the vessel is restored without the restrictions of a permanent metal structure. We believe our stent has the potential to minimize disease progression downstream as the artery and blood flow are restored.
- ***Minimization of Thrombosis Risk and Reduction of Long-Term Drug Therapy*** **:** We believe the potential for late-stent thrombosis is reduced because *ReZolve* becomes fully encapsulated into the artery where it safely dissolves over time. 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*** **:** We believe that as *ReZolve* dissolves, the potential complications of subsequent medical treatments are reduced. A patient can likely undergo restenting, receive treatment for lesions located downstream from the original stent, and undergo surgical procedures to the arteries because there is no metal obstruction. In addition, we believe our products have a significant potential application for use as a delivery vehicle for agents such as drugs and genes in coronary arteries to treat a number of different lesions, including the treatment and reduction of vulnerable plaque. As a result, we believe the *ReZolve* scaffold will be able to treat a broader range of lesions more safely than today's stent alternatives. Also, since *ReZolve* does not inhibit the use of MRI, it allows physicians to non-invasively study coronary flow. As the stent loses radiopacity following implant, we believe the same will be true with CT imaging.

We believe that due to risks associated with the commercially available bare-metal and drug-eluting metal stents, bioresorbable stents will be the next major advance in coronary stent development. Bioresorbable stents or scaffolds can potentially provide interventional cardiologists with more treatment options to better address a broader range of coronary lesions. Our *ReZolve* scaffold is designed with the following features to overcome a number of the limitations of other bioresorbable stents currently under development:

- ***Proprietary Design and Strong and Resilient Polymer*** **:** Our proprietary "slide & lock" design enables *ReZolve* to be expanded with minimal deformation of the polymer and, therefore, maintain the strength of the material. Our proprietary polymer is also less prone to breaking than other polymers that have been tested for this application, and we believe the strength is maintained during the critical 90-day healing period following implant. We believe our ability to customize our polymer formulation will allow us to create products for additional applications. For example, we believe our polymer and stent technology could be developed for use in peripheral arteries of the leg where stents are prone to crushing and fracturing.

- ***No Change to Clinical Practice*** **:** The *ReZolve* scaffold with its sheath can be implanted using a standard balloon catheter and does not require any change to storage or handling. The sheath is removed in a simple step during the interventional procedure. The stent can be stored at controlled room temperature conditions without the necessity of heating or refrigerating prior to use.
- ***Controlled Resorption Rate*** **:** The polymer we use is designed to degrade and be cleared from the body in a predictable and safe manner. We may adjust the degradation profile of future polymer formulations to maximize the benefit for patient outcomes.
- ***Biocompatible and Safe*** **:** In 2007, we performed a human clinical trial with an earlier version of our polymer and that version has not shown any adverse biological reactions to date. The earlier polymer version was modified to the current version to enhance mechanical properties and address structural issues identified in the 2007 clinical trial. The current polymer is similar in composition and contains approximately 85% of the same material as the earlier version. The previous and current polymers have demonstrated equal biocompatibility in preclinical testing. Our studies have shown that 12 months after implant in pigs and rabbits, the current polymer has no indications of adverse biological reactions while the stent material is degrading, consistent with the original version of the polymer. We believe the current version of our polymer addresses the structural issues identified in our human clinical trials without adversely affecting biocompatibility.
- ***Visible Using Standard Imaging Techniques*** **:** Our *ReZolve* scaffold is visible under x-ray, thereby allowing physicians to see the stent during implant and at early patient follow-up. It is also compatible with MRI and CT imaging, both of which imaging technologies may become more widely used in the diagnosis and treatment of coronary artery disease.

The disadvantage of the *ReZolve* scaffold is that, at this time, it is not designed to address smaller diameter vessel applications or highly calcified, or hard and complex, lesions. As a result, it will not be able to address the needs of all patients requiring a coronary stent. We may further develop *ReZolve* in the future to address some of these limitations.

Our Strategy

Our goal is to become a world leader in the development and commercialization of bioresorbable stent products for use in coronary and peripheral arteries of the human body. To achieve this goal, we are pursuing the following business strategies:

- ***Demonstrate Clinical Safety and Efficacy and Gain Regulatory Approval for ReZolve*** **:** We intend to demonstrate the clinical safety and efficacy of our *ReZolve* scaffold through human clinical trials and have developed a clinical and regulatory strategy covering these trials and the pathway to application for commercial sales. We initiated a pilot clinical study in December 2011, which is a prospective, multi-center safety study designed to evaluate the *ReZolve* scaffold in 50 patients at multiple centers in Brazil and Europe. We anticipate enrollment to be completed in the second quarter of 2012 and, upon acceptable data from the pilot study, we plan to initiate a pivotal clinical trial that would provide the data required to apply for CE Mark approval in the European Union, or the "EU" by the end of 2013. If and when we receive CE Mark approval, we plan to launch commercial sales of the *ReZolve* scaffold in the EU. We intend to use the data from the CE Mark clinical trials to support applications for an Investigational Device Exemption, or "IDE," for larger, more costly, U.S. clinical trials in order to seek FDA approval for commercial sales of our products in the U.S.
- ***Commercialize and Drive Adoption of ReZolve*** **:** Following regulatory approvals, we plan to commercially sell our products. Once the CE Mark clinical trials are underway, we plan to focus on our commercialization readiness in anticipation of commercial sales in the EU and related markets such as Australia. In order to meet commercial demands, we intend to invest in the expansion of our manufacturing capabilities to required levels. We have granted BSC an option for a worldwide, exclusive right to market, distribute, and sell our products, subject to certain requirements. See "— Distribution and License Agreements" for additional information.
- ***Build Awareness and Support Among Leading Physicians*** **:** Our clinical development strategy is to closely collaborate with key opinion leaders in the field of interventional cardiology. We believe these key opinion leaders can be valuable advocates of our technology and be important in the market adoption of our products once our products are approved and commercialized. In addition, we intend to look to these physicians to generate and publish scientific data that further supports the benefits of our stent technology.

- ***Leverage Our Technology Platform into Other Therapeutic Areas*** **:** We believe that 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 femoral artery, have demonstrated only marginal benefit. We believe the application of our technology to the development of a bioresorbable peripheral stent could be significant.
- ***Provide the Highest Quality Products for Our Customers and Patients*** **:** We have assembled a team of experienced professionals in the medical device industry who are focused on patient safety and product quality. We incorporate these principles in every aspect of our business including product development, manufacturing, quality assurance, and clinical research. We intend to build on this foundation by offering 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 originate, license, and acquire additional intellectual property to enhance our existing position and enable us to more effectively protect our technology.
- ***Explore Licensing Opportunities*** **:** We intend to explore opportunities to leverage our intellectual property portfolio through licensing our technology to third parties or through the establishment of partnerships. For example, we may seek a partner to license our side-chain crystalizable polymer for use as a flowable cement for orthopedic applications.

Our Technology

Our *ReZolve* scaffold is a drug-eluting fully bioresorbable polymer stent. The underlying technology primarily consists of a proprietary "slide & lock" design, a proprietary polymer, and a drug coating.

Our patent protected "slide & lock" mechanism is based on a ratchet system where, as the stent expands on a catheter mounted balloon, the "teeth" on the sliding parts pass through brackets in the stent, preventing them from passing back, and locks in the stent diameter. The current version of the "slide & lock" design is uniform throughout and is implemented with two sets of components: backbones and U-shaped struts. We believe our "slide & lock" design offers the following advantages as compared to commercially available bare metal stents and drug-eluting metal stents and competing bioresorbable stents under development:

- ***Non-Deformable Design*** **:** All commercially available metal stents use deforming technology; a "deformable" metal stent is crimped onto a catheter mounted balloon and, as the balloon expands, the stent bends open until it reaches the desired implant size. Polymers do not lend themselves to a deformable technology because they can lose strength and become prone to breakage when stretched or bent. We believe our non-deformable ratcheting design is a key component to developing a strong bioresorbable stent.
- ***Spiral Design Maximizes Strength while Minimizing Bulk*** **:** With metal stents, the ultimate strength of the metal prevents excessive recoil of the device after implant. Polymer stents do not have the strength of metal and often break, recoil to a smaller diameter, or collapse entirely. We believe our spiral design offers an appropriate level of radial strength to overcome these issues while minimizing bulk.
- ***Large Expansion Range*** **:** A potential drawback of utilizing traditional stent technology for polymer stents is the lack of expansion range, that is, the diameter to which a stent can open during implant. This drawback generally requires a physician to more accurately assess the size of the coronary artery based on angiography prior to implant, since expansion of the device after implant, a common technique to improve the position of the stent in relation to the artery wall, is limited due to potential fracture and recoil. Also, with a limited expansion range, additional stent sizes may be required to accommodate existing clinical practice. Our "slide & lock" mechanism allows a stent to ratchet open to achieve various diameters, similar to commercially available metal stents. We believe that with our "slide & lock" technology, the physician will be able to further expand the stent, as currently done in clinical practice, without the need for numerous stent sizes.

Our patent protected polymer is an iodinated, tyrosine-derived polycarbonate. In January 2004, we entered into an exclusive license for a polymer material for use in stents, stent coatings, and embolics that was invented at Rutgers, The State University of New Jersey, or "Rutgers." We have continued to develop and enhance the polymer in collaboration with Rutgers. In July 2010, we entered into a new license agreement with Rutgers that broadens our exclusive rights to the original polymer family and all new polymer compositions developed from this family to cover all vascular applications. See "— Distribution and License Agreements" for additional information.

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 design, 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 less prone to cracking and breakage than other polymers.
- ***Biocompatibility*** : In 2007, we performed a human clinical trial with an earlier version of our polymer and that version has not shown any adverse biological reactions to date. The earlier polymer version was modified to the current version to enhance mechanical properties and address structural issues identified in the 2007 clinical trial. The current polymer is similar in composition and contains approximately 85% of the same material as the earlier version. The previous and current polymers have demonstrated equal biocompatibility in preclinical testing. Our studies have shown that 12 months after implant in pigs and rabbits, the current polymer has no indications of adverse biological reactions while the stent material is degrading, consistent with the original version of the polymer. We believe the current version of our polymer addresses the structural issues identified in our human clinical trials without adversely affecting biocompatibility or safety.
- ***Predictable Degradation and Resorption*** **:** Our polymer degrades into metabolites (being three monomers and carbon dioxide) and can then be cleared from the body. We may adjust the degradation profile of future polymer formulations for specific applications. We believe future generations of our bioresorbable stent may employ formulations that will allow a more rapid degradation process to occur which will facilitate, for example, the short-term treatment of vulnerable plaque with drugs.
- ***Visibility*** **:** The use of iodine in our polymer enables our stent to be visible under x-ray as well as standard fluoroscopy. This visibility is similar to commercially available metal stents, and we believe this differs from other bioresorbable stents currently in development where only the end markers on the device are visible. Improved visibility allows interventional cardiologists to more accurately assess the implant quality and position.

Our *ReZolve* scaffold is drug-eluting so that it may help to inhibit restenosis of the artery in the location of the stent. For our commercial device, we intend to use the drug sirolimus, an anti-restenotic drug used in other drug-eluting stents. This drug is commercially available from a number of different sources and is FDA approved.

We coat the outside surface of the *ReZolve* scaffold using a polymer solution containing a target dose of 80 µg of sirolimus. The polymer used for the coating solution is the same polymer used for the stent 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.

Preclinical Testing

We have undertaken significant laboratory and preclinical testing during the development of our stent technology, with more than 1,000 stents tested across various animal models. This testing has shown that our technology, including the *ReZolve* scaffold, is safe and effective in animals. Our 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. We used the data from our preclinical tests in our submissions to the Brazilian and European regulatory bodies, for which we received approval to proceed with our pilot clinical trial of the *ReZolve* scaffold.

Clinical Development Program

We have developed a clinical and regulatory strategy that covers our clinical trials and the pathway to application for commercial sales. We initiated a pilot clinical study in December 2011, the RESTORE clinical trial (pilot study of the *Re Zolve ™* s irolimus-elu t ing bi ore sorbable coronary scaffold), which is a non-randomized, prospective, multi-center safety study designed to evaluate the *ReZolve* scaffold in 50 patients at multiple centers in Brazil and Europe. We anticipate enrollment to be completed in the second quarter of 2012 and, upon acceptable data from the pilot study, we plan to initiate a pivotal clinical trial in additional countries, including Australia and New Zealand, that would provide the data required to apply for CE Mark approval in the EU. If and when we receive CE Mark approval, we plan to launch commercial sales of the *ReZolve* scaffold in the EU. We intend to use the data from the CE Mark clinical trials to support an IDE application for a larger, more costly, clinical trial to provide data for commercial sales of our products in the U.S., which can only occur after completion of a U.S. FDA human clinical trial and a Premarket Approval, or “PMA,” from the FDA.

Our pilot clinical trial utilizes standard industry measures of safety in evaluating *ReZolve's* performance. Enrolled patients will be monitored on a regular basis including at one-, six-, and 12-month intervals after implant, and annually thereafter for a period of up to five years. The pilot study is not designed to enable scientific conclusions to be drawn or regulatory approvals to be received.

In the EU, the European Medical Devices Directive, or "MDD," 93/42/EEC sets out the general requirements for clinical trials and other essential requirements to support CE Mark approval and there are numerous other directives and standards regulating the design, manufacture, clinical trials, and labeling for medical devices. For the *ReZolve* scaffold to bear the CE Mark and be sold commercially throughout the EU, we will need to complete a CE Mark human clinical trial, as well as complete supporting work to comply with the requirements of MDD.

In Australia, the Therapeutic Goods Administration, or "TGA," is responsible for administering the Therapeutic Goods Act and maintaining the Australian Register of Therapeutic Goods. Unless exempt, all therapeutic goods for human use, including 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 ethical approvals at these centers, we will seek an exemption from the Australian Register of Therapeutic Goods for the CE Mark human clinical trial of the *ReZolve* scaffold in Australia.

We plan to conduct our pivotal human clinical trial of the *ReZolve* scaffold for CE Mark approval based on:

- the enrollment of up to 350 patients (we will evaluate enrolling fewer patients if CE Marks continue to be approved for similar products with data from less than 350 patients);
- the non-inferiority of *ReZolve* compared to a commercially available drug-eluting metal stent, if required, with implants being randomized on a two-to-one basis (two of our stents implanted for every control stent);
- patient enrollment in 20 to 25 centers across the EU, Brazil, Australia, and New Zealand;
- the primary endpoint to be late loss (reduction of internal artery diameter) and comparable MACE (death, ischemia, heart attack);
- clinical follow-up of all patients on a regular basis including at one, six, and 12 months, and annually thereafter for a period of up to five years; and
- interventional follow-up at nine or 12 months on a subset of patients in order to visualize the healing process.

While we plan to commence enrollment of patients for the CE Mark trial in 2012 following successful results from our pilot study and be in a position to apply for CE Mark by the end of 2013, no guarantee can be given that we will achieve our expected results from the clinical trials or that CE Mark will be attained in a timely fashion or at all.

In the United States, medical devices are subject to review and approval by the FDA, which regulates the clinical testing, manufacture, labeling, storage, record keeping, distribution, and promotion of medical devices, primarily pursuant to the requirements of the Food, Drug, and Cosmetic Act and other regulatory requirements. Medical devices are classified as Class I, II, or III according to risk. Devices classified as Class III, such as the *ReZolve* scaffold, require FDA approval of a PMA application prior to commercialization.

To obtain FDA approval to market our products, the FDA requires proof of safety and efficacy in human clinical trials performed under an IDE. An IDE application must contain preclinical test data supporting the safety of the product for human investigational use, information on manufacturing processes and procedures, proposed clinical protocols, and other information. The IDE application is generally approved by the FDA for a specified number of patients and investigational sites. Clinical trials may begin once the FDA approves the IDE and the Institutional Review Board at each participating clinical site approves the trial protocol.

Based on the outcome of the pivotal CE Mark human trial, we plan to conduct human clinical trials in the United States. The trial is expected to be a randomized trial of at least 2,000 patients. Pursuant to our clinical and regulatory strategy, the timing of the commencement of the U.S. FDA clinical trial will be determined after consideration of the CE Mark results, our capacity to manage multiple trials concurrently and the availability of future funding.

Manufacturing

Our operations are based at our ISO 13485-2003 certified facility in San Diego, an approximately 37,000 square foot facility dedicated to the development and manufacture of our products. The facility includes laboratories for polymer development, chemistry, engineering, and product assembly, including clean rooms and quality assurance laboratories. We believe that the San Diego facility will have the capacity to produce the quantities of the *ReZolve* scaffold required for our planned clinical trials. In the future, if we receive the necessary regulatory approvals for our products, we expect to expand our manufacturing capacity in line with demand for our products. Our lease expires in January 2018.

Although certain portions of our stent manufacturing process are completed by external parties, we have not entered into any material agreements with any third parties regarding our manufacturing process. Our suppliers have no contractual obligation to supply, and we are not obligated to purchase, any components used in our *ReZolve* scaffold, which may result in supply interruptions. The strategy of outsourcing selected manufacturing processes is intended to minimize capital and operating costs while at the same time maintaining required quality standards.

Our process to manufacture our *ReZolve* scaffold 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*** **:** Currently outsourced to a domestic supplier.
- ***Polymer Film Pressing*** **:** Performed at our facility.
- ***Lasing Stent Parts from the Polymer Films*** **:** Currently outsourced to a domestic fabricator.
- ***Drug Coating*** **:** Drug currently purchased from foreign supplier; coating prepared and applied at our facility.
- ***Catheter and Sheath System*** **:** Finished system currently purchased from foreign supplier.
- ***Assembly, Mounting on the Catheter, Quality Assurance, and Packaging*** **:** Performed at our facility.
- ***Sterilization*** **:** Currently outsourced to a domestic lab.

Currently, our polymer manufacture, catheter supply, and lasing process are single-sourced. While certain other products and components come from single source suppliers, we believe alternative suppliers are readily available, though in many cases we have not qualified these suppliers. If necessary, we could locate second source suppliers; however, any interruption or delay in obtaining products from third-party suppliers, or our inability to obtain products from alternate 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.

We have implemented a quality management system which is designed to comply with FDA regulations and ISO standards governing our medical device products. These regulations carefully control the design, manufacture, testing, and release of products and product components, as well as raw material receipt and control. We also have controlled methods for the consistent manufacturing of our products and product components at our facility. All key outsourcing partners are generally ISO-certified to help assure a continual supply of high quality components.

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 more established reputations with our target customers. These competitors include Abbott Vascular, BSC, Johnson & Johnson, and Medtronic. Smaller or early-stage companies may also prove to be significant competitors, particularly if they enter into collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, 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 high performance requirements for 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 will be drug-eluting stents and other bioresorbable stents. There have been a number of companies working to develop bioresorbable or polymer stents. Abbott Vascular is developing its Bioresorbable Vascular Scaffold, called *Absorb*, which received CE Mark approval in January 2011, but has not yet been made available for sale. Biotronik, a private, European company, is developing its second generation *Dreams* magnesium-based resorbable stent. Biotronik has announced that clinical trials of this device commenced in August 2010.

Because of the size of the market opportunity for coronary artery disease, competitors have historically dedicated and, we expect, will continue to dedicate significant resources to aggressively promote their products. New product developments that could compete with us more effectively are likely because the coronary artery disease treatment market 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 *ReZolve* .

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 *ReZolve* scaffold. 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 were $10.3 million in 2009, $6.8 million in 2010, and $13.4 million in 2011. We expect our research and development expenditures to increase as we devote significant resources to the continuing development of our products, in particular, completing the clinical trials necessary to support regulatory approval of the *ReZolve* scaffold.

Sales and Marketing

As a development stage company, we do not have a sales and marketing organization and currently have no experience in the sale, marketing, or distribution of stents or bioresorbable scaffolds. To achieve commercial success for any approved product, we will need to develop a sales and marketing organization or enter into arrangements with others to market and sell our products.

In most countries throughout the world, a significant portion of a patient’s medical expenses is covered by third-party payors. In the United States, hospitals and physicians generally rely on third-party payors, such as Medicare, private health insurance plans, and health maintenance organizations to reimburse all or part of the cost of medical devices and the related surgical procedures. Reimbursement in the EU varies from country-to-country and often hospital-to-hospital. We believe that numerous hospitals have established budgets to purchase coronary stents and the purchase decision is often driven by the interventional cardiologists.

Currently, coronary stents are sold through distribution channels in the United States and around the developed world, primarily targeting interventional cardiologists who treat patients likely to require stenting. We believe the costs and barriers are large to develop a distribution channel focused around one group of products. We may therefore consider partnering with a distribution or sales channel. In addition, we have entered into a Distribution Option agreement with BSC relating to the sale and distribution of our stent technology in markets in which the technology is approved for sale. The terms of this agreement are described under “— Distribution and License Agreements.”

Our sales strategy will depend on the types and timing of our product roll-out, which is dependent upon receipt of the necessary regulatory approvals and clearances:

- The EU will be our initial target commercial market because CE Mark is our first targeted regulatory approval;
- Australia will be our second target commercial market because we believe regulatory approval in Australia will closely follow CE Mark, and Australia can serve as a base for the Asian market; and
- The U.S. will be our third target commercial market upon completion of U.S. FDA trials and PMA approval.

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 & lock" design have been developed internally, while the polymer has been either licensed or developed by us.

As of February 15, 2012, our patent portfolio comprises, on a worldwide basis, approximately 280 issued and pending U.S. and foreign patents that we own directly or for which we are the exclusive licensee. We have been issued 31 U.S. patents and have 31 U.S. patent applications that are pending in the United States Patent and Trademark Office. Our latest patent expiration date is 2031. For these 62 technology patents, we have sought intellectual property protection outside of the U.S. and have been issued 139 foreign patents and have 79 pending foreign applications. We do not know if any of our patent applications will be issued, nor do we know whether our patents, if issued, will 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 stent like ours, despite our patent rights. We have received no communications from third parties concerning the patentability, validity, or enforceability of our patents or patent applications. We believe that the remaining life of our patents provides adequate time to generate revenues from commercialization, subject to timing of the regulatory and clinical pathway.

We actively monitor our intellectual property position and review new developments periodically to identify prudent extensions to our patent portfolio to ensure that we lockup key technology, as well as to maximize our defensive strategy through the coverage of similar technology developments. We have an in-house patent counsel and also employ external patent attorneys to assist us in managing our intellectual property portfolio.

The industry we operate in has been subject to a large number of patent filing and patent infringement lawsuits. Whether we would, upon commercialization, infringe any patent claim will not be known with certainty unless and until a court interprets the 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 issued patents in the U.S. 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 secret protection 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, or "BSC," in which we granted BSC an option to negotiate for a worldwide exclusive right to sell, market, and distribute our stent products, subject to certain exceptions. If BSC exercises its option, we will negotiate in good faith to enter into a mutually acceptable distribution agreement that will include the following provisions: (i) the distribution agreement shall last at least five (5) years; (ii) the transfer price for our products shall be equal to 50% of BSC's average selling price for such products; (iii) BSC shall not be required to make any payments, other than the transfer price for products, with respect to 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 all 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 during the term of such distribution agreement so long as BSC does not commence the

selling, marketing, or distribution of a directly competitive stent product (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 agreement with BSC within 90 days of BSC's exercise of its option, or if BSC provides us written notice that it has elected not to exercise its option, then we shall be permitted to sell, market, and distribute our products to a third party; provided, however, the terms of an offer to any third party and the definitive agreement establishing such third party's right to sell, market, and distribute such products, shall not be on terms more favorable than the terms offered by us to BSC.

BSC's distribution option, if not previously exercised, terminates 90 days after our delivery of clinical data to BSC from the following clinical milestones: (i) imaging, death, acute myocardial infarction, stent thrombosis, and target lesion revascularization data from one year follow-up of at least 200 of our implanted resorbable drug coated stents from human clinical trials, or "Implanted Stents;" (ii) core lab acute gain, late loss, and binary angiographic restenosis data from eight- to nine-month angiographic follow-up of at least 100 Implanted Stents; and, (iii) eight- to nine-month intravascular ultrasounds of at least 40 Implanted Stents.

Under the Distribution Option Agreement, we have also agreed not to take certain actions which would prevent BSC from exercising its distribution option, provided that we may market, sell, or distribute any product on a non-exclusive basis in any country or territory where BSC directly competes with such product. In addition, if we receive regulatory approval for any product in any country or territory outside of the U.S. prior to submission to the FDA, and (i) BSC does not exercise its distribution option within 90 days following written notice from us of the approval, or (ii) if BSC exercises it distribution option but is unable to agree with us on the terms of the distribution arrangement within 90 days of BSC's exercise of its option, then we may sell, market, and distribute such product in any foreign country or territory where the product has received approval, directly or through any third party that is not a direct competitor of BSC, provided however, that any such arrangement must be terminable without cost to BSC on no more than 90 days' written notice.

Significant License Agreements

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 new 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 2030, or ten years after commercialization. The License allows Rutgers to sublicense certain technology Rutgers invented, we jointly invented with Rutgers, or that we solely invented. 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.

In 2004, we entered into a Royalty and License Agreement, or the "Integra License," with Integra LifeSciences Corporation, or "Integra" in which Integra granted us an exclusive license, with the right to sublicense, to develop and commercialize products that are covered by patent rights in the field of blood vessels. The Integra License requires us to pay to Integra a per-unit royalty on stent products that incorporate certain polycarbonates. The term of the Integra License continues until the later of (i) expiration of the last to expire of the patents licensed to us, which we believe is 2018 or (ii) the expiration of certain patent rights licensed by Rutgers to us.

The royalties due under the Rutgers License and the Integra 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 $70 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 licenses require that 20% of the milestone amount be paid to the licensors.

The Rutgers License requires annual licensing payments of $175,000 until the underlying technology has been commercialized and royalties would be due. The Rutgers 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, and payment of patent filing, maintenance, and defense fees.

Third-Party Reimbursement

In most countries throughout the world, a significant portion of a patient's medical expense is covered by third-party reimbursement. In the U.S. and other countries, third-party payors consist 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 the existing reimbursement guidelines, although some refinement in policies may be needed for our products. Before we can obtain reimbursement for our *ReZolve* scaffold in Europe, Australia, or the United States, we will need to obtain appropriate regulatory approvals for product sales.

In the U.S, the Center for Medicare and Medicaid Services, or "CMS," is the 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 that are currently being sold; however, we have no assurances these existing policies or reimbursement codes would apply to the bioresorbable stents that we are developing. We also have no assurance that existing payment rates under these reimbursement codes will continue.

Outside of the U.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 reimbursement for stents, a small number of countries may require us to gather additional clinical data before agreeing to coverage and reimbursement for our products. We intend to complete the requisite clinical studies and obtain coverage and reimbursement approval in countries where it makes economic sense to do so.

In certain regions, such as Europe, innovative pricing and reimbursement agreements are being used to balance the interests and objectives of medical technology manufacturers, payors, parties assessing health technology, clinicians, and patients. Manufacturers and health technology assessors/assessments, or "HTAs," are increasingly using risk sharing and value-based schemes as a way to obtain HTA approval. 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, or "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 the resorbable stents that we are developing 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. We believe that the economic benefits provided by the *ReZolve* scaffold to physicians and hospitals through shorter procedure times and lower overall procedure costs will be viewed by providers and third-party payors as cost-effective. However, 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 that are physically combined into a single product: a drug and a device. In the U.S., 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, or "CDER," or the Center for Devices and Radiological Health, or "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 our products will be regulated as devices by the FDA under the Federal Food, Drug, and Cosmetic Act, and CDRH will have primary jurisdiction over our PMA application. However, it is possible the FDA may assign our products to CDER. We believe that the drug component of our products will not require separate FDA approval and that it will be reviewed by CDER, which will assist CDRH in its review of our PMA application. If the FDA does assign our products to be regulated by CDER, the drug component of the product will in all likelihood not require separate CDER approval.

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 and development;
- product testing;
- product manufacturing;
- product safety;
- product labeling;
- product storage;
- record keeping;
- premarket approval;
- advertising and promotion;
- production; and
- product sales and distribution.

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. All of our current products in development are Class III devices and will require FDA approval after submission and review of our PMA application. 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 that the supplement is limited to information needed to support any changes from the device covered by the original PMA application. Certain modifications may not require as extensive clinical data or the convening of an advisory panel.

Clinical Trials **:** Clinical trial data is almost always required to support a PMA application. Clinical trials for our product candidates require the submission of an IDE application and approval from the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory data showing that it is safe to test the device in humans and that the testing protocol is scientifically sound, and the application must be for a specified number of patients. Clinical trials may begin once the application is cleared by the FDA, as well as the appropriate institutional review boards at the clinical trial sites. Clinical trials must be conducted in accordance with applicable regulations and policies and are subject to extensive record keeping and reporting requirements. Our clinical trials must be conducted under the oversight of an institutional review board at the relevant clinical trial site and in accordance with applicable regulations and policies including, but not limited to, the FDA's good clinical practice regulations. 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 clinical trial outweigh the anticipated benefits.

Pervasive and Continuing Regulation **:** After a device is placed on the market, numerous regulatory requirements apply. These include:

- Good Manufacturing Practices, or "GMP," and the Quality System Regulation, or "QSR," that require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation, and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions for promotion of products for unapproved or "off-label" uses;
- medical device reporting regulations, which require that manufacturers 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; and
- 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.

The FDA has broad post-market and regulatory enforcement powers. 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 the QSR and other regulations. The manufacturing facilities of our suppliers and subcontractors may also be inspected by the FDA or other regulatory authorities to determine their compliance with the strictly enforced GMP regulations.

In addition, discovery of previously unknown problems with a medical device, manufacturer, or facility may result in restrictions on the marketing or manufacturing of an approved device, including costly recalls or withdrawal of the device from the market. For instance, BSC and Johnson & Johnson have experienced safety and manufacturing problems with their drug-eluting stent products, and have conducted significant and costly recalls in response to these issues. 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:

- 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 that are already granted; and/or
- criminal prosecution.

The FDA also has the authority to require us to repair, replace, or refund the cost of any medical device that we have manufactured or distributed. If any of these events were to occur, they could have a material adverse effect on our business. We are also subject to a wide range of federal, state, and local laws and regulations, including those related to the environment, health and safety, and land use.

Fraud and Abuse **:** Our operations will be directly, or indirectly through our customers, 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 remuneration, 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 in businesses outside of the health care industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, Congress authorized the Department of Health and Human Services to issue a series of regulations, known as the "safe harbors." These safe harbors set forth provisions that, if all their applicable requirements are met, will assure health care providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities. Penalties for violations of the federal 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 also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for health care items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing or causing to be filed a false claim to, or the knowing use of 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, sometimes known as "relators" or, more commonly, as "whistleblowers," may share in any amounts paid by the entity 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 a False Claim action. When an entity is determined to have violated the federal 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.

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.

If our operations are found to be in violation of any of the laws described above or other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government health care programs, and the curtailment or restructuring of our operations.

Patient Protection and Affordable Care Act **:** Our operations will be impacted by the federal Patient Protection and Affordable Care Act of 2010, as modified by the Health Care and Education Reconciliation Act of 2010, which we refer to as the "Health Care Act." The Health Care Act imposes a 2.3 percent excise tax on sales of medical devices by manufacturers. Taxable devices include any medical device defined in section 201(h) of the FDCA and intended for use by humans, with limited exclusions. There is no exemption for small companies, and we expect to begin paying the tax when we begin commercial sales of our products. The Health Care Act also requires manufacturers to report details to the Department of Health and Human Services about 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 Health Care Act to impose significant administrative and financial burdens on us.

International

International sales of medical devices are subject to relevant 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.

Europe's primary regulatory environment is that of the EU, which consists of 27 countries encompassing most of the major countries in Europe. 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 and allow the marketing of medical devices that meet EU requirements. The EU has three core directives concerning medical devices: Medical Devices Directive, 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.

Before a medical device can be marketed or used in the EU, it must undergo a conformity assessment process as set forth in the relevant medical devices directives. Upon compliance with the relevant directives requirements, medical devices will be entitled to bear CE Marking and, accordingly, can be commercially distributed throughout the EU, the member states of the European Free Trade Association, and countries that have entered into a Mutual Recognition Agreement. 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 designated Notified Body, an independent and neutral institution appointed in one of the EU countries. The assessment may also include an audit of the manufacturer's quality system and specific testing of the device to ensure compliance with ISO 13485, which are voluntary harmonized standards. Each member state country of the EU has implemented the Medical Device Directives into national laws and these laws are enforced by competent authorities in each member state. For example, in the United Kingdom the authority is the Medicines and Healthcare Products Regulatory Agency.

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. Compliance generally requires, among other things:

- 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.

However, much of the documentation produced for obtaining the CE Marking in Europe can be used to obtain registration in Australia and the regulatory requirements with respect to the approval of medical devices are similar to European regulations.

Employees

As of December 31, 2011, we had 62 employees, including 60 full-time employees and two part-time employees, of which 52 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 represented by a labor union.

Executive Officers

Our executive officers and their ages and backgrounds as of December 31, 2011, are as follows:

Robert B. Stockman , age 58, our co-founder, has served as Chairman of the Board and director since 1999 and Chief Executive Officer since August 2010. He has served as a director of HeartWare Limited, and subsequently HeartWare International, Inc., an ASX and NASDAQ listed medical device company, since December 2006. Since 1999, Mr. Stockman has been the President and Chief Executive Officer of Group Outcome LLC, a U.S.-based merchant banking firm that deploys its capital and that of its financial partners in private equity and venture capital investments in medical technology companies. Mr. Stockman also co-founded Centrimed, Inc., an internet-based software company, that was acquired by the Global Healthcare Exchange, LLC, and led the buyouts of Iopter, an intraocular lens manufacturer, and two Johnson & Johnson divestitures, “A” Company Orthodontics, Inc. and Critikon Company, LLC, each of which was subsequently acquired. Prior to establishing Group Outcome LLC, Mr. Stockman spent 18 years with Johnston Associates, Inc. and Narragansett Capital Corporation, where he focused on venture capital investments and merger advisory work in health care. Mr. Stockman holds a Bachelors Degree from Harvard College and a Master in Business Administration from The Tuck School at Dartmouth College.

Robert K. Schultz, Ph.D. , age 55, has served as our President and Chief Operating Officer since 2003. His background comprises more than 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. degree in Pharmacy from the University of Minnesota.

Katrina Thompson , age 53, 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 in 2003, Ms. Thompson held senior positions in the telecom, real estate development, commercial nursery, and high tech 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 45, has served 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. 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 Brandom, Ph.D. , age 52, is our Vice President of Product Development. He has directed all biomaterials development activities since 2003 and the stent development program since 2010. In his over 20 years of industry experience, he has held 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.

Joan Zeltinger, Ph.D. , age 49, has served as our Vice President of Scientific Affairs since June 2004 and has directed our biological and preclinical activities since 2000. Dr. Zeltinger has 20 years of industry research and business experience that includes numerous 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 for 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.

General Information

The address of our principal place of business is 5751 Copley Drive, San Diego, CA 92111. We maintain a website at *www.revamedical.com* . 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 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.

The public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room located at 100 F Street, N.E., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at (202) 551-8090. The SEC also maintains electronic versions of our reports on its website at *www.sec.gov* .

Item 1A. Risk Factors

You should carefully consider the risks described below and all of the other information set forth 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 we may never achieve or maintain profitability.

We are a development stage medical device company. We have incurred net losses since our inception, including net losses of approximately $13.8 million, $23.5 million, and $20.9 million for the fiscal years ended December 31, 2009, 2010, and 2011 respectively. As of December 31, 2011, our accumulated deficit was approximately $149.8 million. Currently, we have no products approved for sale in any jurisdiction. We expect to continue to incur significant operating losses for the foreseeable future as we incur costs associated with:

- conducting our pilot and CE clinical trials to obtain human data on our *ReZolve* scaffold;
- seeking regulatory approvals in the EU, Australia, and the U.S. for our *ReZolve* scaffold;
- additional product research and development efforts;
- growing, maintaining, and protecting our intellectual property;
- expanding our manufacturing, sales, and marketing capabilities;
- broadening our infrastructure and systems in order to meet the needs of our operations; and
- complying with the requirements related to being a public company in the U.S. and listed on the Australian Securities Exchange, or ASX.

We cannot predict the extent of our future operating losses and accumulated deficit, and we may never generate sufficient revenues to achieve or sustain profitability. To become and remain profitable, we must succeed in developing and obtaining required regulatory approvals and 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 never succeed in these activities, and we may never obtain regulatory approvals in the markets in which we expect to operate or otherwise generate revenues sufficient to achieve profitability. If we do achieve profitability, we may not be able to sustain it.

Our ability to generate revenue depends upon the successful clinical development, regulatory approval, and commercialization of our ReZolve scaffold.

Our *ReZolve* scaffold and any other products that we develop in the future will require extensive clinical testing, regulatory approval, and significant marketing 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 with the *ReZolve* program, including the enrollment and successful completion of our pilot clinical trial and our planned CE and other clinical trials;
- our *ReZolve* scaffold may not demonstrate safety and efficacy in our clinical trials;
- we may not be able to obtain regulatory approvals for *ReZolve* in the markets in which we expect to operate, or the approved indications for *ReZolve* may be narrower than we currently anticipate;
- our *ReZolve* scaffold may not be accepted in the marketplace by physicians and patients;
- physicians may not receive adequate coverage and reimbursement for procedures using *ReZolve* ;
- new product introductions by our competitors or any rapid technological change may make our technology and product candidates, including the *ReZolve* scaffold, obsolete;
- we may not be able to manufacture *ReZolve* in commercial quantities or at an acceptable cost;
- we are wholly dependent on suppliers of critical components for the *ReZolve* scaffold, including the stent's polymer, the process of lasing the stent components, and the balloon catheter system it deploys from, and we may be significantly impacted by any regulatory delays or barriers that our suppliers may encounter; and
- we may be sued for infringement of intellectual property rights and could be prevented from manufacturing or selling *ReZolve* or our future product candidates.

We cannot market the *ReZolve* scaffold in the EU until we receive a CE Mark or in the U.S. until we receive a PMA. We cannot guarantee that we will receive regulatory approval on a timely basis, or at all. Our operating plan is based in part on our expectations regarding the timing for receipt of the required regulatory approvals and if we experience significant delays in the regulatory approval process, we may be unable to reduce our expenditures in a timely manner to compensate for such delays and we may not have adequate financial or other resources to complete the regulatory approval process. Accordingly, a significant delay in the regulatory approval process for our *ReZolve* scaffold would have a material adverse effect on our business and financial condition. In addition, we may be required to raise additional financing, including equity or debt financing, to fund our operations, which could be dilutive to existing stockholders or require us to relinquish important rights to our technology or products.

We will depend heavily on the success of our lead product, our ReZolve scaffold. Any factors that negatively impact sales of this product will adversely affect our business, financial condition, and results of operations.

If we can obtain the required regulatory approvals, we expect to derive substantially all of our revenues from sales of our first product candidate, the *ReZolve* scaffold. Accordingly, our ability to generate revenues in the future is reliant on our ability to market and sell this device. The degree of market acceptance for *ReZolve* will depend on a number of factors, including:

- the perceived advantages and disadvantages of *ReZolve* compared to existing stents and other treatments and technologies;
- the safety and efficacy of *ReZolve* and prevalence and severity of any adverse events or side effects especially as it relates to survival, quality of life, and bleeding;

- the ease of use of *ReZolve* compared to existing products and competitive treatments and technologies;
- our ability to provide additional clinical data regarding the potential long-term benefits provided by *ReZolve* ;
- the strength of our sales and marketing initiatives; and
- the selling price and the third-party coverage and reimbursement for procedures using *ReZolve* .

If the *ReZolve* scaffold does not achieve an adequate level of acceptance by physicians, patients, and health care payors, we may not generate or maintain positive gross margins and we may not become profitable or be able to sustain profitability. Even if the *ReZolve* scaffold 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.

Physicians may not widely adopt our ReZolve scaffold unless they determine that the use of ReZolve provides a safe and effective alternative to other existing treatments for coronary artery disease.

We believe that physicians will not widely adopt our *ReZolve* scaffold unless they determine, based on experience, long-term clinical data, and published peer reviewed journal articles, that the use of *ReZolve* provides a safe and effective alternative to other existing treatments for coronary artery disease. We cannot provide any assurance that the data collected from our current and planned clinical trials will be sufficient to demonstrate that the *ReZolve* scaffold is an attractive alternative to other stent procedures. If we fail to demonstrate safety and efficacy that is at least comparable to other stents that have received regulatory approval and that are available for sale, our ability to successfully market *ReZolve* will be significantly limited. Even if the data collected from clinical studies or clinical experience indicate positive results, each physician's actual experience with the *ReZolve* scaffold will vary. We also believe that published peer-reviewed journal articles and recommendations and support by influential physicians regarding the *ReZolve* scaffold will be important for market acceptance and adoption, and we cannot assure you that we will receive these recommendations and support, or that supportive articles will be published.

We may need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce, or eliminate our product development programs or commercialization efforts.

Our capital requirements will depend on many factors, including achievement of regulatory approval of our products and the growth of revenue, the amount of expenditures on intellectual property and technologies, the number and size of clinical trials that we conduct, and the extent of new product development. To the extent that our existing capital is insufficient to meet these requirements and cover any losses, we will need to raise additional funds through financings or borrowings and our commercialization efforts would be delayed or reduced or may cease entirely. 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 security holders, and the securities issued in future financings may have rights, preferences, and privileges that are senior to those of our existing security holders. If our need for capital arises because of significant losses, the occurrence of these losses may make it more difficult for us to raise the necessary capital.

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 medical device industry is intense. Our products will compete against products offered by substantial, global, public companies, such as Johnson & Johnson, Medtronic, Abbott Laboratories, and BSC, as well as private companies, such as Biotronik SE & Co. KG. The four global medical device competitors have significantly greater technical, regulatory, financial, manufacturing, and human resources than we do and have established reputations and approved metal stent products and/or significantly greater name recognition, as well as distribution channels and sales and marketing capabilities that are significantly larger and more established than ours. For example, Johnson & Johnson, Medtronic, Abbott Laboratories, and BSC constituted over 95% of the $4.9 billion in global stent sales in 2011.

Additional competitors, including those with a bioresorbable stent technology, may enter the market, and we are likely to compete with companies offering new technologies in the future. We also face competition from other medical therapies which may focus on our target market as well as competition from manufacturers of pharmaceutical and other devices that have not yet been developed. Competition from these companies could adversely affect our business.

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 industry in which we operate has also undergone, and is expected to continue to undergo, rapid and significant technological change, and we expect competition to intensify 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 any products that we may develop. For example, we are aware of companies that are developing various other less-invasive technologies for treating cardiovascular disease, which could limit the market potential for our stents. We also compete with our competitors in recruiting and retaining qualified scientific and management personnel, 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. For all the foregoing reasons, we may not be able to compete successfully against our current and future competitors.

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

The design, manufacture, and sale of human medical devices, particularly implantable life-sustaining medical devices, carries an inherent risk of product liability claims and other damage claims. Such liability claims may be expensive to defend and may result in large judgments against us. A product liability or other damages claim, product recall, or product misuse, regardless of the ultimate outcome, could require us to spend significant time and money 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 financial condition and results of operations. Such claims against us, regardless of their merit, could result in significant awards against us that could materially adversely harm our business, financial condition, results of operations, and prospects. A product liability or other damages claim, product recall, or product misuse involving any type of coronary stent, but especially involving one of ours, could also materially and adversely damage our reputation and affect our ability to attract and retain customers, irrespective of whether or not the claim or recall was meritorious.

We have limited capabilities and manufacturing personnel, and if we are unable to provide an adequate supply of our ReZolve scaffold to support our clinical trials, our regulatory approval timeline may be delayed.

We currently manufacture our *ReZolve* scaffold at our facilities in San Diego, California. If we encounter a disruption to our existing manufacturing facility or the surrounding area, for example, due to a natural disaster, we would have no other means to manufacture *ReZolve* until we were able to restore the manufacturing capability at our facility or develop alternative manufacturing facilities. If we are unable to produce sufficient quantities of *ReZolve* for use in our current and planned clinical trials, or if our manufacturing process yields substandard product, our regulatory approval process may be delayed.

Assuming we receive regulatory approval for our *ReZolve* scaffold, we currently have limited resources and facilities and no prior history of commercially manufacturing products. In addition, we will need to obtain the necessary regulatory approvals to manufacture *ReZolve* for commercialization. In order to produce commercial quantities of *ReZolve* , 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 the investment of additional funds

and hiring and retaining additional management and technical personnel who have the necessary manufacturing experience. We may not successfully complete any required increase 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 the *ReZolve* scaffold or any other product we are developing, or if we cannot do so efficiently, our revenues, business, and financial prospects would be adversely affected.

We rely on specialized suppliers for certain components and processes to manufacture our ReZolve scaffold.

We rely on suppliers for several critical components of the *ReZolve* scaffold, including the stent polymer and the process of lasing the stent components. We purchase the balloon catheter system and outsource sterilization of the finished product. Our reliance on third-party suppliers subjects us to risks that could harm our business, including:

- we are not a major customer of many of our suppliers, and therefore, these suppliers may give other customers' needs higher priority than ours;
- our suppliers have no contractual obligation to supply, and we are not obligated to purchase from them, any components used in our *ReZolve* scaffold, which may result in supply interruptions;
- our suppliers source raw materials through supply chains that periodically are unable to provide needed materials in a timely manner, which may cause delays in providing critical components to us;
- our polymer is complex and must be manufactured to extremely tight tolerances. Our suppliers, especially new suppliers, may make errors in manufacturing that could negatively affect the efficacy or safety of *ReZolve* or cause our components not to be delivered on time or at all, or to be delivered outside of specifications;
- the availability of second-source suppliers may be extremely limited or their implementation as a supplier may be lengthy due to the tight tolerances and specifications that we require for the *ReZolve* scaffold; and
- switching suppliers or changes to our service providers may require product redesign and submission to the regulatory authorities to whom we are seeking approval for *ReZolve* .

Additionally, we may experience problems or delays in our own manufacturing and assembly process. Our current product development plan is predicated on maintaining strong relationships and supply with several external parties to manufacture components of our *ReZolve* scaffold. If we are unsuccessful in this regard or are unable to secure or maintain agreements with these manufacturers on favorable terms or at all, our ability to obtain regulatory approval for our products will be harmed.

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 Robert B. Stockman, our Chief Executive Officer, Robert Schultz, our President and Chief Operating Officer, Katrina Thompson, our Chief Financial Officer, and Jeffrey Anderson, our Vice President of Clinical and Regulatory Affairs, we have not entered into any employment agreements with our executive officers, nor do we maintain key man life insurance on the lives of any of the members of our senior management. Although we have a stock option plan pursuant to which we provide our executive officers with various economic incentives to remain employed with us, these incentives may not be sufficient to retain them. The loss of key personnel for any reason or our inability to hire, retain, and motivate additional qualified personnel in the future could prevent us from sustaining or growing our business.

BSC has an option to distribute our ReZolve scaffold, which may limit our ability to negotiate more favorable terms with other potential distributors.

In December 2007, we entered into a Distribution Option Agreement with BSC under which we granted BSC an option to negotiate the right to be the worldwide, exclusive distributor of our *ReZolve* scaffold. If BSC exercises its option, we are required to negotiate in good faith with BSC to enter into a mutually acceptable definitive distribution agreement. If we are unable to agree on the terms of a definitive distribution agreement with BSC, the restrictions in the Distribution Option Agreement may limit our ability to negotiate more favorable terms with other potential distribution partners.

If we do not enter into a distribution arrangement with BSC, we will need to find another distribution partner for the sale of our product or develop our own sales network. 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 do not have any experience in marketing, selling, or distributing products. Our current strategy is to select a distribution partner to assist in the marketing and sale of our product in jurisdictions where it is approved for commercial sale. There is no guarantee that BSC will exercise its option to distribute our products under the Distribution Option Agreement, or that we will be able to reach a definitive distribution agreement with BSC. If we do not enter into a distribution arrangement with BSC, we will need to find another distribution partner for the sale of our product 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. In the event that we decide to develop our own sales, distribution, and marketing capabilities, we will have to invest significant amounts of financial and management resources. In developing these sales, marketing, and distribution functions ourselves, we will face a number of risks, including:

- the inability to attract and build a significant, successful, or qualified marketing or sales force;
- the cost of establishing, training, and providing regulatory oversight for a marketing or sales force may be substantial; and
- the significant legal and regulatory risks in medical device marketing and sales, and any failure to comply with all legal and regulatory requirements for sales, marketing, and distribution, which could result in enforcement actions by the FDA or other authorities and could jeopardize our ability to market the product or could subject us to substantial liability.

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.

Based on our current operating plan, we may be subject to the risks associated with operating in multiple foreign markets.

Our operations are primarily located in the U.S. In addition to seeking a PMA in the U.S., we currently intend to seek regulatory approvals for our *ReZolve* scaffold in the EU and Australia. If we expand into these and additional 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 the *ReZolve* scaffold or other future products;
- availability of, and changes in, reimbursement within prevailing foreign health care payment systems;
- adapting to the differing laws and regulations, business and clinical practices, and patient preferences in foreign countries;
- difficulties in managing foreign relationships and operations, including any relationships that we establish with foreign partners, distributors, or sales or marketing agents;
- limited protection for intellectual property rights in some countries;
- difficulty in collecting accounts receivable and longer collection periods;
- costs of enforcing contractual obligations in foreign jurisdictions;
- recessions in relevant foreign countries;
- political instability and unexpected changes in diplomatic and trade relationships;
- currency exchange rate fluctuations; and
- potentially adverse tax consequences.

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

Risk Factors Related to Regulation

In order to commence additional human clinical trials we will need to obtain regulatory and other approvals. Any delay in achieving such approvals, or any denial of approval, could have a significant adverse effect on our timeline and ability to commercialize our technology.

To date, we have received all approvals for our pilot human clinical trial, but will need to submit additional applications and receive regulatory approval for any future trials of the *ReZolve* scaffold, including the pivotal CE Mark human clinical trial. There is no guarantee that we will be able to obtain regulatory approval for future clinical trials, and there is no guarantee that additional work and preclinical testing will not be required before regulatory approval is granted. Before we can commence any future clinical trials, we require approvals from:

- relevant Ethics Committees (Investigational Review Boards) in each of our chosen clinical trial centers; and
- relevant regulatory bodies in the applicable countries, such as Brazil, Germany, Australia, and New Zealand.

In the U.S., prior to conducting human clinical trials, we will need to obtain approval of an IDE application from the FDA. Before we can sell our products in the U.S., PMA approval is required from the FDA, which is a lengthy and uncertain process. The procedure for submitting an application for PMA is lengthy, expensive, and typically requires extensive preclinical and clinical trial data as well as considerable technical data. Submitted data will need to be obtained in accordance with FDA QSR. We are planning to use the clinical trial data obtained from our CE Marking trial to facilitate a more expedient U.S. approval process. There is a risk that the FDA may not allow the data to be used in the PMA application, which would result in a delay and increase in costs of U.S. approvals.

We cannot predict the outcome of our human clinical trials. If the ReZolve scaffold does not meet its intended clinical results or causes adverse or unexpected events, we may need to further modify its design or other technology. There is no guarantee that we will be able to address any issues arising from the clinical trials, which could be catastrophic for our future prospects.

The outcome of human clinical trials cannot be predicted, even when preclinical results are favorable. If our *ReZolve* scaffold causes adverse issues such as restenosis, stroke, thrombosis, and/or death, it is likely the human clinical trial will need to be halted. In such case, we may need to modify our technology to address these issues while also meeting the market requirements for stent products. Our clinical trials may also be suspended or terminated at any time by EU regulatory authorities, the U.S. Data Safety and Monitoring Board, or by us, including during the closing stages of enrollment of the trial and the subsequent patient follow-up period lasting up to 12 months. There is no guarantee that we will be able to successfully address and overcome any adverse events arising in the human 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.

We performed a small human clinical trial in 2007 with 25 patients in Brazil and Germany on an early version of our stent. We achieved deployment success, demonstrating the stent’s ability to dilate and hold the lesion, as anticipated and consistent with the results of our preclinical data. However, at approximately four months, we saw adverse device performance resulting in a higher than anticipated number of patients requiring retreatment with another stent. These issues were primarily associated with the brittle nature of the polymer that resulted in fractured supporting elements of the stent. We addressed these issues by modifying the design and the composition of the polymer used in our *ReZolve* scaffold. These modification activities have been our primary focus for the past four years, during which time we used cash for operating activities of nearly $50.8 million, to the exclusion of other development activities and opportunities.

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

- delays in receiving the necessary regulatory approvals to commence the CE Mark Trial;
- slower than expected rates of patient recruitment and enrollment, including as a result of our competitors' undertaking similar clinical trials or having functionally comparable products that are approved for sale;
- failure of patients to complete the clinical trial;
- patients preferring to use approved devices or other experimental treatments or devices, rather than our *ReZolve* scaffold;
- unforeseen safety issues;
- inability or unwillingness of patients or medical investigators to follow our clinical trial protocols;
- inability to monitor patients adequately during or after treatment;
- risks associated with trial design, which may result in a failure of the trial to show statistically significant results even if the product is effective;
- 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.

The process of obtaining marketing approval or clearance from regulatory authorities for our *ReZolve* 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;
- require changes to our products; and
- 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 will otherwise be able to satisfy the conditions of such approval, if any. The failure to receive product approval clearance by the regulatory authorities will have a material adverse effect on our business, financial condition, and results of operations.

We do not have long-term data regarding the safety and efficacy of our ReZolve scaffold. Any long-term data that is generated 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 *ReZolve* scaffold may be measured, is the rate of restenosis, or the renarrowing of the treated artery over time, and the rate of reintervention, or retreatment, following procedures that use *ReZolve* . We believe that physicians and regulators will compare the rates of long-term restenosis and reintervention for *ReZolve* against other bioresorbable, drug-eluting, or bare-metal stent procedures and other alternative procedures.

If we fail to demonstrate restenosis and reintervention rates, as well as other clinical trial endpoints and product performance comparable to other stents that have been approved by the FDA and other regulatory authorities, our ability to successfully market our *ReZolve* scaffold may be significantly limited. If the long-term rates of restenosis and reintervention do not meet regulators' or physicians' expectations, *ReZolve* may not receive regulatory approval or, if approved, may not become widely adopted and physicians may recommend that patients receive alternative treatments. Another performance measurement of *ReZolve* will be the incidence of late-stent thrombosis. We cannot assure you that our long-term data, once obtained, will prove a lower incidence of late-stent thrombosis as compared to drug-eluting metal stents. If the results obtained from our clinical trials indicate that our products are not as safe or effective as other treatment 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 *ReZolve* scaffold. 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 planned manufacturing facilities and the manufacturing facilities of our suppliers must comply with applicable regulatory requirements. If we fail to achieve regulatory approval for these manufacturing facilities, 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, manufacturing facilities that meet applicable regulatory standards to manufacture a sufficient supply of our products. Approvals are required to achieve CE Marking in Europe, and similar approvals must be obtained from the FDA for facilities that manufacture our products for U.S. commercial 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 have received marketing approval or clearance, 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, including the FDA's QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage, and shipping of our products. The FDA enforces the QSR through periodic unannounced site inspections.

In addition, the U.S. federal medical device reporting regulations require us to provide information to the FDA whenever there is evidence that reasonably suggests a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. If we fail to comply with the QSR or to take satisfactory corrective action in response to an adverse QSR inspection, we could be subject to enforcement actions, including a public warning letter, a shutdown of or restrictions on our manufacturing operations, delays in approving or clearing 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.

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 13485:2003. In the future, if we fail to continue to comply with ISO regulations, the FDA or EU regulatory authorities may withdraw clearance to market, require a product recall, or take other enforcement action.

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

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

If we fail to obtain and maintain adequate level of 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 availability and levels of reimbursement by governmental and other third-party payors affect the market for our products. Reimbursement and health care payment systems vary significantly by country, and include both government sponsored health care and private insurance. Payors may attempt to limit coverage and the level of reimbursement of new therapeutic products. Government and other third-party payors also continually attempt to contain or reduce the costs of health care by challenging prices charged for health care products and services.

To obtain reimbursement or pricing approval in some countries, we may be required to produce 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 U.S. 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 would 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 to, among other things, conduct, support, or synthesize research that compares and evaluates the risks and benefits, clinical outcomes, effectiveness, and appropriateness of medical products. Although Congress has indicated that this funding is intended to improve the quality of health care, 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 U.S., there have been numerous initiatives on federal and state levels for comprehensive reforms affecting the availability of, and reimbursement for, health care services. These initiatives have ranged from proposals that would fundamentally change federal and state health care reimbursement programs, including providing comprehensive health care coverage to the public under governmental funded programs, to minor modifications of existing programs. Recently, President Obama and members of Congress passed and continue to propose significant reforms to the U.S. health care system. Both the U.S. Senate and House of Representatives have conducted hearings about U.S. health care reform and a number of bills have been proposed in Congress.

In addition, recent 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 U.S. or other health care systems, they may have a material adverse effect on our financial condition and results of operations.

In March 2010, Congress enacted comprehensive health care reform legislation known as the Patient Protection and Affordable Care Act of 2010, or the “PPACA.” While the PPACA expands coverage to more individuals, it includes new regulatory mandates and other measures designed to constrain medical costs. The PPACA also imposes significant new taxes on medical device manufacturers that are expected to cost the medical device industry up to $20 billion over the next decade. There are also stringent new reporting requirements of financial relationships between device manufacturers and physicians and teaching hospitals. Complying with the PPACA could significantly increase our costs and adversely affect our business and financial condition.

Our operations will also be impacted by the PPACA, as modified by the Health Care and Education Reconciliation Act of 2010, which we refer to as the “Health Care Act.” The Health Care Act imposes a 2.3 percent excise tax on sales of medical devices by manufacturers. There is no exemption for small companies and we expect our stent products to fall within the scope of this tax; consequently, we expect to incur this tax upon commercialization. The Health Care

Act also requires manufacturers to report to the Department of Health and Human Services detailed information about 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 Health Care Act 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, including anti-kickback, self-referral, false claims, and fraud laws, and any violations by us of such laws could result in fines or other penalties.

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

The federal False Claims Act, or "FCA," imposes liability on persons who, among other things, present or cause to be presented 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.

State and federal authorities have aggressively targeted medical device companies for alleged violations of these anti-fraud statutes, based on 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. Companies targeted in such prosecutions have paid substantial fines in the hundreds of millions of dollars or more, have been forced to implement extensive corrective action plans, and have often become subject to consent decrees severely restricting the manner in which they conduct their 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 confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

There are a number of federal and state laws in the U.S. protecting the confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services promulgated patient privacy rules under the Health Insurance Portability and Accountability Act of 1996, or "HIPAA." These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend, and seek accounting of their own health information, and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. If we are found to be in violation of the HIPAA privacy rules, we could be subject to 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 depend on licenses to certain patents and other technology used in our *ReZolve* scaffold. For example, we rely on certain licensed patents from Rutgers University for the polymer we use. 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 and licenses to these patents were provided to one or more of our competitors, our ability to

compete may be diminished. Furthermore, if we fail to comply with our material obligations under this license agreement, the license may be terminated and we could lose license rights that are important to our business. In addition, the license agreement expires on the expiration of last to expire patents under this agreement which is approximately 2030, and there is no guarantee we will be able to renew the license agreement on commercially reasonable terms.

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

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

Our commercial success is dependent in part on obtaining, maintaining, and enforcing intellectual property rights, including patents, covering our *ReZolve* scaffold and future product candidates. 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 that are substantially the same as ours without incurring the sizeable development and licensing costs that 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 close to 290 issued U.S. and foreign patents which we own directly or for which we are the exclusive licensee and that expire as late as 2031. Pending patent applications could further extend our patent portfolio life. However, patents may not be issued based on any pending 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. Also, 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 and maintain patents and otherwise protect the licensed 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 U.S. 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 patent laws of the U.S. 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 which 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 a number of foreign patents and applications. However, the laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as laws in the U.S. 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 U.S. 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 the stent and stent delivery systems in the medical device industry. We face significant risks relating to patents, in our own patent position as well as to patents held by third parties. If any third-party intellectual property claim against us is successful, we could be prevented from commercializing our *ReZolve* scaffold or other products.

There are numerous U.S. and foreign issued patents and pending patent applications owned by third parties with patent claims in areas that are the focus of our product development efforts. We are aware of patents owned by third parties, to which we do not have licenses, that relate to, among other things:

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

Moreover, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that pose a material risk to us.

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 Laboratories, Johnson & Johnson, 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. 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 the expenditure of significant financial resources 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 or license the infringed or similar technology on a timely and cost-effective basis, our revenues may decrease substantially and we could be exposed to significant liability. A court could enter orders that temporarily, preliminarily, or permanently prevent us or our customers from making, using, selling, offering to sell, or importing our current or future products, or could enter an order mandating that we undertake certain remedial activities. Claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our reputation, business, financial condition, or results of operations.

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

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

- assert claims of infringement;

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

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

Risks Related to Our CDIs and Common Stock

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

We are a development stage company without a product that has been approved for sale; consequently, we have no revenues and continue to generate operating losses. Our CDIs and common stock had not been publicly traded prior to our initial public offering, which was completed in December 2010. Our securities are listed for sale only on the ASX. Until we achieve commercialization and start generating revenues and cash receipts 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 be continue to be volatile. Among the factors that may cause the market price of our CDIs to fluctuate are the risks described in this "Risk Factors" section and other factors, including:

- announcements regarding our development progress, including delays or advancements in our timelines;
- announcements regarding the regulatory status of our *ReZolve* scaffold and future product candidates;
- any reported adverse effects in our human clinical trials for our *ReZolve* scaffold;
- announcements of technological innovations or new products by us or our competitors;
- announcements of 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 our executive management team;
- 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 trading volume of our CDIs; and
- changes in general economic, industry, and market conditions.

The stock markets in general, and the markets for medical technology companies in particular, have experienced volatility that has often been unrelated to the operating performance of particular companies. These broad market and industry factors may materially harm 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 further materially harm our financial condition and results of operations.

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

Although our CDIS are listed on the ASX, there can be no guarantee of a ready liquid market for our CDIs, particularly since a small number of security holders own a majority of our outstanding capital. It may be more difficult for an investor to realize his or her 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 or the NASDAQ Stock Market.

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

We cannot assure investors that we will always retain a listing on ASX. If we fail to retain such a listing, certain investors may decide to sell their securities, which could have an adverse impact on the share price. In addition, our common stock is not listed for trading on any U.S. securities exchange. There is no assurance that we can qualify in the future for listing any of our securities on the New York Stock Exchange or the NASDAQ Stock Market.

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

As of February 15, 2012, officers, directors, and stockholders holding more than five percent of our outstanding shares collectively controlled approximately 67% of our outstanding common stock based on their respective beneficial ownership of our common stock (assuming conversion of CDIs). 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.

Sales of a substantial number of common shares or CDIs in the public market, or the perception that these sales may occur, could cause the market price of our CDIs to decline. The holders of an aggregate of approximately 21.5 million shares of our outstanding 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. Additionally, the holders of an aggregate of approximately 21.1 million shares of our outstanding common stock had been subject to escrow agreements prohibiting sales since the date of our initial public offering; the escrow agreements expired in June 2011 and, therefore, those shares are no longer restricted from sale.

In April 2011, we filed a registration statement covering common stock issued or reserved for such issuance under our stock incentive plans; the underlying shares can now 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, subject to vesting provisions or other contractual arrangements. In addition, our 2010 Equity Incentive Plan provides for annual increases in the number of shares available for issuance under the plan, which we intend to register annually.

We may sell additional common stock in subsequent public offerings, which may adversely affect the market price for our CDIs and common stock.

We have broad discretion in the use of our assets, including the net proceeds from our initial public offering, and our investment of these proceeds 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, including the remaining proceeds from our initial public offering, and may use them for a broad range of purposes. Accordingly, security holders will have to rely upon the judgment of our management with respect to the use of the Company's assets. Our management may spend a portion or all of the Company's assets, including the net proceeds from our initial public offering, 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 the net proceeds from our initial public offering 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 of directors and will depend on our results of operations, capital requirements, financial condition, future prospects, contractual arrangements, restrictions imposed by applicable law, any limitations on payments of dividends present in any debt agreements we may enter into, and other factors our board of directors may deem relevant. If we do not pay dividends, your ability to achieve a return on your investment in our company will depend on any future appreciation in the market price of our CDIs. 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, our reporting currency is 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.

We expend substantial costs and management resources to comply with the laws and regulations affecting public companies in the U.S. as well as listing requirements of the ASX, which may adversely affect our operating results, and failure to maintain effective internal control over financial reporting in accordance with the Sarbanes-Oxley Act could cause investors to lose confidence in our operating results and in the accuracy of our financial reports and could have a material adverse effect on our business and on the market price of our CDIs.

As a public company in the U.S. with equity securities listed on the ASX, we are required, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or "Section 404," to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. The controls and other procedures are designed to ensure that information required to be disclosed by us in the 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 or the degree of compliance with these policies or procedures may deteriorate, or weaknesses in our internal control over financial reporting may be discovered. If we or our auditors are unable to certify that our internal control over financial reporting is effective and in compliance with Section 404, or we are unable to produce timely or accurate financial statements, we may be subject to sanctions or investigations by regulatory authorities such as the SEC, 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.

As a U.S. public company with securities listed on the ASX, we incur substantial legal, accounting, and other reporting and shareholder expenses. In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC, may increase legal and financial compliance costs and make some activities more time consuming. Since our securities are publicly traded on the ASX in the form of CDIs, we must comply with ASX Listing Rules. We have policies and procedures that we believe are designed to provide reasonable assurance of our compliance with the ASX Listing Rules; however, if we do not follow those procedures and policies, or they are not sufficient to prevent non-compliance, we could be subject to 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.

Failure to comply with these rules 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.

Provisions of our certificate of incorporation, our bylaws, and Delaware corporation law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove the current members of our board and management.

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. Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions:

- allow the authorized number of directors to be changed only by resolution of our board of directors;
- provide that our stockholders may only remove our directors for cause;
- establish a classified board of directors so that not all members of the board may be elected at one time;
- authorize our board of directors to issue, without stockholder approval, 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 our board of directors;
- require that stockholder actions must occur at a duly called stockholder meeting or by unanimous written consent;
- establish advance notice requirements for stockholder nominations to our board of directors or for stockholder proposals that can be voted at stockholder meetings;
- limit who may call stockholder meetings; and
- require approval from 80% of the outstanding shares of our capital stock in order to amend certain provisions of our certificate of incorporation and bylaws.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% 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. The lease on this facility expires in January 2018. Prior to November 2011, we leased approximately 17,000 square feet of space in this facility; we expanded our lease to include the entire building, adding an additional 20,000 square feet, in November 2011. We are currently remodeling a portion of the added space, installing additional chemical and engineering lab space, and plan to add additional clean room capacity during 2012.

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 enrollment of our planned CE Mark clinical trial. We may consider additional or different facilities and locations for manufacturing our commercial products.

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 of this Annual Report on Form 10-K.

Item 4. Mine Safety Disclosures

None.

PART II

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

Market Information

Commencing December 23, 2010, our shares of 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." Prior to such time, there was no public market for our securities. Between January 1, 2011 and December 31, 2011, the closing price of our CDIs ranged from a low closing price of A$0.57 to a high closing price of A$1.38, or a low closing price per share of common stock of $5.63 and a high closing price of $14.31 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.

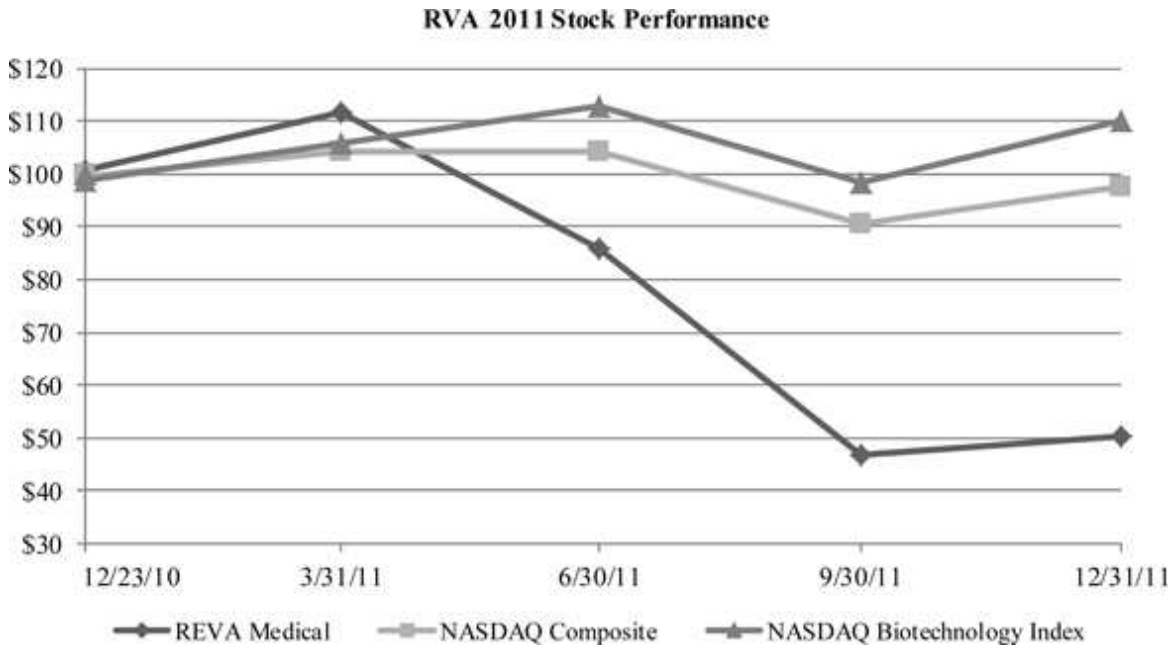
The high and low closing prices for our CDIs during each quarter in 2011, and on an equivalent basis as converted to common stock and U.S. dollars, were as follows:

- First quarter 2011: High of A$1.38 and low of A$1.15 per CDI
High of $14.15 and low of $11.45 per common share
- Second quarter 2011: High of A$1.35 and low of A$0.88 per CDI
High of $14.31 and low of $9.26 per common share
- Third quarter 2011: High of A$1.00 and low of A$0.59 per CDI
High of $10.73 and low of $5.87 per common share
- Fourth quarter 2011: High of A$0.62 and low of A$0.57 per CDI
High of $6.49 and low of $5.63 per common share

As of February 15, 2012 we had 33,076,203 shares of common stock issued and outstanding with approximately 769 holders of record. The holders included CHESS Depositary Nominee Pty Limited, which held 14,738,224 shares of our common stock in the form of CDIs on behalf of the CDI holders; there were approximately 707 registered owners of our CDIs on February 15, 2012.

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 Australian Securities Exchange) through December 31, 2011. 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 into shares of common stock. The comparisons in the table are required by the SEC 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.

Use of Proceeds from Public Offering of Common Stock

In December 2010, we completed an initial public offering of our common stock, in which we sold 77,272,730 CDIs, representing 7,727,273 shares of common stock, at a price to the public of A$1.10 per CDI or A$11.00 per share. The aggregate offering price for CDIs sold in the offering was A$85.0 million (which equated to approximately US$84.3 million). The CDIs 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. We also lodged a Prospectus with the Australian Securities and Investments Commission prior to the allotment and issuance of CDIs under the offering. We raised approximately US$76.2 million in net proceeds after deducting placement agent fees and other offering expenses. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service.

Of the net proceeds received in the IPO, we had expected, and continue to expect, to use approximately:

- $40.0 million for research and development activities, including continuing development of our *ReZolve* scaffold;
- $10.0 million for clinical trials;
- $4.0 million for commercial infrastructure, including manufacturing capacity expansion; and
- the balance for working capital and other general corporate purposes.

The foregoing expected use of the net proceeds represents our current intentions based upon our present plans and business condition. The amounts and timing of our actual expenditures may vary significantly and will depend upon numerous factors, including the timing and success of our development efforts and clinical trials. We plan to commence clinical trials in the U.S. after we receive acceptable data from the European clinical trials. Due to the regulatory requirements in the United States that require a study with a large number of patients, we anticipate needing additional funding in order to carry out the U.S. clinical trials.

Pending the use of net proceeds, we have invested the offering proceeds in accordance with our investment policy, which allows for short-term and long-term interest-bearing obligations, investment grade instruments, certificates of deposit, or guaranteed obligations of the U.S. government.

Item 6. Selected Financial Data

We have derived our statements of operations data for the years ended December 31, 2007 and 2008 and our balance sheet data as of December 31, 2007, 2008, and 2009 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, 2009, 2010, and 2011 and our balance sheet data as of December 31, 2010 and 2011 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 U.S., 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 Annual Report on Form 10-K.

	Year Ended December 31,				
	2007	2008	2009	2010	2011
	(In thousands, except per share data)				
Statements of Operations Data:					
Operating Expense:					
Research and development	$ 8,536	$ 11,378	$ 10,272	$ 6,826	$ 13,401
General and administrative	2,247	2,205	2,241	3,292	7,695
Loss from operations	(10,783)	(13,583)	(12,513)	(10,118)	(21,096)
Other Income (Expense):					
Interest income	94	124	26	116	188
Interest expense [1]	(2,745)	(1,874)	(1,579)	(1,549)	—
Interest from amortization	—	—	—	2,283	—
Gain (loss) on change in fair value of preferred stock rights and warrant liabilities	(47)	2,617	215	(990)	—
Loss on extinguishment of notes payable	—	—	—	(13,285)	—
Other income	2	2	7	36	—
Net Loss	(13,479)	(12,714)	(13,844)	(23,507)	(20,908)
Cumulative dividends and deemed dividends on Series H convertible preferred stock	(63)	(1,074)	(2,358)	(7,200)	—
Net Loss Attributable to Common Stockholders	$ (13,542)	$ (13,788)	$ (16,202)	$ (30,707)	$ (20,908)
Net Loss Per Share [2] :					
Net loss per share, basic and diluted	$ (5.02)	$ (5.06)	$ (5.91)	$ (7.72)	$ (0.64)
Shares used to compute net loss per share, basic and diluted	2,695,245	2,727,191	2,739,229	3,975,144	32,777,509

(1) Includes amounts pertaining to related parties of $2,619, $1,794, $1,532, and $1,510 for the years ended December 31, 2007, 2008, 2009, and 2010, respectively.

(2) 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,				
	2007	2008	2009	2010	2011
			(In thousands)		
Balance Sheet Data:					
Cash and cash equivalents	$ 8,648	$ 8,036	$ 7,233	$ 81,747	$ 59,161
Short- and long-term investments	—	—	—	—	5,226
Working capital	7,244	13,621	6,085	80,984	59,847
Total assets	9,436	16,524	8,442	83,475	67,320
Notes payable (1)	19,822	19,883	20,304	—	—
Accrued interest on notes payable (2)	4,375	5,813	6,971	—	—
Repayment premium on notes payable (3)	11,100	11,100	11,100	—	—
Preferred stock warrant liability	800	995	780	—	—
Total liabilities	41,654	39,867	40,402	1,528	2,737
Convertible preferred stock	39,994	61,913	69,071	—	—
Deficit accumulated during the development stage	(74,172)	(86,887)	(101,033)	(128,903)	(149,811)
Total stockholders' equity (deficit)	(72,212)	(85,256)	(101,031)	81,947	64,583

(1) Includes $19,547, $19,636, and $20,029 as of December 31, 2007, 2008, and 2009, respectively, held by related parties.
(2) Includes $4,298, $5,718, and $6,857 due to related parties as of December 31, 2007, 2008, and 2009, respectively.
(3) Includes $10,550 due to related parties as of December 31, 2007, 2008, and 2009.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the "Selected Consolidated Financial Data" and our consolidated financial statements and the related notes thereto that appear elsewhere in this Annual Report on 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" elsewhere in this Annual Report on Form 10-K. See also "Forward-Looking Statements" included elsewhere in this Annual Report on Form 10-K.

Overview

We are a development stage medical device company working toward commercialization of our proprietary technologies to provide minimally invasive medical devices for treatment of conditions in the human body. Since the inception of our company 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 developing a bioresorbable drug-eluting coronary stent that we have named the *ReZolve* scaffold. In a clinical use, the scaffold is implanted by an interventional cardiologist during a minimally invasive surgery to a coronary artery location with a delivery catheter system. The scaffold combines our proprietary stent design with a proprietary polymer that is metabolized and cleared from the body over time, leaving the body free of a permanently implanted device. We have invested significant time and funds in the development of the *ReZolve* scaffold and have performed significant scientific research, engineering development, and testing of the stent in laboratory and preclinical studies. We believe the results of this testing have shown the technology to be safe and effective and that it is suitable for final development and human clinical studies; accordingly, we initiated a 50-patient pilot clinical trial in December 2011 in Brazil and Europe.

We believe that due to the risks and limitations associated with commercially available metal stents, bioresorbable stents will be the next major advance in coronary stent technology. Because we have designed our stent to provide the same benefits as traditional metal stents, but with the additional benefit of eliminating the need for a permanently implanted device, we believe that if we are able to complete development and clinical testing of the stent, if we are able to successfully implement manufacturing processes and procedures, and if it is approved for sale by the relevant regulatory authorities, our stent will enable us to compete effectively in the worldwide stent market. Worldwide revenues from coronary stent sales approximated $4.9 billion in 2011.

The initiation of our RESTORE pilot clinical trial in Brazil and Europe followed extensive development efforts. During the development of the *ReZolve* scaffold, we 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 stent. We designed and performed extensive preclinical tests that ranged from bench and engineering studies to in vitro and in vivo laboratory studies. As part of the development, in 2007 we enrolled patients in a small clinical study that proved the viability of our technology while confirming the areas needing further development and we have been advancing the product design and features since.

We anticipate completing enrollment in the pilot clinical trial during the second quarter of 2012 and obtaining data from the trial throughout 2012. If acceptable results from the pilot trial are achieved, we will initiate a larger scale human clinical trial that will provide the data needed to apply for CE Mark approval in Europe. If and when we receive CE Mark approval, we plan to sell our *ReZolve* scaffold in Europe. In order to produce quantities of the stent large enough to accommodate the clinical trials and 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 stent dimensions. We have begun preliminary development of the methods and processes for the manufacturing scale-up and we plan to work on the dimensional and other aspects in 2012.

During our development of the *ReZolve* scaffold, 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 perform feasibility tests on additional technologies in our patent portfolio at the same time we are finalizing our *ReZolve* scaffold and, if feasibility is proven, determine a course of development for potential products and, thus, provide a follow-on product pipeline.

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 million had been invested and used, this technology became the basis for the “slide & lock” mechanism we are currently using. Additionally, the company 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 stent product. Although the drug’s development was abandoned in 2004 after we had invested approximately $6 million, the knowledge we gained from that program was used in our development of the drug coating for the *ReZolve* scaffold. We also 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.

We have performed all of our research and development activities from one location in San Diego, California. As of December 31, 2011, we had 62 employees, a majority of which are degreed professionals and four of whom are PhDs. We leverage our internal expertise with contract research and preclinical laboratories, outside polymer and catheter manufacturing, and other outside services as needed. We have two clean rooms and multiple engineering and chemistry labs at our facility, in addition to our corporate and administrative office. We are ISO certified to the medical device standard 13485:2003 and intend to maintain the certification to support our commercialization plans.

We have not yet developed a product to a saleable stage and we have not, therefore, generated any product or other revenues. Our development efforts have been funded with a variety of capital received from angel investors, venture capitalists, strategic partners, hedge funds, and the proceeds from our IPO. Since our inception, we have received approximately $154 million in equity proceeds and $29 million from issuance of notes payable (such notes payable were converted to common stock upon consummation of our IPO in December 2010). As of December 31, 2011, we had approximately $64 million in cash and investments available for operations. We have incurred substantial losses since our inception; as of December 31, 2011, we had accumulated a deficit of approximately $150 million. We expect our losses to continue for the next several years as we continue our development work and, if these efforts are successful and we are able to obtain approval to sell our products, we expect to commence commercial sales thereafter.

Key Components of our Results of Operations

Since we are still in a pre-revenue stage and our activities are focused on further developing and testing our bioresorbable coronary stent with the goal of commercially selling it, as well as performing minimal research and tests to determine the feasibility of other product possibilities, our operating results primarily consist of research and development expenses, including costs to perform clinical trials, and general and administrative expenses.

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 stents and other product possibilities. Our external costs primarily consist of contract research, engineering consulting, polymer 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. Through December 31, 2011, we have incurred approximately $87.7 million in research and development expenses since our inception, which represents approximately 76% of our cumulative operating expenses. We increased the level of our research and development activities in 2011 as we prepared for human clinical trials. We expect a significant increase in our clinical study costs in the future due to the initiation of our pilot clinical trial in December 2011 and, if the pilot trial is successful, our larger scale follow-on clinical trial that will provide the data for a CE Mark application in Europe.

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. Through December 31, 2011, we have incurred approximately $27.9 million in general and administrative expenses since our inception, which represents approximately 24% of our cumulative operating expenses. We anticipate that we will continue to invest in patents at similar levels as we have in the past. Upon completion of our initial public offering ("IPO") in December 2010, we began to expand our corporate infrastructure including the addition of personnel and reporting systems, and also began to incur public company reporting and other costs. We anticipate that we will continue to expand our corporate infrastructure, 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.

Other Expense and Income: A majority of our non-operating expenses consist of interest expense that arose from our notes payable. The notes were issued to individuals and investment funds that also provided equity capital to us. All the notes, along with the accumulated accrued interest, converted into common stock upon our IPO in December 2010. Although the notes were issued between 2003 and 2006, the terms of the notes allowed us to accrue and record the interest due on them, but defer payment of both the principal balance and the interest. Through December 31, 2010, we recorded approximately $9.6 million of interest and $11.1 million in repayment premiums on our notes payable. Additionally, in October 2010, we modified the conversion features of the notes payable, but did not repay or change any repayment terms of the notes. In accordance with applicable accounting requirements, the conversion feature modifications resulted in our recording $13.3 million of loss on extinguishment of notes payable and $2.3 million in interest income from amortization of note premium during the year ended December 31, 2010.

In conjunction with issuing our notes payable, we issued warrants to purchase preferred stock; these warrants were exercised for cash and on a net issuance basis upon consummation of our IPO in December 2010 and none remained outstanding at December 31, 2010. We recorded non-cash interest expense for the initial value of the warrants and recorded gains and losses for subsequent changes in fair value of the warrants. Through December 31, 2010, a total of $1.8 million in net expense has been recorded for these warrants.

Concurrent with the completion of our IPO, all of our outstanding convertible preferred stock, non-voting common stock, notes payable, and accrued interest on notes payable converted to common stock. Additionally, all outstanding warrants were exercised for common stock, either through a cash payment to us or on a net exercise basis. We also issued common stock for cumulative dividends on our Series H convertible preferred stock. A total of 22,419,771 shares of common stock were issued from these conversions, exercises, and dividends.

Since our inception, when we have had excess cash on hand we have invested in short- and long-term high-quality marketable securities such as certificates of deposit and U.S. Treasury Bills. Earnings from these investments are recorded as interest income; through December 31, 2011, we have recorded a total of approximately $1.3 million in such interest income.

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 Notes 3 and 4 to our consolidated financial statements included elsewhere in this Annual Report on 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 enroll patients in our pilot trial, which began in December 2011, and, if successful, our follow-on larger clinical trial. We expect to make estimates as to the work performed throughout the term of these trials, which is expected to be five years or longer. As a public company, we are required to make these estimates in shorter time frames and with less actual data than we have in the past, which may result in our estimates being less accurate and subject to possible material changes in our accruals, which could also 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 have granted stock options to employees and consultants for the purchase of common stock. These options generally have a ten-year life during which the option holder can exercise at any time, they generally vest over a four- or five-year service period, and their exercise price equals the fair market value of our common stock on the date they are granted.

For options granted to employees, we determine the amount of compensation expense by estimating the fair value of each option on its date of grant and then we amortize that fair value on a straight-line basis over the period the employee provides service, which generally is the five-year expected life, and record the expense in our statement of operations as either research and development expense or general and administrative expense based on the employee's work classification. We estimate the fair value by using the Black-Scholes option pricing model, which is more fully described above. For the model inputs, we use the estimated value of the underlying common stock, a risk-free interest rate that corresponds to the vesting period of the option, an expected life of the option ranging from 6.25 to 6.5 years, and an estimate of volatility based on the market trading prices of comparative peer companies. Additionally, we reduce the amount of recorded compensation expense to allow for potential forfeitures of the options; the forfeiture rate is based on our actual historical forfeitures and has ranged from approximately 2.5 percent to 5.3 percent. For options granted to consultants, we estimate the fair value at the date of grant and at each subsequent accounting date and record compensation expense in our statement of operations based on the fair value during the service period of the consultant, which is generally the five-year vesting period. 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. As a result of our use of estimates, if factors change and we use different assumptions, the amount of our stock-based compensation expense could be materially different in the future.

During the past five years, we have made very few grants of options. We made one grant of options to purchase 401,000 shares to employees in 2011; there were no grants made to non-executive directors or to our CEO, COO, or CFO during 2011. We made one grant of options to purchase a total of 1,467,500 shares to three employees and five directors during 2010. We made one grant of options to purchase a total of 50,000 shares to three consultants in 2009. We expect to increase our frequency of granting options beginning in 2012 and, combined with the effects of the 2010 and 2011 option grants, expect our stock-based compensation to continue to increase.

Operating Leases: We currently lease our office 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, a leasehold improvement allowance of $478,000, and a retroactive rent credit of $45,000. We recognize rent expense on a straight-line basis in accordance with accounting guidance; differences between actual cash payments compared to rent expense recognized are aggregated as a deferred liability.

Critical Accounting Policies of Financial Statement Components Discontinued upon IPO: Concurrent with the completion of our IPO in December 2010, all of our outstanding convertible preferred stock, non-voting common stock, notes payable, and accrued interest on notes payable converted to common stock. Additionally, all outstanding warrants were exercised for common stock, either through a cash payment to us or on a net exercise basis. We also issued common stock for cumulative dividends on our Series H convertible preferred stock. Following are the significant accounting policies related to those debt and equity instruments, which have no effect on our financial statements after December 2010.

Notes Payable: We recorded our notes payable at their face values, accrued interest on the notes at their stated interest rates, and amortized or accreted any related discounts or premiums over the original term of a note using the effective interest method. When we amended a note, such as extending its maturity date, we performed an analysis based on applicable accounting guidelines to determine if the amendment results in an accounting impact. We first considered whether the amendment would qualify as a troubled debt restructuring. If the amendment was not considered a troubled debt restructuring, we considered whether the amendment should be accounted for as an extinguishment or a modification of debt. If the amendment was determined to be an extinguishment of a note, we removed the carrying value of the note, recording an extinguishment gain or loss to non-operating expense in our statement of operations, and recorded the note at its fair value as determined using the amended terms. We then amortized or accreted the difference between the fair value and the face value of the note over the amended term of the note using the effective interest method. If the note had an embedded conversion feature and the amendment is determined to be a modification of the note, as defined by accounting standards, then any increase in the fair value of the conversion feature resulting from the amendment was accounted for as a reduction in the carrying amount of the note (as an additional discount or reduction in premium) with a corresponding increase in additional paid-in capital. All amounts amortized or accreted over the term of a note were recorded as interest expense or interest income in our statement of operations. All notes payable and related accrued interest were converted to common stock upon our IPO.

Preferred Stock Warrant Liability: Periodically, we had issued warrants to purchase preferred stock in conjunction with issuing notes payable. When we issued a warrant to purchase preferred stock, we recorded the fair value of the warrant as a liability, as required by accounting standards, with the related expense amortized to interest in our statement of operations over the term of the note payable. The warrant liability was adjusted to its current fair value at each reporting date until the earlier of its exercise or the end of its contractual life. Our warrants had lives ranging from five to ten years. To determine the fair value of the warrant liability, we utilized the Black-Scholes option-pricing model, which required use of subjective assumptions. The assumptions used represented our best estimates, but these estimates involved inherent uncertainties. We used an estimate of the value of the underlying preferred stock, a life equal to the warrant's contractual life, risk-free interest rates that corresponded to the warrant's remaining life, and an estimate of volatility based on the market trading prices of comparative peer companies. All preferred stock warrants were exercised upon our IPO.

Common Stock Warrants: We had issued warrants to purchase common stock only in conjunction with issuances of convertible preferred stock; those warrants had five-year lives. When we issued a warrant to purchase common stock, we recorded the fair value of the warrant on the date of issuance as a component of stockholders' equity and reduced the recorded proceeds of the related preferred stock by an equal amount. To determine the fair value of a common warrant, we utilized the same approach as we used to value warrants issued to purchase preferred stock. All of our common stock warrants were exercised upon our IPO.

Fair Value of Stock: Because our stock was not publicly traded prior to our initial public offering in December 2010, its fair value was determined by our board of directors on various dates, including the dates we granted options to purchase common stock. Our board, which includes members who were experienced in valuing the securities of early-stage companies, considered a number of subjective and objective factors in their determination, including:

- the prices of our convertible preferred stock sold to outside investors in arm's-length transactions, and the rights, preferences, and privileges of each series of stock;

- our results of operations, our financial position, the status of our research and development efforts, including preclinical trial results, and the length of time until occurrence of clinical trials and a commercial product;
- the market values of medical device companies that were in a stage of development or industry similar to us;
- the lack of liquidity of both our preferred and common stock as a private company;
- contemporaneous valuations performed by an unrelated valuation specialist in accordance with methodologies outlined in the *AICPA Practice Aid Valuation of Privately-Held-Company Equity Securities Issued as Compensation* ;
- the likelihood and timing of achieving a liquidity event, such as an initial public offering, given prevailing market conditions; and
- the material risks related to our business.

We believe our historical fair value estimates of our common and preferred stock were reasonable and consistent with the AICPA valuation guidance for private companies. In connection with preparing our financial statements for our IPO, we reassessed the estimated fair values of our stock for financial reporting purposes for the period from January 1, 2009 through the date of our initial public offering and incorporated our conclusions into our contemporaneous valuations during that period. We reviewed the valuation models and the related inputs we were using and, due to the proximity of the initial public offering, determined that a probability weighted expected return model ("PWERM") was more appropriate and would provide a better estimate of the value of our stock than the option pricing method we had used previously. Accordingly, we applied the PWERM model to reassess our common stock fair values for 2009 and to calculate the values for 2010. The type and timing of each potential liquidity event used for the 2010 valuations were heavily influenced by the commencement of our IPO process while the December 31, 2009 valuation was based on our best estimate at the time of the type and timing of a liquidity event for the Company. Since we had no corporate milestones during 2009 or 2010 that would significantly affect the valuation of our stock, we ratably increased the values during 2009 and 2010. We used these reassessed fair values as inputs in our valuations of options to purchase common stock and warrants to purchase common and preferred stock for the years ended December 31, 2009 and 2010 and in our deemed dividend calculations during 2010.

Results of Operations

Comparison of the Years Ended December 31, 2010 and 2011

	Year Ended December 31,		% Change
	2010	2011	
	(In thousands)		
Research and development expense	$ 6,826	$13,401	96%
General and administrative expense	$ 3,292	$ 7,695	>100%
Interest income	$ 116	$ 188	62%
Interest expense	$ 1,549	$ —	(100%)
Interest income from amortization of notes payable premium	$ 2,283	$ —	(100%)
Loss on extinguishment of notes payable	$13,285	$ —	(100%)
Loss on change in fair value of preferred stock warrant liability	$ 990	$ —	(100%)
Other income	$ 36	$ —	(100%)
Cumulative dividends on Series H convertible preferred stock	$ 7,200	$ —	(100%)

Research and development expense increased $6.6 million, or 96 percent, for the year ended December 31, 2011 compared to the year ended December 31, 2010. The increase was due to several factors. Personnel costs, including recruitment costs and stock-based compensation expense, increased $2.5 million primarily due to increased headcounts for engineering, manufacturing, and clinical employees. Stent material costs increased $1.4 million primarily due to polymer and lasing needs in 2011 as design finalization, preclinical testing, and manufacturing process development required greater quantities. During 2010 our expenses were reduced by the award of a non-recurring U.S. federal government grant of $714,000 for reimbursement of research and development costs; we had no corresponding receipts in 2011. Preclinical study costs increased $710,000 in 2011 as a result of additional quantities and varieties of studies performed to test the stent. Other engineering and testing costs, including lab supplies and consultants, increased $580,000 in support of the testing and manufacturing development efforts. Clinical costs increased $322,000 as we prepared and submitted requests for trial approval and began site selection and activities. The remainder of the change in research and development expenses between periods is due to increases in facilities costs and other individually immaterial items.

General and administrative expense increased $4.4 million, or more than 100 percent, for the year ended December 31, 2011 compared to the year ended December 31, 2010. Stock-based compensation expense increased $1.6 million primarily due to stock option grants made to senior executives and non-employee directors in October 2010. Salary and benefits increased $808,000 due to increased headcount. We employed a chief executive officer in August 2010 and added five other administrative positions, including a financial controller, in 2011 to support public company reporting and other needs; personnel overhead for benefits, taxes, and other costs range between 15% and 20% of salary costs. Legal fees increased $393,000 primarily as a result of greater patent maintenance and foreign filing costs and greater general counsel costs related to both U.S. and Australian public company reporting requirements. Travel and entertainment expenses increased $258,000 due to increased travel outside the U.S. for shareholder relations and clinical trial preparation. Audit fees increased $229,000 due to public company requirements. Marketing costs increased $473,000 due to tradeshow, trademarking and branding initiatives in 2011 to support entry into clinical trials. Board costs were $190,000 and investor relations and related costs of being a public company were $401,000 in 2011; we had minimal corresponding costs in the prior year period. The remainder of the change in general and administrative expenses between periods was due to increases in general office, insurance, and other expenses.

Interest income increased $72,000 for the year ended December 31, 2011 compared to the year ended December 31, 2010, primarily as a result of interest earned on proceeds from our IPO that was completed in December 2010.

Interest expense, interest income from amortization of notes payable premium, loss on extinguishment of notes payable, and the change in the fair value of preferred stock warrant liability were zero in 2011 due to the conversion to common stock of all outstanding notes payable and the exercise of all warrants upon our IPO in December 2010.

Other income and expense remained relatively immaterial in 2011 and did not change significantly compared to 2010. This income or expense primarily arises from gains and losses in foreign currency exchange rates when we purchase goods or services from foreign suppliers and our purchasing activity did not change significantly in 2011.

The cumulative dividends on Series H stock were paid in common stock and the underlying preferred stock was converted to common stock upon consummation of our IPO in December 2010. As a result, there were no dividends or related financial effects in 2011.

Comparison of the Years Ended December 31, 2009 and 2010

	Year Ended December 31,		%
	2009	2010	Change
	(In thousands)		
Research and development expense	$10,272	$ 6,826	(34%)
General and administrative expense	$ 2,241	$ 3,292	47%
Interest income	$ 26	$ 116	>100%
Interest expense	$ 1,579	$ 1,549	(2%)
Interest income from amortization of notes payable premium	$ —	$ 2,283	>100%
Loss on extinguishment of notes payable	$ —	$13,285	>100%
Gain (loss) on change in fair value of preferred stock warrant liability	$ 215	$ (990)	>100%
Other income (expense)	$ 7	$ 36	>100%
Cumulative dividends on Series H convertible preferred stock	$ 2,358	$ 7,200	>100%

Research and development expense decreased $3.4 million for the year ended December 31, 2010 compared to the year ended December 31, 2009. The decrease was primarily due to development progress on our *ReZolve* scaffold program. During 2009, we produced and tested polymer formulations. After selecting a formulation in mid-2009, we reduced the number of batches we were producing, which resulted in a $1.5 million decrease in polymer costs. Additionally, work performed in 2009 on our delivery system was not repeated in 2010, which resulted in a decrease of $610,000. Due to the stage of development, our need for contracted research and engineering services decreased, resulting in a $347,000 decrease in related expense. Additionally, during 2010 we were awarded a non-recurring U.S. federal government grant of $714,000 for reimbursement of research and development expenses. The remainder of the change between years is due to decreases in expenses related to compensation, engineering tools, lab supplies, and preclinical and clinical study costs.

General and administrative expense increased $1.1 million for the year ended December 31, 2010 compared to the year ended December 31, 2009, primarily due to an increase of $1.0 million in stock-based compensation as a result of options granted to executives and board members in the fourth quarter of 2010.

Interest income increased $90,000 for the year ended December 31, 2010 compared to the year ended December 31, 2009, primarily as a result of interest earned on proceeds from our initial public offering during December 2010. Absent the IPO proceeds, our interest earning would have decreased due to lower rates at which we earned interest due to general economic conditions.

Interest expense remained relatively unchanged for the year ended December 31, 2010 compared to the year ended December 31, 2009 since the balances of our notes payable and the rates of interest on those notes remained consistent between periods.

Interest income from amortization of notes payable premium and the loss on extinguishment of notes payable are non-recurring items that arose during the fourth quarter of 2010 when we modified the conversion features of our notes payable. Although we did not repay the notes or modify any repayment terms and although the notes converted into common stock upon the IPO, our evaluation of the modifications to the notes required that we record these non-recurring items in accordance with generally accepted accounting principles.

The fair value change in our preferred stock warrant liability resulted in a loss of $1.0 million for the year ended December 31, 2010 compared to a gain of $215,000 for the year ended December 31, 2009, primarily as a result of increases in the estimated value of the underlying preferred stock. These increases in estimated values resulted from a change in our valuation assumptions due to our initial public offering that was completed in December 2010.

Other income remained relatively immaterial for the year ended December 31, 2010 and did not change significantly compared to the same period in 2009.

The $4.8 million increase in cumulative and deemed dividends recorded for the year ended December 31, 2010 compared to the same period in 2009 relates to the issuance of Series H convertible preferred stock in the third quarter of 2009 and the second quarter of 2010. Terms of the Series H stock provided for a six percent cumulative dividend, compounded quarterly, from the date of issuance. The deemed dividends, totaling $4.4 million in 2010, were non-recurring and non-cash items that arose when we issued Series H stock under previously agreed terms at a price per share that was lower than the estimated fair value of our common stock on the dates of issuance. The cumulative dividends were paid in common stock and the underlying preferred stock was converted to common stock upon consummation of our initial public offering in December 2010. As a result, there will be no continuing dividends or related financial effects.

Liquidity and Capital Resources

Sources of Liquidity

We are considered a “development stage” enterprise, as we have not yet generated revenues from the sale of products. Although we have been researching and developing new technologies and product applications and we initiated a pilot clinical trial in 2011, we do not anticipate having a product available for sale for at least the next several years. Until revenue is generated from a saleable product, we expect to continue to incur substantial operating losses and experience significant net cash outflows. We have incurred losses since our inception in June 1998 and, through December 31, 2011, we had an accumulated deficit of approximately $149.8 million.

In December 2010 we completed an IPO of our common stock on the Australian Securities Exchange in the form of CHESS Depositary Interests, or “CDIs,” primarily to investors in Australia, the United States, Hong Kong, and London. We issued 7,727,273 shares of common stock at $10.91 per share (equivalent to A$11.00 per share, or A$1.10 per CDI) for gross proceeds of $84.3 million. We incurred $8.1 million in net issuance costs in connection with our IPO. Concurrent with the completion of our IPO, all of our outstanding convertible preferred stock, non-voting common stock, notes payable, and accrued interest on notes payable converted to common stock. Additionally, all outstanding warrants were exercised for common stock, either through a cash payment to us or on a net exercise basis. We also issued common stock for cumulative dividends on our Series H convertible preferred stock. A total of 22,419,771 shares of common stock were issued from these conversions, exercises, and dividends.

Based on our current operating plans, we believe that our cash and investments as of December 31, 2011 of $64.4 million, which represents the remaining proceeds from our IPO, will be sufficient to meet our capital and operating needs beyond the next year and will be sufficient to satisfy our liquidity requirements and provide sufficient working capital to carry out our business objectives during that time.

Cash Flows

Below is a summary of our cash flows from operating activities, investing activities, and financing activities for the periods indicated.

	Year Ended December 31,		
	2009	2010	2011
		(In thousands)	
Net cash used for operating activities	$(12,569)	$ (8,719)	$(16,876)
Net cash provided by (used for) investing activities	6,766	(300)	(6,165)
Net cash provided by financing activities	5,000	83,535	455
Effect of foreign exchange rates	—	(2)	—
Net increase (decrease) in cash and cash equivalents	$ (803)	$74,514	$(22,586)

Net Cash Flow from Operating Activities

Net cash used for operating activities during 2009 primarily reflects the net loss of $13.8 million. We also used cash of $790,000 for the net changes in operating assets and liabilities, including payments of certain long-term preclinical study costs, and $215,000 related to the change in the fair value of the preferred stock warrant liability. These items were offset by $1.6 million of non-cash interest on notes payable, $466,000 of depreciation and amortization, including additional amortization related to the clean room and lab space we added in the beginning of 2009, and $235,000 of stock-based compensation and other expense.

Net cash used for operating activities during 2010 primarily reflects the net loss of $23.5 million, cash used of $372,000 for changes in operating assets and liabilities, and non-cash interest income of $734,000. These items were offset by non-cash expenses of $13.3 million for extinguishment of notes payable, $990,000 from the change in the fair value of the preferred stock warrant liability, $471,000 of depreciation and amortization, and $1.1 million of stock-based compensation and other expense.

Net cash used for operating activities during 2011 primarily reflects the net loss of $20.9 million, offset by cash non-cash expenses of $3.1 million for stock-option compensation, $452,000 of depreciation and amortization, $464,000 from changes in operating assets and liabilities, and $28,000 of other expense.

Net Cash Flow from Investing Activities

Net cash provided by investing activities in 2009 resulted from the maturity of $7.5 million in short-term investment securities offset by $733,000 in purchases of property and equipment. Net cash used for investing activities in 2010 consisted of the purchase of property and equipment. Net cash used in investing activities during 2011 consisted of the purchase of $5.2 million of short- and long-term investment securities and $945,000 in purchases of property and equipment.

Net Cash Flow from Financing Activities

Net cash provided by financing activities during the years ended December 31, 2009 and 2010 consisted of net proceeds of $5.0 million, and $7.5 million respectively, from the sale of our Series H convertible preferred stock, net of repurchases. Additionally, during 2010, we received $84.3 million in cash proceeds from issuance of common stock upon our initial public offering, $263,000 in cash proceeds from exercises of warrants, and we paid $8.5 million in costs related to our initial public offering. Net cash provided by financing activities during the year ended December 31, 2011 comprises the refund of $422,000 for taxes withheld from our IPO proceeds in the prior year and $33,000 in proceeds from the issuance of common stock.

Operating Capital and Capital Expenditure Requirements

To date, we have not commercialized any products. We do not anticipate generating any revenue unless and until we successfully obtain CE Mark or FDA marketing approval for, and begin selling, the *ReZolve* scaffold or one of our other product possibilities. We anticipate that we will continue to incur substantial net losses for the next several years 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.

We believe that our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements beyond the next year. If our available cash and cash equivalents are insufficient to satisfy our liquidity requirements, or if we develop additional products or pursue additional applications for our products, we may seek to sell additional equity or debt securities, or obtain a credit facility. The sale of additional equity and debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. For example, we will need to raise additional funds in order to build our sales force and commercialize our products. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay, or eliminate some or all of our planned clinical trials, research, development, and commercialization activities, which could materially harm our business.

Our forecasts for the period of time through which our financial resources will be adequate to support our operations and the costs to complete development of products are forward-looking statements and involve risks and uncertainties, and actual results could vary materially and negatively as a result of a number of factors. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Because of the numerous risks and uncertainties associated with the development of medical devices, such as our *ReZolve* scaffold, we are unable to estimate the exact amounts of, or timing of, capital outlays and operating expenditures necessary to complete development, continue ongoing preclinical studies, conduct human clinical trials, and successfully deliver a commercial product to market. Our future funding requirements will depend on many factors, including, but not limited to:

- the time and effort it will take to successfully complete the development and testing of the *ReZolve* scaffold;
- the time and effort it will take to identify, develop, and scale-up manufacturing processes;
- the scope, enrollment rate, and costs of our human clinical trials;
- 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;
- the requirements, cost, and timing of regulatory approvals;
- the cost and timing of establishing sales, marketing, and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our products and any products that we may develop;
- the effect of competing technological and market developments; and
- the cost and ability to license technologies for future development.

Future capital requirements will also depend on the extent to which we acquire or invest in businesses, products, and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Contractual Obligations, Commitments, and Contingencies

The following table summarizes our outstanding contractual obligations as of December 31, 2011:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
			(In thousands)		
Operating lease obligations	$3,743	$ 406	$1,232	$1,334	$ 771
Purchase obligations	159	150	9	—	—
Employment agreements	508	508	—	—	—
Total contractual obligations	$4,410	$ 1,064	$1,241	$1,334	$ 771

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Recent Accounting Pronouncements

In June 2011, the FASB issued ASU No. 2011-05, “Presentation of Comprehensive Income.” ASU 2011-05 eliminates the option to report other comprehensive income and its components in the statement of changes in stockholders’ equity and requires an entity to present the total of comprehensive income, the components of net income or loss, and the components of other comprehensive income either in a single continuous statement or in two separate but consecutive statements. This pronouncement is effective for us beginning in the first quarter of 2012. We believe the adoption of ASU 2011-05 relates to presentation and disclosure only and will not have an impact on our consolidated financial position or results of operations.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Sensitivity

Our cash, cash equivalents, and short-term investments of $61.2 million at December 31, 2011 consisted of cash, money market funds, and time deposits that will be used for working capital purposes. Our long-term investments of $3.2 million at December 31, 2011 consisted of fixed maturity time deposits. We have the positive intent and ability to hold both our short- and long-term investments to maturity. We do not enter into investments for trading or speculative 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 U.S. Because of the short-term nature of our cash, cash equivalents, and short-term investments and our positive intent and ability to hold our long-term investments to maturity, 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 in accumulated other comprehensive income within stockholders’ equity. 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.

Related Party Transactions

Our related parties include the members of our Board of Directors and investors with five percent or more of our outstanding securities. As of December 31, 2011, our related parties collectively represented approximately 67 percent of our outstanding stock. Transactions with our related parties historically consisted of notes payable issued to members of our board of directors, or firms they represented, or to the investors that held in excess of five percent of our securities. All of our notes payable together with accrued interest converted into common stock upon our IPO in December 2010.

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements, and accompanying notes, and the Report of Ernst & Young LLP, our Independent Registered Public Accounting Firm, are included in this Annual Report on Form 10-K on pages F-1 through F-20.

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

None.

Item 9A. Controls and Procedures

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the Company's Board of Directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the Company's assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit the preparation of financial statements in accordance with generally accepted accounting principles, and that the receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and,
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

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

Our management, including our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of the end of the fiscal year covered by this Annual Report on Form 10-K. In making this assessment, our management used the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or "COSO." Based on their assessment, management has concluded that, as of December 31, 2011, our Company's internal control over financial reporting is effective based on the COSO criteria.

Ernst & Young LLP, an independent registered public accounting firm, who audited the Company's consolidated financial statements included in this Form 10-K, has issued an attestation report on the Company's internal control over financial reporting, which is included herein.

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, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
REVA Medical, Inc.

We have audited REVA Medical, Inc.'s internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). REVA Medical, Inc.'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, REVA Medical, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of REVA Medical, Inc. as of December 31, 2011 and 2010, and the related consolidated statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2011 and for the period from June 3, 1998 (inception) to December 31, 2011 of REVA Medical Inc. and our report dated February 28, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 28, 2012

Item 9B. Other Information

None.

PART III

Certain information required by Part III is omitted from this report because the Company will file a definitive proxy statement within 120 days after the end of its fiscal year pursuant to Regulation 14A (the "Proxy Statement") for its annual meeting of stockholders to be held on May 21, 2012 (Australian time), and certain information included in the Proxy Statement is incorporated herein by reference.

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 2012 Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission within 120 days of December 31, 2011 (the "2012 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 amendments to this code, or any waivers of its requirements, 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 Security Holders at February 15, 2012

The number of equivalent CHESS Depositary Interests, or "CDIs," held by our substantial shareholders (i.e., those shareholders, who together with their associates, have an interest in at least five percent of our voting securities), assuming the conversion of common stock held by those shareholders into CDIs (ten CDIs are equivalent to one share of common stock) as of February 15, 2012 are as follows:

	Number of Securities Held (stated as CDIs)	% of Total Outstanding Capital
Domain Partners	53,869,050	16.3%
Saints Capital Everest, L.P.	45,774,651	13.8%
Group Outcome Investors/Robert B. Stockman	30,394,755	9.2%
Brookside Capital Partners	29,650,222	9.0%
Cerberus and affiliates	28,844,260	8.7%
Medtronic, Inc.	22,558,280	6.8%

Distribution of Security Holders as of February 15, 2012

As of February 15, 2012, we had a total of 33,076,203 shares of common stock issued and outstanding, which equates to 330,762,030 CDIs (ten CDIs are equivalent to one share of common stock). The following table presents the number of shares of common stock and CDIs held, as well as the number of shares underlying outstanding stock options and restricted stock issuances.

	Common Stock		CDIs		Options (unlisted)		Restricted Stock (unlisted)	
	Number of Holders	Number of Shares	Number of Holders	Number of CDIs	Number of Holders	Number of Shares	Number of Holders	Number of Shares
1 – 1,000	10	3,614	77	36,937	6	5,500	—	—
1,001 – 5,000	9	22,700	182	588,488	7	18,000	1	2,500
5,001 – 10,000	5	38,963	120	1,053,626	4	34,500	—	—
10,001 – 100,000	20	781,639	276	9,178,637	16	678,500	—	—
100,001 and over	17	17,488,563	52	136,524,552	7	2,295,000	—	—
	61	18,335,479	707	147,382,240	40	3,031,500	1	2,500

The number of shareholders holding less than a marketable parcel of CDIs (being a parcel of securities not less than A$500) as of February 15, 2012 was 56.

Top 20 CDI Holders as of February 15, 2012

Following are the top 20 holders of our CDIs as of February 15, 2012 (these amounts do not include holdings in common stock):

		Number of CDIs Held	% of CDIs Outstanding
1.	Merrill Lynch (Australia) Nominees Pty Limited	38,576,959	26.2%
2.	Brookside Capital Partners Fund LP	27,832,040	18.9%
3.	Citicorp Nominees Pty Limited	12,007,577	8.2%
4.	Credit Suisse Securities (Europe) Ltd <Collateral A/C>	12,000,000	8.1%
5.	HSBC Custody Nominees (Australia) Limited – GSCO ECA	9,781,821	6.6%
6.	HSBC Custody Nominees (Australia) Limited	8,369,879	5.7%
7.	Frederic H. Moll	3,345,610	2.3%
8.	UBS Nominees Pty Ltd	3,082,196	2.1%
9.	Kenneth Rainin Charitable Lead Annuity Trust <No 3 dtd 3/26/90>	2,454,545	1.7%
10.	HSBC Custody Nominees (Australia) Limited <No 2 A/C>	2,255,490	1.5%
11.	JP Morgan Nominees Australia Limited <Cash Income A/C>	1,715,732	1.2%
12.	National Nominees Limited	1,547,000	1.0%
13.	Warman Investments Pty Ltd	1,376,771	0.9%
14.	Saints Capital Everest LP	909,091	0.6%
15.	Asia Union Investments Pty Ltd	909,000	0.6%
16.	Viking Management Services Pty Ltd <VHK Superannuation Fund A/C>	750,000	0.5%
17.	Mr Stephen Ross + Mrs Melissa Ross	668,000	0.5%
18.	Eric V. Schmid	600,000	0.4%
19.	Mr Robert Arthur Schneider	525,000	0.4%
20.	Moore Family Nominee Pty Ltd <Moore Family A/C>	500,000	0.3%
	Total CDIs held by top 20 CDI holders	129,206,711	87.7%
	Total CDIs held by all other CDI holders	18,175,529	12.3%

The table below provides a list of the top 20 holders of our securities as of February 15, 2012, taking into account securities held in the form of both common stock and CDIs and prepared on the assumption that all common stock is held as CDIs. Related but separate legal entities are not aggregated.

		Number of Securities Held	% of Capital Outstanding
1.	Domain Partners V, L.P.	52,625,830	15.9%
2.	Saints Capital Everest L.P.	45,774,651	13.8%
3.	Merrill Lynch (Australia) Nominees Pty Limited	38,576,959	11.7%
4.	Brookside Capital Partners Fund LP	29,650,222	9.0%
5.	Kenneth Rainin Charitable Lead Annuity Trust No. 3 dtd 3/26/90	13,470,695	4.1%
6.	Group Outcome Investors I, LLC	13,411,750	4.1%
7.	Citicorp Nominees Pty Limited	12,007,577	3.6%
8.	Credit Suisse Securities (Europe) Ltd <Collateral A/C>	12,000,000	3.6%
9.	Cerberus Series Four Holdings, LLC	10,464,860	3.2%
10.	Cerberus International LTD	9,955,530	3.0%
11.	HSBC Custody Nominees (Australia) Limited – GSCO ECA	9,781,821	3.0%
12.	HSBC Custody Nominees (Australia) Limited	8,369,879	2.5%
13.	Gordon E. Nye	8,235,310	2.5%
14.	Cerberus Partners L.P.	5,206,410	1.6%
15.	C. Raymond Larkin Jr.	3,517,490	1.1%
16.	Frederic H. Moll	3,345,610	1.0%
17.	UBS Nominees Pty Ltd	3,082,196	0.9%
18.	Gabriel Assets LLC	2,955,790	0.9%
19.	Timothy J. Barberich	2,702,680	0.8%
20.	Lisa Stockman	2,277,180	0.7%
	Total securities held by top 20 holders (stated as CDIs)	287,412,440	87.0%
	Total securities held by all other holders (stated as CDIs)	43,349,590	13.0%

Options Unlisted

As of February 15, 2012, we had 3,031,500 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 40 individuals.

Restricted Stock Unlisted

As of February 15, 2012, we had 2,500 shares of restricted stock on issue under our 2010 Equity Incentive Plan. These shares of restricted stock are held by one individual.

Restricted Securities

The following shareholders are subject to the escrow periods outlined below, for the number of securities listed below, commencing from the date of quotation of our CDIs on the ASX, which was December 23, 2010.

Escrowed Party	Type	Shares of Common Stock/Options Subject to Escrow	Expiration of Escrow Period (Australian time)
Robert Stockman	ASX imposed	805,042	23 December 2012
Group Outcome Investors I, LLC	ASX imposed	1,205,132	23 December 2012
Lisa Stockman	ASX imposed	205,404	23 December 2012
Gordon Nye	ASX imposed	821,029	23 December 2012
Brian Dovey	ASX imposed	62,500	23 December 2012
Robert Thomas	ASX imposed	62,500	23 December 2012
Anne Keating	ASX imposed	62,500	23 December 2012
James Schiro	ASX imposed	62,500	23 December 2012
Daniel Frank	ASX imposed	56,022	23 December 2012

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 held of record by such stockholder. In addition, although holders of restricted stock are subject to restrictions on transfer until vesting, restricted stockholders have the same voting rights as holders of shares of common stock (including prior to vesting).

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:

(a) instructing CHESS Depositary Nominee or "CDN," as the legal owner, to vote the shares of REVA Medical common stock underlying their CDIs in a particular manner. The instruction form must be completed and returned to our share registry prior to the meeting;

(b) 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;

(c) 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 to purchase stock are not entitled to vote.

Required Statements

REVA Medical makes the following disclosures:

(a) There is no current on-market buy-back of the Company's securities.

(b) REVA Medical, Inc. was incorporated in the state of Delaware in the United States of America.

(c) 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).

(d) 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 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% 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.

(e) REVA Medical, Inc. has used the cash (and assets in a form readily convertible to cash) that it had at the time of admission to the ASX in a manner consistent with its stated business objectives (as described in the Australian prospectus and supplementary prospectus lodged with the Australian Securities and Investments Commission with respect to our IPO) from the time of our admission to the ASX to December 31, 2011.

(f) 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 registered office in Australia is c/o Inteq Limited, Level 6, 175 Macquarie Street, Sydney NSW 2000, telephone +61 2 9231 3322.

Registers of securities are held at Computershare Investor Services Pty. Limited, Level 3, 60 Carrington Street, Sydney NSW 2000, Investor Enquiries: 1300 855 080.

Quotation has been granted for CDIs on the ASX Limited.

Australian Corporate Governance Statement

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 ("ASX Corporate Governance Principles") in force for the Company's financial year ended December 31, 2011 and is pleased to confirm that the Company's corporate governance framework is generally consistent with the ASX Corporate Governance Principles, other than as set forth below. A summary of the approach adopted and used by the Company during the financial year ended December 31, 2011 is set forth below, using the same numbering sequence as contained in the ASX Corporate Governance Principles.

Principle 1 — Lay solid foundations for management and oversight

Recommendation 1.1 – Establish the functions reserved to the board and those delegated to senior executives and disclose those functions

The Board's responsibilities are defined by the Company's Corporate Governance Guidelines, a copy of which is available on the Company's website at *www.revamedical.com* , and there is a clear delineation between the Chairman of the Board's responsibility for the Company's strategy and activities, and the day-to-day management of operations conferred upon the Company's officers.

Recommendation 1.2 – Disclose the process for evaluating the performance of senior executives

In accordance with its charter, the Compensation Committee reviews and approves corporate and personal performance goals and objectives relevant to the compensation of all executive officers, evaluates the performance of each executive officer in light of those goals and objectives, and sets each executive officer's compensation, including but not limited to salary, bonus, incentive compensation, and equity awards based on such an evaluation. In addition, the Compensation Committee is responsible for regularly reviewing the Company's compensation, recruitment, retention, and termination policies for senior executives.

In setting the compensation for our executive officers, our Board places significant emphasis on the recommendation of our Chief Executive Officer (other than with respect to determining his own compensation), considering our overall performance during the prior fiscal year, the executive's individual contributions during the prior fiscal year, the individual's annual performance reviews based on achievement of annual goals, and relevant market data. With respect to new hires, our Board considers an executive's background and historical compensation in lieu of prior year performance. For 2011, our Board evaluated the performance of senior executives by utilizing research and informal benchmarking based on its knowledge of companies in the medical device industry, as well as the evaluation process described above. We retained an independent compensation consultant to assist us with our benchmarking process going forward. Further information regarding executive compensation for the year ended December 31, 2011, as required by Item 11 of this Annual Report on Form 10-K, is incorporated by reference to the applicable information in our Definitive Proxy Statement for our 2012 Annual Meeting of Stockholders, to be filed pursuant to Registration 14A with the Securities and Exchange Commission (the "SEC") and the ASX within 120 days of December 31, 2011 (the "2012 Proxy Statement"). Such information is incorporated herein by reference.

Recommendation 1.3 – Provide the information required to be disclosed under Principle 1

Reporting Requirement

The Company fully complied with Recommendations 1.1 through 1.3 during the year ended December 31, 2011.

Principle 2 — Structure the board to add value

Recommendation 2.1 – A majority of the board should be independent directors

The Company's Board comprises six directors The directors include four independent non-executive directors, one executive director (being the Chief Executive Officer & Chairman) and one non-independent, non-executive director.

The Board held six meetings during 2011; five members attended all six meetings and one member attended five meetings. Further information regarding our Directors, as required by Item 10 of this Annual Report on Form 10-K, will be contained in our 2012 Proxy Statement. Such information is incorporated herein by reference.

The current composition of the Board and length of tenure of each member is as follow:

				Committees		
Director	Director Position	Year Appointed	Independent	Audit	Compensation	Nominating and Corp. Governance
Robert B. Stockman	Chair & CEO	1999	No	—	—	—
Brian Dovey*	Non-Executive	2001	*	X	X	—
Anne Keating	Non-Executive	2010	Yes	—	—	Chair
Gordon Nye	Non-Executive	1999	Yes	—	Chair	X
James Schiro	Non-Executive	2010	Yes	X	—	X
Robert Thomas	Non-Executive	2010	Yes	Chair	X	—

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

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.

Recommendation 2.2 – The chair should be an independent director

Recommendation 2.3 – The roles of chair and chief executive officer should not be exercised by the same individual

While the Company has complied with Recommendation 2.1, is not compliant with Recommendations 2.2 and 2.3. While the majority of the Board is comprised of independent directors for ASX purposes, the Chairman is not an independent director and he also serves as the Company's Chief Executive Officer, contrary to ASX recommendation. The Board believes that Mr. Stockman is not able to exert undue influence on the decision-making process or the governance functions of the Board, despite Mr. Stockman's not being independent. In addition, while the Chairman and Chief Executive Officer roles have not been separated, the Company has also appointed Dr. Schultz as President and Chief Operating Officer with responsibility for the Company's day-to-day operations and Ms. Thompson as Chief Financial Officer with responsibility for the Company's day-to-day financial and corporate administrative functions. Dr. Schultz and Ms. Thompson attend board meetings by invitation but not as Directors. The Board believes that this creates a collaborative management style approach between the Chairman and management with appropriate checks and balances.

Recommendation 2.4 – The board should establish a nomination committee

The Board has established a Nominating and Corporate Governance Committee to oversee the selection and appointment practices of the Company. The members of the Committee are Anne Keating (Chair), Gordon Nye, and James Schiro. All members are non-executives and are considered independent directors for both ASX and SEC purposes. The Committee held one meeting during the year ended December 31, 2011, which all Committee members attended. A copy of the Nominating and Corporate Governance Committee Charter is available on the Company's website at *www.revamedical.com* .

During 2011, the Committee developed a skills matrix, which they are utilizing to identify strengths and gaps in director backgrounds, as well as to ensure an appropriately diverse skill set among the Board. The results of their assessment will be reflected in the 2012 Proxy Statement.

Recommendation 2.5 – Disclose the process for evaluating the performance of the board, its committees, and individual directors

The Company's Corporate Governance Guidelines provide for an annual self-assessment of the Board's performance to be provided to the Nominating and Corporate Governance Committee. Such an assessment is being performed and evaluated for the year ended December 31, 2011 in conjunction with the preparation of our 2012 Proxy Statement.

The skills, experience, expertise, diversity, independence, and related information for each of our directors holding office as of the date of the filing of this Annual Report on Form 10-K relevant will be included in our 2012 Proxy Statement and, as such, are not included in this Form 10-K.

Recommendation 2.6 – Provide the information required to be disclosed under Principle 2

Reporting Requirement

Except as disclosed above, the Company fully complied with Recommendations 2.1 to 2.6 during the year ended December 31, 2011.

Principle 3 — Promote ethical and responsible decision-making

Recommendation 3.1 – Establish a code of conduct and disclose the code or a summary of the code as to (a) the practices necessary to maintain confidence in the company's integrity, (b) the practices necessary to take into account their legal obligations and the reasonable expectations of their stakeholders, and (c) the responsibility and accountability of individuals for reporting and investigating reports of unethical practices

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 on the Company's website at *www.revamedical.com* .

Recommendation 3.2 – Establish a policy concerning diversity and disclose the policy or a summary of that policy. The policy should include requirements for the board to establish measurable objectives for achieving gender diversity for the board to assess annually both the objectives and progress in achieving them

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 on the Company's website at *www.revamedical.com.*

Recommendation 3.3 – Disclose in each annual report the measurable objectives for achieving gender diversity set by the board in accordance with the diversity policy and progress towards achieving them

The Board initially evaluated the gender diversity of the Company's employees, its senior management, and its Board in 2011 and determined that, based on the initial assessment, future diversity should remain at the same relative proportions, if not higher, of females in each category measured.

Recommendation 3.4 – Disclose in each annual report the proportion of women employees in the whole organization, women in senior executive positions and women on the board

As of December 31, 2011, a total of 41% of the Company's employees was female, 33% of its executive management was female, and 17% of its Board members was female.

Recommendation 3.5 – Provide the information required to be disclosed under Principle 3

Reporting Requirement

The Company fully complied with Recommendations 3.1 through 3.5 for the year ended December 31, 2011.

Principle 4 — Safeguard integrity in financial reporting

Recommendation 4.1 – The board should establish an audit committee

The Board has established an Audit Committee to oversee the management of financial and internal risks and reporting.

Recommendation 4.2 – The audit committee should be structured so that it (a) consists only of non-executive directors, (b) consists of a majority of independent directors, (c) is chaired by an independent chair, who is not chair of the board, and (d) has at least three members

Members of the Audit Committee are Robert Thomas (Chair), James Schiro, and Brian Dovey. Robert Thomas and James Schiro are both considered independent directors for ASX purposes; however, Brian Dovey is not considered to be independent for ASX purposes but is considered to be independent under SEC rules. The Committee held five meetings during 2011, of which two Committee members attended all meetings and one Committee member attended four meetings.

Recommendation 4.3 – The audit committee should have a formal charter

The Audit Committee has adopted a formal charter, a copy of which is available on the Company's website at *www.revamedical.com.*

Recommendation 4.4 – Provide the information required to be disclosed under Principle 4

Reporting Requirement

The Company fully complied with Recommendations 4.1 through 4.4 during the year ended December 31, 2011.

Further information regarding the audit committee, as required by Item 10 of this Annual Report on Form 10-K, will be contained in our 2012 Proxy Statement. Such information is incorporated herein by reference.

Principle 5 – Make timely and balanced disclosure

Recommendation 5.1 – Establish written policies designed to ensure compliance with ASX Listing Rule disclosure requirements and to ensure accountability at a senior executive level for that compliance and disclose those policies or a summary of those policies

The Company is committed to providing timely and balanced disclosure to the market in accordance with its continuous disclosure obligations. A copy of the Company's Continuous Disclosure Policy is available on its website at *www.revamedical.com* .

Recommendation 5.2 – Provide the information required to be disclosed under Principle 5

Reporting Requirement

The Company fully complied with Recommendations 5.1 and 5.2 during the year ended December 31, 2011.

Principle 6 — Respect the rights of shareholders

Recommendation 6.1 – Design a communications policy for promoting effective communication with shareholders and encouraging their participation at general meetings and disclose their policy or a summary of that policy

The Company has adopted a Shareholder Communication Policy for shareholders wishing to communicate with the Board, which is included in the Company's Corporate Governance Guidelines, a copy which is available 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.

All shareholders are invited to attend the Company's annual meeting either in person or by proxy. 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 6.2 – Provide the information required to be disclosed under Principle 6

Reporting Requirement

The Company has fully complied with Recommendations 6.1 and 6.2 during the year ended December 31, 2011.

Principle 7 — Recognize and manage risk

Recommendation 7.1 – Establish policies for the oversight and management of material business risks and disclose a summary of those policies

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. A copy of the Policy is available on the Company's website at *www.revamedical.com* .

Recommendation 7.2 – The board should require management to design and implement the risk management and internal control system to manage the company's material business risk and report to it on whether those risks are being managed effectively. The board should disclose that management has reported to it as to the effectiveness of the company's management of its material business risks

The Board's role in risk oversight includes receiving reports from members of management on a regular basis regarding material risks faced by the Company and applicable mitigation strategies and activities, at least on a quarterly basis. 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 identify and evaluate any potential strategic or operational risks and appropriate activity to address those risks.

Recommendation 7.3 – The board should disclose whether it has received assurance from the chief executive officer (or equivalent) and the chief financial officer (or equivalent) that the declaration provided in accordance with section 295A of the Corporations Act is founded on a sound system of risk management and internal control and that the system is operating effectively in all material respects in relation to financial reporting risks

As the Company prepares and files its financial statements under United States accounting practices and laws, management is required to provide representations to the Board on a wide range of issues, including the effectiveness of the Company's disclosure controls and procedures as well as the design or operation of internal control over financial reporting. However, as the Company is incorporated in the United States and is not bound by the financial reporting provisions under the Australian Corporations Act 2001 (Cth), no declaration is required under section 295A of the Corporations Act. To this end, shareholders' attention is drawn to Item 9A of this Annual Report on Form 10-K and the certifications provided by the Chief Executive Officer and the Chief Financial Officer at the end of the Form 10-K. As stated above, Item 9A discloses information regarding the Company's controls and procedures and management's evaluation of the effectiveness of our internal control over financial reporting.

Recommendation 7.4 – Provide the information required to be disclosed under Principle 7

Reporting Requirement

Except as disclosed above, the Company fully complied with Recommendations 7.1 through 7.4 during the year ended December 31, 2011.

Principle 8 — Remunerate fairly and responsibly

Recommendation 8.1 – The board should establish a remuneration committee

The Board has established a Compensation Committee to review and assess executive and director compensation.

Recommendation 8.2 – The remuneration committee should be structured so that it (a) consists of a majority of independent directors, (b) is chaired by an independent chair, and (c) has at least three members

The members of the Compensation Committee are Gordon Nye (Chair), Brian Dovey, and Robert Thomas. Gordon Nye and Robert Thomas are both considered to be independent for ASX purposes; however, Brian Dovey is not considered to be independent for ASX purposes but is considered to be independent under the SEC rules. The Committee held two meetings during 2011, of which two Committee members attended both meetings and one Committee member attended one meeting. A copy of the Compensation Committee Charter is available on the Company's website at *www.revamedical.com.*

Recommendation 8.3 – Clearly distinguish the structure of non-executive directors' remuneration from that of executive directors and senior executives

In accordance with its charter, the Compensation Committee is responsible for ensuring that the structure of non-executive and executive directors' compensation is clearly distinguished. 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 grants of options at the Board's discretion. 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. The Company's Chairman, who is also currently serving as our Chief Executive Officer, is eligible to receive a cash bonus at the discretion of the Board of up to 30% of his salary each year. None of the Company's non-executive directors will be entitled to any retirement benefits.

Recommendation 8.4 – Provide the information required to be disclosed under Principle 8

The Company fully complied with Recommendations 8.1 through 8.4 during the year ended December 31, 2011.

Further information regarding the Compensation Committee, as required by Item 10 of this Annual Report on Form 10-K, will be contained in our 2012 Proxy Statement Such information is incorporated herein by reference.

Item 11. Executive Compensation

Information required by this item is incorporated by reference to our 2012 Proxy Statement.

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

Information required by this item is incorporated by reference to our 2012 Proxy Statement.

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

Information required by this item is incorporated by reference to our 2012 Proxy Statement.

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Item 14. Principal Accountant Fees and Services

Information required by this item is incorporated by reference to our 2012 Proxy Statement.

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:

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.

3. 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.

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SIGNATURES

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

REVA Medical, Inc.

Dated: February 28, 2012

By: /s/ Robert B. Stockman
Name: **Robert B. Stockman**
Title: **Chairman of the Board and Chief 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/ Robert B. Stockman **Robert B. Stockman**	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	February 28, 2012
/s/ Katrina Thompson **Katrina Thompson**	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 28, 2012
/s/ Robert K. Schultz, Ph.D. **Robert K. Schultz, Ph.D.**	President and Chief Operating Officer	February 28, 2012
/s/ Brian Dovey **Brian Dovey**	Director	February 28, 2012
/s/ Anne Keating **Anne Keating**	Director	February 28, 2012
/s/ Gordon E. Nye **Gordon E. Nye**	Director	February 28, 2012
/s/ James J. Schiro **James J. Schiro**	Director	February 28, 2012
/s/ Robert Thomas **Robert Thomas**	Director	February 28, 2012

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INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheets of REVA Medical, Inc. (a development stage company) (the Company) as of December 31, 2011 and 2010, and the related consolidated statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2011 and for the period from June 3, 1998 (inception) to December 31, 2011. 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 audits.

We conducted our audits in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits 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 consolidated financial position of REVA Medical, Inc. at December 31, 2011 and 2010, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, and for the period from June 3, 1998 (inception) to December 31, 2011, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), REVA Medical, Inc.'s internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 28, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 28, 2012

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

	December 31, 2010	December 31, 2011
Assets		
Current Assets:		
Cash and cash equivalents	$ 81,747	$ 59,161
Short-term investments	—	1,992
Prepaid expenses and other current assets	765	913
Total current assets	82,512	62,066
Property and equipment, net	963	1,960
Long-term investments	—	3,234
Other non-current assets	—	60
Total Assets	$ 83,475	$ 67,320
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 937	$ 1,284
Accrued expenses and other current liabilities	591	935
Total current liabilities	1,528	2,219
Long-term liabilities	—	518
Total Liabilities	1,528	2,737
Commitments and Contingencies (Note 9)		
Stockholders' Equity:		
Common stock — $0.0001 par value; 100,000,000 shares authorized; 32,760,503 and 32,810,503 shares issued and outstanding at December 31, 2010 and December 31, 2011, respectively	3	3
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	210,847	214,391
Deficit accumulated during the development stage	(128,903)	(149,811)
Total Stockholders' Equity	81,947	64,583
Total Liabilities and Stockholders' Equity	$ 83,475	$ 67,320

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

REVA Medical, Inc.
(a development stage company)
Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	Year Ended December 31,			Period from June 3, 1998 (inception) to December 31,
	2009	2010	2011	2011
Operating Expense:				
Research and development	$ 10,272	$ 6,826	$ 13,401	$ 87,722
General and administrative	2,241	3,292	7,695	27,887
Loss from operations	(12,513)	(10,118)	(21,096)	(115,609)
Other Income (Expense):				
Interest income	26	116	188	1,283
Related party interest expense	(1,532)	(1,510)	—	(21,113)
Interest expense	(47)	(39)	—	(952)
Interest from amortization of notes payable premium	—	2,283	—	2,283
Gain (loss) on change in fair value of preferred stock rights and warrant liabilities	215	(990)	—	1,795
Loss on extinguishment of notes payable	—	(13,285)	—	(13,285)
Other income (expense)	7	36	—	(40)
Net Loss	(13,844)	(23,507)	(20,908)	(145,638)
Cumulative dividends and deemed dividends on Series H convertible preferred stock	(2,358)	(7,200)	—	(10,695)
Net Loss Attributable to Common Stockholders	$ (16,202)	$ (30,707)	$ (20,908)	$ (156,333)
Net Loss Per Common Share :				
Net loss per share, basic and diluted	$ (5.91)	$ (7.72)	$ (0.64)	
Shares used to compute net loss per share, basic and diluted	2,739,229	3,975,144	32,777,509	

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

REVA Medical, Inc.
(a development stage company)
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,			Period from June 3, 1998 (inception) to December 31, 2011
	2009	2010	2011	
Cash Flows from Operating Activities:				
Net loss	$(13,844)	$(23,507)	$(20,908)	$ (145,638)
Non-cash adjustments to reconcile net loss to net cash used for operating activities:				
Depreciation and amortization	466	471	452	3,293
Loss (gain) on property and equipment disposal and impairment	—	—	(1)	584
Stock-based compensation	227	1,185	3,089	5,117
Interest on notes payable	1,579	(734)	—	8,562
Repayment premium on notes payable	—	—	—	11,100
Loss (gain) on change in fair value of preferred stock warrant liability	(215)	990	—	970
Gain on change in fair value of preferred stock rights liability	—	—	—	(2,765)
Loss on extinguishment of notes payable	—	13,285	—	13,285
Other non-cash expenses (income)	8	(37)	28	71
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	47	(697)	(148)	(913)
Other non-current assets		7	(60)	(60)
Accounts payable	(426)	120	(162)	775
Accrued expenses and other current liabilities	(411)	198	375	935
Other long-term liabilities	—	—	459	459
Net cash used for operating activities	(12,569)	(8,719)	(16,876)	(104,225)
Cash Flows from Investing Activities:				
Purchases of property and equipment	(733)	(300)	(945)	(5,495)
Sales of property and equipment	—	—	6	167
Purchases of short-term investments	—	—	(1,992)	(19,878)
Purchases of long-term investments	—	—	(3,234)	(3,234)
Maturities of short-term investments	7,499	—	—	17,886
Net cash provided by (used for) investing activities	6,766	(300)	(6,165)	(10,554)
Cash Flows from Financing Activities:				
Proceeds from issuances of convertible preferred stock, net of costs	5,000	8,034	—	68,917
Proceeds from issuances of common stock	—	84,278	33	84,966
Initial public offering costs, net	—	(8,490)	422	(8,068)
Proceeds from exercises of warrants	—	263	—	263
Repurchases of stock	—	(550)	—	(638)
Proceeds from issuances of notes payable	—	—	—	28,600
Repayments of notes payable	—	—	—	(100)
Net cash provided by financing activities	5,000	83,535	455	173,940
Effect of foreign exchange rates	—	(2)	—	—
Net increase (decrease) in cash and cash equivalents	(803)	74,514	(22,586)	59,161
Cash and cash equivalents at beginning of period	8,036	7,233	81,747	—
Cash and cash equivalents at end of period	$ 7,233	$ 81,747	$ 59,161	$ 59,161
Supplemental Cash and Non-Cash Information (also see Consolidated Statements of Stockholders' Equity for non-cash transactions that arose upon our IPO in December 2010) **:**				
Cash paid for interest	$ —	$ —	$ —	$ 126
Preferred stock issued upon conversion of notes payable	$ —	$ —	$ —	$ 7,950

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

REVA Medical, Inc.
(a development stage company)
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
Period from June 3, 1998 (inception) to December 31, 2011
(in thousands, except share and per share amounts)

	Convertible Preferred Stock		Common Stock				Additional Paid-In Capital	Accumulated Other Compre-hensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Stock-holders' Equity (Deficit)
			Voting		Non-Voting					
	Shares	Amount	Shares	Amount	Shares	Amount				
Common stock issued June 1998 to July 1999 for cash at $0.0001 to $0.67 per share	—	$ —	2,452,088	$ —	—	$ —	$ 278	$ —	$ —	$ 278
Net loss June 3, 1998 (inception) to November 30, 1999	—	—	—	—	—	—	—	—	(492)	(492)
Recapitalization of Company December 1999	—	—	—	—	—	—	(492)	—	492	—
Series A preferred stock issued December 1999 in exchange for common stock on a 1-for-1 basis upon recapitalization of Company	1,618,058	185	(1,618,058)	—	—	—	(185)	—	—	(185)
Series A and Series B preferred stock issued December 1999 for cash at $1.007 and $1.20 per share, respectively	1,029,833	1,197	—	—	—	—	—	—	—	—
Series C preferred stock issued July 2000 for cash at $1.97 per share	558,374	1,100	—	—	—	—	—	—	—	—
Series D preferred stock issued February 2001 for cash at $2.44 per share	819,673	2,000	—	—	—	—	—	—	—	—
Series E preferred stock issued June 2001 to February 2002 for cash at $6.12 per share	2,450,980	15,000	—	—	—	—	—	—	—	—
Series G-1 preferred stock issued October 2004 for cash at $9.86 per share	709,939	7,000	—	—	—	—	—	—	—	—
Issuance costs on Series G-1 preferred stock	—	(500)	—	—	—	—	—	—	—	—
Series G-1 preferred stock issued October 2004 upon conversion of notes payable and accrued interest at $9.86 per share	304,260	3,000	—	—	—	—	—	—	—	—
Series H preferred stock issued 2007 and 2008 for cash at $6.5066 per share	4,610,701	30,000	—	—	—	—	—	—	—	—
Issuance costs on Series H preferred stock	—	(100)	—	—	—	—	—	—	—	—
Series H preferred stock issued December 2007 upon conversion of notes payable and accrued interest at $6.5066 per share	793,629	5,164	—	—	—	—	—	—	—	—
Value of rights in 2007 of possible future issuances of Series H preferred stock	—	(3,905)	—	—	—	—	—	—	—	—
Realized value of rights to possible future issuances of Series H preferred stock	—	1,140	—	—	—	—	—	—	—	—
Cumulative dividends on Series H preferred stock at $0.3995 per share per year	—	1,137	—	—	—	—	(1,137)	—	—	(1,137)
Value of beneficial conversion feature on convertible notes payable	—	—	—	—	—	—	365	—	—	365
Fair value of warrants to purchase Series E and Series F preferred stock reclassified to long-term liability upon adoption of accounting pronouncement	—	—	—	—	—	—	(435)	—	—	(435)
Change in fair value of embedded conversion conversion feature	—	—	—	—	—	—	1,082	—	—	1,082
Fair value of warrants issued September 2003 in connection with notes payable to purchase 82,805 shares of Series E preferred stock	—	—	—	—	—	—	315	—	—	315

(continued on page 2 of 3)

REVA Medical, Inc.
(a development stage company)
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
Period from June 3, 1998 (inception) to December 31, 2011
(in thousands, except share and per share amounts)

(continued from page 1 of 3)

	Convertible Preferred Stock		Common Stock				Additional Paid-In Capital	Accumulated Other Compre-hensive Income(Loss)	Deficit Accumulated During the Development Stage	Total Stock-holders' Equity (Deficit)
			Voting		Non-Voting					
	Shares	Amount	Shares	Amount	Shares	Amount				
Fair value of warrants issued April 2004 in connection with notes payable to purchase 53,354 shares of Series F preferred stock	—	—	—	—	—	—	230	—	—	230
Fair Value of warrants to purchase common stock issued in connection with Series H preferred stock	—	(505)	—	—	—	—	505	—	—	505
Common stock issued December 1999 to October 2000 for cash at $0.10 to $0.20 per share	—	—	910,500	—	—	—	106	—	—	106
Common stock issued February 2001 to October 2006 upon exercise of stock options for cash at $0.10 to $1.00 per share	—	—	1,055,715	—	—	—	456	—	—	456
Common stock repurchased August 2000 for cash at $0.0001 per share	—	—	(189,500)	—	—	—	—	—	—	—
Non-voting common stock issued May 2001 for technology license valued at $0.25 per share	—	—	—	—	481,813	—	13	—	—	13
Non-voting common stock repurchased August 2004 for cash at $0.25 per share	—	—	—	—	(353,329)	—	(88)	—	—	(88)
Non-voting common stock vested July 2005	—	—	—	—	—	—	60	—	—	60
Non-cash distribution of assets to stockholders July 2002	—	—	—	—	—	—	(60)	—	—	(60)
Stock-based compensation expense	—	—	—	—	—	—	616	—	—	616
Translation adjustment	—	—	—	—	—	—	—	2	—	2
Net loss December 1, 1999 (recapitalization) to December 31, 2008	—	—	—	—	—	—	—	—	(86,887)	(86,887)
Balance at December 31, 2008	12,895,447	$ 61,913	2,610,745	$ —	128,484	$ —	$ 1,629	$ 2	$ (86,887)	$ (85,256)
Net loss and comprehensive loss	—	—	—	—	—	—	—	—	(13,844)	(13,844)
Series H preferred stock issued September for cash at $6.5066 per share	768,454	5,000	—	—	—	—	—	—	—	—
Fair value of warrants to purchase 153,692 shares of common stock issued in connection with Series H preferred stock issuance	—	(200)	—	—	—	—	200	—	—	200
Cumulative dividends on Series H preferred stock at $0.3995 per share per year	—	2,358	—	—	—	—	(2,056)	—	(302)	(2,358)
Stock-based compensation expense	—	—	—	—	—	—	227	—	—	227
Balance at December 31, 2009	13,663,901	$ 69,071	2,610,745	$ —	128,484	$ —	$ —	$ 2	$ (101,033)	$(101,031)
Net loss	—	—	—	—	—	—	—	—	(23,507)	(23,507)
Translation adjustment	—	—	—	—	—	—	—	(2)	—	(2)
Comprehensive loss										(23,509)
Series H preferred stock issued June for cash at $6.5066 per share	1,075,831	7,000	—	—	—	—	—	—	—	—
Proceeds in June from Series H preferred stock escrow fund	—	484	—	—	—	—	—	—	—	—

(continued on page 3 of 3)

REVA Medical, Inc.
(a development stage company)
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
Period from June 3, 1998 (inception) to December 31, 2011
(in thousands, except share and per share amounts)

(continued from page 2 of 3)

	Convertible Preferred Stock		Common Stock				Additional Paid-In Capital	Accumulated Other Compre-hensive Income(Loss)	Deficit Accumulated During the Development Stage	Total Stock-holders' Equity (Deficit)
			Voting		Non-Voting					
	Shares	Amount	Shares	Amount	Shares	Amount				
Fair value of warrants to purchase 215,165 shares of common stock issued in connection with Series H preferred stock issuance	—	(840)	—	—	—	—	840	—	—	840
Purchase for reissuance in March of Series H preferred stock and warrants to purchase 92,214 shares of common stock for cash at $0.99 per share	(461,071)	(550)	—	—	—	—	—	—	—	—
Reissuance in May of Series H preferred stock and warrants to purchase 92,214 shares of common stock for cash at $0.99 per share	461,071	550	—	—	—	—	—	—	—	—
Deemed dividends on Series H preferred stock	—	—	—	—	—	—	4,363	—	(4,363)	—
Cumulative dividends on Series H preferred stock at $0.3995 per share per year	—	2,837	—	—	—	—	(2,837)	—	—	(2,837)
Change in fair value of embedded conversion feature	—	—	—	—	—	—	11,161	—	—	11,161
Common stock issued February upon exercise of stock options for cash at $0.10 to $1.40 per share	—	—	2,714	—	—	—	—	—	—	—
Common stock issued December upon conversion of preferred convertible stock	(14,739,732)	(78,552)	14,929,713	1	—	—	78,551	—	—	78,552
Common stock issued December upon conversion of non-voting common stock	—	—	128,484	—	(128,484)	—	—	—	—	—
Common stock issued December upon conversion of long-term notes payable and accrued interest	—	—	5,638,778	1	—	—	28,664	—	—	28,665
Transfer of repayment premium on long-term notes payable in December upon conversion of notes	—	—	—	—	—	—	11,100	—	—	11,100
Common stock issued December upon exercise of warrants for cash at $3.28 to $6.5066 per share	—	—	49,535	—	—	—	263	—	—	263
Common stock issued December upon net exercise of warrants at $3.28 to $6.5066 per share	—	—	700,034	—	—	—	—	—	—	—
Transfer of preferred stock warrant liability in December upon exercise of warrants	—	—	—	—	—	—	1,770	—	—	1,770
Common stock issued December upon initial public offering at $10.9065 per share	—	—	7,727,273	1	—	—	84,277	—	—	84,278
Issuance costs of initial public offering	—	—	—	—	—	—	(8,490)	—	—	(8,490)
Common stock issued December for cumulative dividends on Series H convertible preferred stock	—	—	973,227	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	1,185	—	—	1,185
Balance at December 31, 2010	—	$ —	32,760,503	$ 3	—	$ —	$ 210,847	$ —	$ (128,903)	$ 81,947
Net and comprehensive loss	—	—	—	—	—	—	—	—	(20,908)	(20,908)
Common stock issued upon exercise of stock options for cash at $0.25 to $1.40 per share	—	—	45,000	—	—	—	33	—	—	33
Restricted common stock issued in May at $0.10 to $13.95 per share under the 2010 Equity Incentive Award Plan	—	—	5,000	—	—	—	—	—	—	—
Refund of taxes withheld from initial public offering proceeds in December 2010	—	—	—	—	—	—	422	—	—	422
Stock-based compensation expense	—	—	—	—	—	—	3,089	—	—	3,089
Balance at December 31, 2011	—	$ —	32,810,503	$ 3	—	$ —	$ 214,391	$ —	$ (149,811)	$ 64,583

REVA Medical, Inc.
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1. Description of Business

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

We are currently developing proprietary designs and biomaterial technologies that will be used primarily for a bioresorbable stent to treat vascular disease in humans. We initiated the first human clinical trial of our bioresorbable stent during 2007 and initiated a pilot clinical trial in the fourth quarter of 2011. In December 2010, we completed an initial public offering of our common stock, as more fully described in Note 2 below.

2. Stage of Company, Capital Resources, and Basis of Presentation

Development Stage and Capital Resources **:** We are considered a "development stage" enterprise, as we have not yet generated revenues from the sale of products. Although we have been researching and developing new technologies and product applications and have initiated a pilot human clinical trial of our bioresorbable stent, we do not anticipate having a product available for sale for at least the next several years. Until revenue is generated from a saleable product, we expect to continue to incur substantial operating losses and experience significant net cash outflows. As discussed below, we completed an initial public offering of our common stock in December 2010, and we believe that we have sufficient capital to fund our operations at least through December 31, 2012, and beyond, from the remaining IPO proceeds.

Initial Public Offering **:** In December 2010 we completed an initial public offering (the "IPO") of our common stock in Australia. We issued 7,727,273 shares of common stock at $10.9065 per share for gross proceeds of $84.28 million. We incurred $8.49 million in issuance costs in connection with the IPO. Our stock is traded in the form of CHESS Depository Interests ("CDIs") on the Australian Securities Exchange; each share of our common stock is equivalent to ten CDIs. Our trading symbol is "RVA.AX."

Concurrent with the completion of our IPO, all of our outstanding convertible preferred stock, non-voting common stock, notes payable, and accrued interest on notes payable converted to common stock. Additionally, all outstanding warrants were exercised for common stock, either through a cash payment to us or on a net exercise basis. We also issued common stock for cumulative dividends on our Series H convertible preferred stock. A total of 22,419,771 shares of common stock were issued from these conversions, exercises, and dividends.

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 Securities and Exchange Commission ("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, or have related to, expense accruals and fair market value determinations of notes payable and embedded conversion features, common and preferred stock warrants, preferred stock rights liability, and stock-based compensation. Actual results could differ from our estimates.

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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 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 is removed from the accounts and any gain or loss is recognized in the consolidated statements 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, 2009, 2010, and 2011 we determined there were no indications of asset impairment. During the period from June 3, 1998 (inception) through December 31, 2011 we recorded $502,000 in losses from impairment of long-lived assets.

Concentrations of Credit Risk **:** Our cash, cash equivalents, and investments are subject to concentrations of credit risk to the extent the balances exceed limits that are insured by the Federal Deposit Insurance Corporation. Cash and cash equivalents are maintained in a bank account, the balance of which generally exceeds the insured limits. Investments are held in custody by a large financial asset manager. We maintain our cash balances and investments in accordance with our investment policy to limit exposure to concentrations of credit risk and changes in market conditions. 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.

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.

REVA Medical, Inc.
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Notes to Consolidated Financial Statements

3. Significant Accounting Policies (continued)

Income Taxes **:** Income taxes are accounted for 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.

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. We are subject to taxation in U.S. and California jurisdictions. Our policy is to recognize interest and tax penalties in income tax expense; no interest or tax penalties have been recorded through December 31, 2011. As of December 31, 2011, our tax years beginning January 1, 2001 remain subject to examination by taxing authorities.

Stock-Based Compensation **:** We account for stock-based compensation by measuring and recognizing expense for all stock-based payments made to employees and directors based on estimated grant date fair values. We use the straight-line method to allocate compensation expense to reporting periods over each optionee's requisite service period, which is generally the vesting period, and estimate the fair value of stock-based awards to employees and directors using the Black-Scholes option valuation model. The Black-Scholes model requires the input of subjective assumptions, including volatility, the expected term, and the fair value of the underlying common stock on the date of grant, among other inputs. We record the option value to compensation expense based on the financial statement category for which an optionee's services are rendered and cash compensation is recorded. We adjust stock-based compensation expense for estimated option forfeitures based on our five-year historical average of actual forfeitures.

We account for stock options issued to consultants as expense at their fair value over the related service period, as determined in accordance with authoritative guidance. We periodically revalue the stock options as they vest.

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 accumulated other comprehensive income (loss). These gains and losses, in the aggregate, were insignificant through December 31, 2011.

Comprehensive Loss **:** Comprehensive loss is the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net loss and other comprehensive loss, including unrealized gains and losses from foreign currency translations, are reported net of their related tax effect to arrive at comprehensive loss.

Net Loss Per Common Share **:** Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method and the if-converted method, as applicable. For purpose of this calculation, convertible preferred stock, common stock options, preferred and common stock warrants, and convertible notes payable are considered to be common stock equivalents and are included in the calculation of diluted net loss per share only when their effect is dilutive. The calculation excludes any impact related to accrued but undeclared dividends.

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3. Significant Accounting Policies (continued)

The following table presents the potential common shares outstanding or common share equivalents that were excluded from the computation of diluted net loss per share because including them would have been antidilutive:

	Year Ended December 31,		
	2009	2010	2011
Convertible preferred stock	13,853,882	—	—
Common stock options	1,563,214	3,026,800	3,304,000
Convertible notes payable and accrued interest	3,124,041	—	—
Convertible preferred stock warrants	289,851	—	—
Common stock warrants	1,234,560	—	—
	20,065,548	3,026,800	3,304,000

Fair Value Measurements: Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants as of the measurement date. Applicable accounting guidance provides an established hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in valuing the asset or liability and are developed based on market data obtained from sources independent of us. Unobservable inputs are inputs that reflect our assumptions about the factors that market participants would use in valuing the asset or liability. There are three levels of inputs that may be used to measure fair value:

Level 1 – Inputs are based on quoted market prices for identical assets or liabilities in active markets at the measurement date;

Level 2 – Inputs include quoted prices for similar assets or liabilities in active markets and/or quoted prices for identical or similar assets or liabilities in markets that are not active near the measurement date;

Level 3 – Inputs include management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. The inputs are unobservable in the market and significant to the instrument's valuation.

The fair value of our cash and cash equivalents were determined based on "Level 1" inputs. The cost, gross unrealized losses, and approximate fair values of our investments determined based on "Level 2" inputs at December 31, 2011 are as follows:

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(In thousands)		
Time deposits:				
Due in one year or less	$1,992	$ —	$ 7	$1,985
Due after one year through two years	3,234	—	36	3,198
	$5,226	$ —	$ 43	$5,183

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3. Significant Accounting Policies (continued)

Recent Accounting Pronouncements: In June 2011, the FASB issued ASU No. 2011-05, "Presentation of Comprehensive Income." ASU 2011-05 eliminates the option to report other comprehensive income and its components in the statement of changes in stockholders' equity and requires an entity to present the total of comprehensive income, the components of net income (loss) and the components of other comprehensive income either in a single continuous statement or in two separate but consecutive statements. This pronouncement is effective for us beginning in the first quarter of 2012. We believe the adoption of ASU 2011-05 concerns presentation and disclosure only and will not have an impact on our consolidated financial position or results of operations.

4. Significant Accounting Policies of Components Discontinued upon IPO

Concurrent with the completion of our Initial Public Offering in December 2010, all of our outstanding convertible preferred stock, non-voting common stock, notes payable, and accrued interest on notes payable converted to common stock. Additionally, all outstanding warrants were exercised for common stock, either through a cash payment to us or on a net exercise basis. We also issued common stock for cumulative dividends on our Series H convertible preferred stock. Following are the significant accounting policies related to those debt and equity instruments, which have no effect on our financial statements after December 2010.

Preferred Stock Warrant Liability **:** We recorded the value of warrants issued for the purchase of preferred stock as a liability because the warrants provided for issuance of shares that would be contingently redeemable and, therefore, might have required a future transfer of assets. Until the time the warrants were exercised, the fair value was assessed at each reporting date utilizing Level 3 inputs and the Black-Scholes model and any change in value was recorded as a component of other income (expense). The fair value of the preferred stock warrants was estimated to be $780,000 as of December 31, 2009; there were no warrants outstanding after our IPO in December 2010. The increase and decrease in the fair value was $(215,000) and $990,000 for the years ended December 31, 2009, and 2010, respectively, and was $1.23 million for the period from June 3, 1998 (inception) to December 31, 2011. The following valuation assumptions were used for these reporting dates:

	Year Ended December 31,	
	2009	2010
Assumed risk-free interest rate	1.7 to 2.7%	0.7 to 1.1%
Assumed volatility	78.4%	63.9%
Expected life (in years)	3.0 to 4.3	2.0 to 3.3
Expected dividend yield	0.0 to 6.1%	0.0 to 6.1%

Valuation of Notes Payable **:** After the dates of origination of our various convertible and non-convertible notes payable, there were a number of amendments to the underlying terms of the notes, primarily to extend the notes' maturity dates and change certain conversion provisions. At each amendment date, we performed an analysis based on the applicable accounting guidelines to determine if the amendment resulted in an accounting impact. We first considered whether the amendment would qualify as a troubled debt restructuring. If the amendment was not considered a troubled debt restructuring, we considered whether the amendment should be accounted for as an extinguishment or a modification of debt. If the note had an embedded conversion feature and the amendment was considered a modification, rather than an extinguishment, then any increase in the fair value of the conversion feature as a result of the amendment was accounted for as a reduction in the carrying amount of the note, as an additional discount, with a corresponding increase in additional paid-in capital. If the amendment was considered to cause an extinguishment, we recorded a loss on extinguishment to other income and expense for the carrying value of the note payable at the time of modification and also determined a new fair value for the note and recorded such fair value as a liability with a corresponding decrease in additional paid-in capital. We amortized or accreted any resulting premium

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4. Significant Accounting Policies of Components Discontinued upon IPO (continued)

***Valuation of Notes Payable* (continued):** or discount over the term of the note using the effective interest method as interest expense in our statement of operations. The impact of the accounting for the various amendments to the notes payable resulted in a loss on extinguishment of notes payable of $13.29 million for the year ended December 31, 2010 and an increase or decrease in interest expense for the years ended December 31, 2009, and 2010 and for the period from June 3, 1998 (inception) to December 31, 2010 of $421,000, $(1.88 million), and $(1.04 million), respectively. All the notes converted to common stock upon our IPO in December 2010.

Certain unsecured notes payable contained provisions for repayment premiums. We recorded the premium as interest expense during 2003 and 2004 with a corresponding increase in the carrying value of the debt totaling $11.1 million. We reclassified the repayment premium to additional paid-in capital upon conversion of the notes in December 2010.

***Deemed Dividends* :** During June 2010, we completed the sale of Series H convertible preferred stock. This Series H convertible preferred stock was sold at a price per share below the estimated fair value of our common stock. Accordingly, we recorded a deemed dividend in the amount of $693,000 on the Series H convertible preferred stock equal to the number of shares of Series H convertible preferred stock sold multiplied by the difference between the estimated fair value of the underlying common stock and the Series H conversion price per share. The deemed dividend was recognized as an adjustment to the net loss attributable to common stockholders since the preferred stock was convertible, but not mandatorily redeemable.

***Cumulative Dividends* :** The holders of Series H convertible preferred stock were entitled to receive cumulative dividends in preference to any declaration or payment of dividends on common stock. We recorded the liquidation value for these dividends through the date of our IPO by increasing the carrying value of the Series H convertible preferred stock and reducing additional paid-in capital, or in the case where we had no remaining additional paid-in capital, we increased our deficit accumulated in the development stage. These dividends became payable upon our IPO in December 2010; as a result, we issued shares of common stock for the Series H cumulative dividends. No other series of preferred stock was entitled to receive dividends.

5. Balance Sheet Details

	December 31,	
	2010	2011
	(In thousands)	
Property and equipment:		
Furniture and office equipment	$ 351	$ 407
Laboratory equipment	2,400	3,156
Leasehold improvements	559	1,157
	3,310	4,720
Accumulated depreciation and amortization	(2,347)	(2,760)
	$ 963	$ 1,960
Accrued expenses and other current liabilities:		
Accrued salaries and other employee costs	$ 353	$ 680
Accrued operating expenses	192	203
Accrued use taxes	15	52
Deferred rent	31	—
	$ 591	$ 935

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6. Income Taxes

We have reported net losses for all periods through December 31, 2011; therefore, no provision for income taxes has been recorded.

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 at December 31, 2010 and 2011 are as follows:

	December 31,	
	2010	2011
	(In thousands)	
Deferred Tax Assets:		
Stock-based compensation	$ 421	$ 1,519
Investment write-off loss carryforward	1,034	—
Depreciation	154	156
Accrued operating expenses	38	39
Other	64	100
	1,711	1,814
Less: valuation allowance	(1,711)	(1,814)
Net deferred tax assets	$ —	$ —

At December 31, 2011 we had aggregate federal and California state net operating loss carryforwards of approximately $115 million and $112 million, 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 2012. At December 31, 2011, we also had federal and California state research tax credit carryforwards of approximately $3.88 million and $3.48 million, respectively. The federal carryforwards begin to expire in 2020 and the California carryforwards have no expiration. Additionally, at December 31, 2011, we had California manufacturers' investment tax credit carryforwards of approximately $55,000 that begin to expire in 2012.

Under the 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. We have not completed an IRC Section 382/383 analysis regarding the limitations on carryforwards. Until this analysis is completed, we have removed the deferred tax assets for net operating losses and research credits from our deferred tax asset schedule and recorded a corresponding decrease in the valuation allowance. We do not expect these tax positions to change within 12 months after December 31, 2011 and, as a result, do not expect that the unrecognized tax benefits will change by December 31, 2012.

We have established a valuation allowance against our net deferred tax assets due to the uncertainty surrounding the realization of those assets. We periodically evaluate the recoverability of the deferred tax assets and, when it is determined to be more-likely-than-not that the deferred tax assets are realizable, the valuation allowance is reduced. As a result of the valuation allowance, future changes in our unrecognized tax benefits will not impact our effective tax rate.

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6. Income Taxes (continued)

The following table provides reconciliation between income taxes computed at the federal statutory rate and our provision for income taxes (in thousands):

	Year Ended December 31,		
	2009	2010	2011
		(In thousands)	
Federal income taxes at 34%	$(4,707)	$(7,993)	$(7,109)
State income taxes, net of federal benefit	(807)	(1,370)	(1,219)
Research and development credits	(760)	(682)	(828)
Stock-based compensation expense	90	472	133
Increase in valuation allowance	6,061	310	8,079
Loss on extinguishment of notes payable	—	5,291	—
Loan premium payoff	—	4,421	—
Change in fair value of preferred warrants	(86)	394	—
Other	209	(843)	944
	$ —	$ —	$ —

7. Stock-Based Compensation

Our 2010 Equity Incentive Award Plan was a follow-on to our 2001 Stock Option/Stock Issuance Plan and the two plans are collectively referred to as the “Plan.” The Plan provides for restricted stock awards as well as 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 of our stock on the date of grant. 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, 2011, an additional 981,615 shares were added, resulting in a total of 5,115,953 shares reserved under the Plan as of December 31, 2011. 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 Board of Directors and are generally four- or five-year periods. All options 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.

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7. Stock-Based Compensation (continued)

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, 2008	1,610,500	$ 1.17		
Granted	50,000	$ 1.80		
Cancelled	(109,786)	$ 1.24		
Balance at December 31, 2009	1,550,714	$ 1.19		
Granted	1,467,500	$ 11.00		
Cancelled	(1,200)	$ 1.40		
Exercised	(214)	$ 1.40		
Balance at December 31, 2010	3,016,800	$ 5.96		
Granted	401,000	$ 13.70		
Cancelled	(73,800)	$ 4.62		
Exercised	(40,000)	$ 0.79		
Balance at December 31, 2011	3,304,000	$ 6.99	6.98	$7,428,000
Vested at December 31, 2011	1,726,680	$ 3.90	5.44	$6,418,000
Vested and expected to vest at December 31, 2011	3,189,530	$ 6.85	6.92	$7,379,000

The portion of the outstanding options that had not vested as of December 31, 2011 has vesting scheduled through 2015. The 2011 vesting activity under the Plan is as follows:

	Number of Options	Weighted Average Grant Date Fair Value
Not vested at December 31, 2010	1,853,200	$ 5.21
Granted	401,000	$ 8.35
Vested	(606,080)	$ 5.22
Forefeited	(70,800)	$ 3.08
Non vested at December 31, 2011	1,577,320	$ 6.10

In 2011 we awarded 5,000 shares of restricted stock; we had not previously awarded any restricted stock under the Plan. Fifty percent of the restricted stock award vested in May 2011; the remaining restricted stock vests 25 percent in May 2012 and 25 percent in May 2013.

No tax benefits arising from stock-based compensation have been recognized in the consolidated statements of operations through December 31, 2011.

Stock Options and Restricted Stock to Employees **:** We account for option grants and restricted stock awards to employees based on the 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. We include non-employee directors as employees for this purpose.

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7. Stock-Based Compensation (continued)

Expense recorded for employee options and awards under the Plan is as follows:

	Year Ended December 31,		
	2009	2010	2011
		(In thousands)	
Research and development	$103	$ 81	$ 688
General and administrative	94	865	2,452
Total stock-based compensation	$197	$946	$3,140

At December 31, 2011, we had approximately $8.48 million of total unrecognized compensation costs related to unvested employee options that are expected to be recognized over a weighted average period of 1.91 years.

There were no options granted in 2009. The fair value of options granted during 2010 and 2011 was estimated using the following weighted-average assumptions:

	Year Ended December 31,	
	2010	2011
Risk-free interest rate	1.85%	2.68%
Expected volatility of common stock	63.9%	63.9%
Expected life in years	6.5	6.25
Dividend yield	0%	0%

The assumed risk-free interest rate was based on the implied yield on a U.S. Treasury zero-coupon issue with a remaining term equal to the expected life of the option. The assumed volatility 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. The expected option life was calculated using the simplified method under the accounting standard for stock compensation and a ten-year option expiration. The simplified method is used since we believe our future option activity as a public company will differ from that of our own historical experience. 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 the grant date fair value and intrinsic value information of options granted to employees is as follows:

	Year ended December 31,		
	2009	2010	2011
	(In thousands, except per share data)		
Weighted average grant date fair value per share	$ —	$ 6.26	$ 8.35
Intrinsic value of options exercised	$ —	$ 1	$ 249
Total fair value of options vested during period	$ 198	$ 946	$ 3,140

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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-pricing model. The resulting stock-based compensation expense, or income if the fair value declines in a reporting period, is recorded over the consultant's service period. During September 2009, consultants were granted options to purchase 50,000 shares of common stock. Stock-based compensation, which was recorded as research and development expense (income), arising from these options totaled $30,000, $239,000 and $(51,000) for the years ended December 31, 2009, 2010 and 2011, respectively. The fair value of these awards was determined with the following assumptions: Assumed risk-free interest rate of 1.3% to 3.4%; assumed volatility of 62% to 80%; expected option life of 5.5 to 8.7 years; and, expected dividend yield of zero percent. The total fair value of consultant options vested during 2009, 2010 and 2011 was $16,000, $78,000 and $57,000, respectively.

Non-Plan Options **:** Prior to establishment of the Plan, we had issued non-qualified options to purchase common stock under terms similar to those of the Plan. As of December 31, 2010, a total of 10,000 of these options were outstanding. During the year ended December 31, 2011, a total of 5,000 of the options were exercised and 5,000 expired; none remained outstanding as of December 31, 2011. All stock-based compensation expense related to these options was recorded prior to 2009.

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 25 percent of their total compensation, up to the maximum allowed under IRS regulations, on an annual basis. We are required to match 25 percent of an employee's deferral amount, up to a maximum of four percent of the employee's 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 $28,000, $24,000, $40,000, and $211,000 for the years ended December 31, 2009, 2010, and 2011 and for the period from June 3, 1998 through December 31, 2011, respectively.

9. Commitments and Contingencies

We have licensed certain patents and other intellectual property rights related to the composition and coating of our bioresorbable stent and our other biomaterial products. Terms of these licenses include provisions for royalty payments on any future sales of products, if any, utilizing this technology, with provisions for minimum royalties once product sales begin. The amount of royalties varies depending upon type of product, use of product, stage of product, location of sale, and ultimate sales volume, and ranges from a minimum of approximately $70 per unit to a maximum of approximately $100 per unit sold, with license provisions for escalating minimum royalties that could be as high as $2.2 million per year. Additionally, in the event we sublicense the technology and receive certain milestone payments, the licenses require that 20 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, 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, 2011 the minimum future payments on these contracts totaled approximately $159,000.

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Notes to Consolidated Financial Statements

9. Commitments and Contingencies (continued)

We currently lease our office 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, a leasehold improvement allowance of $478,000, and a retroactive rent credit of $45,000. The long-term liability of $518,000 on our consolidated balance sheet at December 31, 2011 is deferred rent recorded due to the difference in cash payments of rent compared to straight-line expense recognized. We recorded rent expense of $394,000, $436,000, $591,000, and $3.53 million for the years ended December 31, 2009, 2010, and 2011 and for the period from June 3, 1998 (inception) through December 31, 2011, respectively. Future minimum payments under the lease as of December 31, 2011 are as follows:

	Minimum Payment (In thousands)
2012	$ 406,000
2013	607,000
2014	625,000
2015	644,000
2016	690,000
Thereafter	771,000
Total minimum lease payments	$ 3,743,000

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. As of December 31, 2011, our related parties collectively represented approximately 67 percent of our outstanding stock. Transactions with our related parties historically consisted of notes payable issued to members of our board of directors, or firms they represented, or to the investors that held in excess of five percent of our securities. All of our notes payable together with accrued interest converted into common stock upon our initial public offering in December 2010.

11. Selected Quarterly Financial Information (unaudited)

The following table presents selected quarterly financial information for the periods indicated. This information has been derived from our unaudited quarterly consolidated financial statements, which in the opinion of management include all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation of such information. 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				
	First	Second	Third	Fourth	Year
	(In thousands, except per share amounts)				
2010:					
Loss from operations	$(2,231)	$(2,618)	$(2,491)	$ (2,778)	$(10,118)
Net loss	(2,976)	(3,387)	(3,073)	(14,071)	(23,507)
Net loss attributable to common stockholders	(3,631)	(8,456)	(3,870)	(14,750)	(30,707)
Net loss per common share, basic and diluted	$ (1.33)	$ (3.08)	$ (1.41)	$ (1.93)	$ (7.72)
2011:					
Loss from operations	$(5,169)	$(5,414)	$(4,704)	$ (5,809)	$(21,096)
Net loss	(5,133)	(5,351)	(4,655)	(5,769)	(20,908)
Net loss per common share, basic and diluted	$ (0.16)	$ (0.16)	$ (0.14)	$ (0.18)	$ (0.64)

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INDEX TO EXHIBITS

Exhibit Number	Description of Exhibits
3.1	Amended and Restated Certificate of Incorporation.*
3.2	Amended and Restated Bylaws to be effective upon completion of this offering.*
4.1	Form of Stock Certificate.*
4.2	Form of Amended and Restated Investors' Rights Agreement, by and among REVA Medical, Inc. and the holders of our preferred stock set forth therein.*
10.1	Telecom Business Center Business Lease between FSP Telecom Business Center Limited Partnership and REVA Medical, Inc. dated December 18, 2001.*
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.*
10.3	Second Amendment to Telecom Business Center Business Lease between ARI Commercial Properties, Inc. and REVA Medical, Inc. dated February 18, 2006.*
10.4	Third Amendment to Telecom Business Center Business Lease between ARI Commercial Properties, Inc. and REVA Medical, Inc. dated December 14, 2006.*
10.5	Fourth Amendment to Telecom Business Center Business Lease between ARI Commercial Properties, Inc. and REVA Medical, Inc. dated May 7, 2008.*
10.6	Agreement and Plan of Merger, dated October 13, 2004, by and among REVA Medical, Inc., Boston Scientific Corporation, RMI Acquisition Corp. and certain stockholder representatives set forth therein.*
10.7	Amendment No. 1 to the Agreement and Plan of Merger, dated December 7, 2007, by and among REVA Medical, Inc., Boston Scientific Corporation, RMI Acquisition Corp. and certain stockholder representatives set forth therein.*
10.8	Securities Purchase Agreement between Boston Scientific Corporation and REVA Medical, Inc. dated October 13, 2004.*
10.9	Amendment No. 1 to Securities Purchase Agreement between Boston Scientific Corporation and REVA Medical, Inc. dated December 7, 2007.*
10.10	Distribution Option Agreement, dated December 7, 2007, by and between REVA Medical, Inc. and Boston Scientific Corporation.*
10.11	Exclusive License Agreement Number between Rutgers, The State University of New Jersey and REVA Medical, Inc. dated July 1, 2010.++*
10.12	Royalty and License Agreement between Integra/LifeSciences Corporation and REVA Medical, Inc. dated February 2, 2004.++*
10.13	2001 Stock Option/Stock Issuance Plan.+*
10.14	Form of Stock Option Agreement.+*
10.15	Form of Addendum to Stock Option Agreement.+*
10.16	2010 Equity Incentive Plan.+*
10.17	Form of Stock Option Agreement.+*
10.18	Form of Stock Option Agreement entered into with Robert Thomas and Anne Keating.+*
10.19	Form of Director and Officer Indemnification Agreement.+*
10.20	Employment Agreement, dated July 1, 2010, by and between REVA Medical, Inc. and Robert B. Stockman.+*
10.21	Employment Agreement, dated October 21, 2010, by and between REVA Medical, Inc. and Robert Schultz.+*
10.22	Employment Agreement, dated October 21, 2010, by and between REVA Medical, Inc. and Katrina Thompson.+*
10.23	Form of Offer Management Agreement between REVA Medical, Inc. and Inteq Limited.*
10.24	Form of CDI Subscription Application for non U.S. investors.*
10.25	Form of CDI Subscription Application for U.S. investors.*
10.26	Form of Escrow Deed between REVA Medical, Inc. and Computershare Investor Services Pty Limited.*
10.27	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.**
21.1	List of Subsidiaries.*

23.1 Consent of Independent Registered Public Accounting Firm

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Exhibit Number	Description of Exhibits
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.
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.
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.
99.1	Section 13 of the ASX Settlement Rules. *
101(2)	XBRL Instance Document.
101(2)	XBRL Taxonomy Extension Schema Document.
101(2)	XBRL Calculation Linkbase Document.
101(2)	XBRL Taxonomy Definition Linkbase Document.
101(2)	XBRL Taxonomy Label Linkbase Document.
101(2)	XBRL Taxonomy Presentation Linkbase Document.

\+ Management Compensation Plan
++ Confidential Treatment Request
* Filed as exhibits to the Registrant's Registration Statement on Form S-1 (File No. 333-168852), effective November 15, 2010, and incorporated herein by reference.
** Filed as Exhibit 10.27 of the Registrant's Current Report on Form 8-K filed with the SEC on November 23, 2011, and incorporated herein by reference.
(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.
(2) Pursuant to applicable securities laws and regulations, we are deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and are not subject to liability under any anti-fraud provisions of the federal securities laws as long as we have made a good faith attempt to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. Users of this data are advised that, pursuant to Rule 406T, these interactive data files are deemed not filed and otherwise are not subject to liability.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-173371) pertaining to the 2010 Equity Incentive Award Plan and 2001 Stock Option/Stock Issuance Plan of REVA Medical, Inc. of our reports dated February 28, 2012, with respect to the consolidated financial statements of REVA Medical, Inc. and the effectiveness of internal control over financial reporting of REVA Medical, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2011.

/S/ Ernst & Young LLP

San Diego, CA

February 28, 2012

Exhibit 31.1

CERTIFICATION

I, Robert B. Stockman, 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. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) 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
   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2012

/s/ Robert B. Stockman
Robert B. Stockman
Chairman and 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. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) 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
   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2012

/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, 2011, as filed with the Securities and Exchange Commission (the "Report"), Robert B. Stockman, Chairman and Chief Executive Officer of the Company, and Katrina L. Thompson, Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: February 28, 2012

/s/ Robert B. Stockman
Robert B. Stockman
Chairman and Chief Executive Officer
(principal executive officer)

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